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ABSTRACT BOOK

ABSTRACT INDEX

Track	BASIC PHARMACOLOGY			
Paper No.	**Author Name**	**Topic of oral presentation**	**Name of Organization**	**Page No.**
A001	Soni Kinal	Pharmacological Evaluation of Febuxostat in Experimentally Induced Breast Cancer in Rats	Department of Pharmacology, Institute of Pharmacy, Nirma University	37.
A002	Dabral Swarna	Optimization of the Avian Embryo Chorio-Allantoic Membrane Model Protocol As A System for Screening of Angiogenesis Inhibitors	Jamia Hamdard, Mehrauli Badarpur Road, New Delhi	38.
A003	Patel Drashti Rohitkumar	Newer Targets for Cardiac Cachexia	Institute of Pharmacy, Nirma University	39.
A004	Momin Aramash	A short review on Pathogenesis, Diagnosis and Recent Herbal Treatments on Diabetic Nephropathy	Bharati vidyapeeth Poona college of Pharmacy	40.
A005	Mahur Amisha	Role Of Inflammation And Inflammatory Cytokines In Cardiac Cachexia	Institute of Pharmacy, Nirma University	41.
A006	Patidar Pragya	Clinical Evaluation of a Dental Gel Comprising Cranberry and Brindleberry for Prevention of Progression of Periodontitis	Prin. K. M. K kundnani college of Pharmacy	42.
A007	Dave Srusti	Skeletal Muscle Wasting in Cancer Cachexia	Institute of Pharmacy, Nirma University	43.
A008	Khan Sana	Investigating the Role of Hypercoagulation in the Onset and Progression of High Cholesterol Diet Induced Neuropathology	Jamia Hamdard, Mehrauli Badarpur Road, New Delhi	44.
A009	Baidehi Mitra	Repurposing of Anti-histamine Drugs for cancer therapy	Institute of Pharmacy, Nirma University	45.
A010	Patel Richa	Central Histaminergic Transmission via H_1 and H_2 Receptor Modulates the Diazepam Induced Anxiolytic-like Behavior in Mice	Guru Ghasidas Vishwavidyalaya	46.
A011	Chauhan Heena	The Involvement of Acquired immunity in Alzheimer's disease	Institute of Pharmacy, Nirma University	47.
A012	Desai Bhargavi	An Attempt to Fathom the Inhibitory Potential of Pantoprazole Sodium on	Maliba Pharmacy College	48.

		Testosterone Induced Intraepithelial Neoplasia in Rats: Exploring the Role of TRPM7 Channel		
A013	Sharma Ayush	Transient Receptor Potential Cation 6 (Trpc6): A Friend Or Foe?	Institute of Pharmacy, Nirma University	49.
A014	Rawoot Salman	Pre-clinical Safety Assessment of *Cassia tora Linn.* Stem	Bharati Vidyapeeths College Of Pharmacy C.B.D. Belapur Navi-Mumbai.	50.
A015	Patel Dhruvee	Pharmacology of SGLT2 Inhibitors Update on Decade of Progress	Institute of Pharmacy, Nirma University	51.
A016	Rabadia Jay	*Plumeria acuminata*: An Herb with Abortifacient Potential	R K University	52.
A017	Chhipa Abu Sufiyan	Pharmacological Evaluation of Olsalazine in the Treatment of Breast Cancer	Institute of Pharmacy, Nirma University	53.
A018	Shukla Pavan	Short Review on Maternal Deprivation as Potential Animal Model for Early Life Stress	Bharati vidyapeeth Poona college of Pharmacy	54.
A019	Soni Jay Hiralal	Chemokine Receptor CXCR4: A Systematic Review	Institute of Pharmacy, Nirma University	55.
A020	S Geetha	Audit Of Antibiotic Prescription In Suspected Neonatal Sepsis At An Indian Tertiary Care Hospital	East Point College of Medical Sciences and Research Centre	56.
A021	Thakkar Dhwani J	Gene Therapy as an Emerging Trend in Cardiovascular Diseases	Institute of Pharmacy Nirma University, Ahmedabad, Gujarat	57.
A022	Khan Dureshahwar	*In-silico* Investigational Approach of Selected Phytochemicals Against Acetylcholinesterase, a Pesticide Target Protein: As an Ecopharmacovigilance Aid	Y. B. Chavan College of Pharmacy Aurangabad.	58.
A023	Nidhi	An overview of Idiopathic Pulmonary Fibrosis (IPF) on MDM4 and MDM2 and other target	Institute of Pharmacy, Nirma University	59.
A024	Praveenraj S S	A Study to Evaluate the Efficacy of Thanga Parpam in a Mouse Model of Parkinson's Disease	JSS College of Pharmacy	60.

A025	Rana Rinu	A Review on Preclinical Studies on *Carica Papya* Leaf Extract for Antithrombocytopenic Activity	Laureate Institute of Pharmacy	61.
A026	Siddiqui Nazia	Neuroprotective Effect of Linagliptin, a DPP-4 Inhibitor Against Intracerebroventricular Streptozotocin Induced Neurodegeneration in Rat Model of Alzheimer's Disease	Jamia Hamdard, Mehrauli Badarpur Road, New Delhi	62.
A027	Saini Sakshi	The Cognitive Impact of Antiepileptic Drugs in Children	Institute of Pharmacy, Nirma university	63.
A028	Dongre Prashant	Therapeutic potential of Chandraprabha Vati in targeting Immuno- metabolic target to combat obesity induce chronic low- grade inflammation	Bombay College of Pharmacy, Kalina, Santacruz (E)-Mumbai-400098	64.
A030	Shah Nidhi	Phycocyanin: A Marine Pigment with Anti-inflammatory, Anti-oxidant & Neuroprotective Activity.	Institute of Pharmacy, Nirma university	65.
A031	Yadav Varsha	Role of Central Histaminergic Transmission in the Endocannabinoid Induced Effect on Compulsive-like Behavior	Guru Ghasidas Vishwavidyalaya	66.
A032	Patel Disha R	Possible Therapeutic Targets for Idiopathic Pulmonary Fibrosis: Preclinical and Clinical Progress	Institute of Pharmacy, Nirma university	67.
A033	Choudhary Ashok	To Formulate, Characterize and Evaluate the Brain and Systemic Bioavailability of a Novel Intranasal Formulation of Flurbiprofen	Bombay College of Pharmacy	68.
A034	Kanna	Role of Melatonin on Behavioural and Biochemical Paradigm in Gonadectomized Sleep-restricted Animals	JSS college of Pharmacy	69.
A035	Mishra Astha	Takotsubo Related to CNS	Institute of Pharmacy Nirma university, Ahmedabad, Gujarat	70.
A036	Mallurwar Sadanand	Utility of Allometric Scaling Methods for Predicting Human Pharmacokinetics of Pan-JAK	Mandsaur University; Mandsaur	71.

		Inhibitor -Tofacitinib and Dose Extrapolation		
A037	Tulsiyani Khushboo N	Role of Interferon in Various Diseases	Institute of Pharmacy, Nirma University	72.
A038	Sontakke Amit	Phytochemical Screening, Antioxidant Potential and Alpha Amylase Inhibitory Activity of an Antidiabetic Polyherbal Formulation	Anuradha College of Pharmacy, Chikhli	73.
A039	Patel Rujul	Recent Advances in CAR T-Cell Therapy for Lymphoblastic Leukaemia	Institute of Pharmacy Nirma university, Ahmedabad, Gujarat	74.
A040	Nikita Patil Samant	Neuroprotective Effect of Gossypetin Against Cognitive Dysfunction in Chronic Unpredictable Stress- induced Mice	Shobhaben Pratapbhai Patel School of Pharmacy & Technology Management, SVKM\'S NMIMS, Mumbai	75.
A041	Dubey Nandini	Therapeutic Potential of Naringenin with Special Focus on Neurodegenerative Diseases	GLA University, Mathura	76.
A042	Jain Nishant Sudhir	Role of central histamine H1 and H2 receptors in the antidepressant- like effect of endocannabinoids in mice	Guru Ghasidas Vishwavidyalaya	77.
A043	Honey P. Kachhadiya	Dose Dependent Anti-inflammatory Effect of Zn^{2+}-curcumin Complex Inhibits Carrageenan-induced Paw Edema in Rats	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	78.
A044	Chandana A Kumar	A Study on the Safety and Neuroprotective Profile of Sesame Lignans and Nicotinamide Mononucleotide in Sleep-restricted Mice	JSS college of Pharmacy	79.
A045	C Arathi	Pre-clinical Oral Glucose Tolerance Test of Garcinia Indica	Bharati Vidyapeeth\'s College of Pharmacy	80.
A046	Bhavsar Nikhil	Involvement of Myeloperoxidase (MPO)-H_2O_2-Cl_2 pathway in the pathogenesis of Traumatic Brain Injury (TBI).	Institute of Pharmacy, Nirma University	81.
A047	Patil Deepa	Assessment Of Knowledge, Attitude And Practice Of Self-Medication Among	Basaveshwara Medical College	82.

		Undergraduate Medical Students In A Tertiary Care Teaching Hospital		
A048	Kumar Aakash S	Treatment of Diabetes by targeting Tyrosine Kinase Inhibitor	Institue of Pharmacy, Nirma University, Ahmedabad, Gujarat	83.
A049	Misha Aanand	MenSC: A newer approach towards mesenchymal cell derivation from human menstrual blood.	Institue of Pharmacy, Nirma University, Ahmedabad, Gujarat	84.

Track	CLINICAL RESEARCH AND PHARMACOVIGILANCE			
Paper No.	**Author Name**	**Topic of oral presentation**	**Name of Organization**	**Page No.**
B001	Kumar Sneha	To evaluate the Attitude, Knowledge and Practice regarding Pharmacovigilance in Undergraduates Students & Postgraduates Residents at a Tertiary Healthcare Center – A Questionnaire based study	Dr Vasantrao Pawar Medical College, Adgaon, Nashik	86.
B002	Gupta Rohini	Antibiotic Sensitivity Pattern of Bacterial Isolates in Chronic Osteomyelitis in a Tertiary Care Teaching Hospital of North India.	Deptartment of Pharmacology, Govt. Medical College, Jammu, J&K	87.
B003	Parmar Priyanka	Assessment of menstrual patterns and premenstrual symptoms in adolescents: a cross-sectional study	Kadi Sarva Vishwavidhyalaya, Mehsana, Gujarat	88.
B004	Barot Deval	A Review on Renal Calculi: Its Types, Risk factors and comparative treatment with Allopathic, Homeopathic and Ayurvedic medicines	Shri Sarvajanik Pharmacy College, Mehsana, Gujarat	89.
B005	Shah Manushi	Vaccines, their development, importance and mechanism of action	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	90.
B006	Patel Fenil	Cost effectiveness analysis among different oral hypoglycemic agents: A Review	Shri Sarvajanik Pharmacy College, Mehsana. Gujarat	91.
B007	Raghu Prasada MS	Design implementation and comparitive analysis of audio visual aids in distance learning pharmacology in a tertiary care hospital before and after covid 19 outbreak	Department of Pharmacology, SS Institute of Medical Sciences and Research Center, Davangere	92.
B008	Shukla Nirali	Implications of 3D Spheroids in Breast Cancer: Current Challenges and Promises towards Precision Medicine	Institute of Science, Nirma University, Ahmedabad, Gujarat	93.
B009	Raval Tithi	Role Of Post Approval Clinical Trials For Drug Safety	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	94.

B010	Dubey Suryaprakash	Pharmacovigilance Activity on Immunotherapy in Cancer Patients in Tertiary Healthcare Setting	Bombay College of Pharmacy, Mumbai. Maharashtra	95.
B011	Chaudhari Hiral	Causative Factors, Diagnostic Testing and Management of Infertility	Shri Sarvajanik Pharmacy College, Mehsana, Gujarat	96.
B012	Patel Poonam	Therapeutic Potential of Nutraceuticals and Dietary Supplements in Preventing Covid-19 and others Virus Related Complications: A Review	Shri Sarvajanik Pharmacy College, Mehsana, Gujarat	97.
B013	Vaze Varsha	Adverse Event Profiles of TCu380A and TCu200B IUCDs: a Retrospective Analysis	Bombay College of Pharmacy, Mumbai, Maharashtra	98.
B014	Shah Manan	Regulatory requirements for parmacovigilance in various countries	Institute of Pharmacy, Nirma University, S.G. Highway, Ahmadabad, Gujarat	99.
B015	M Kalyan	The Drug Utilization Evaluation of Medications Used in Ischemic Stroke	JSS college of Pharmacy, JSS Academy of Higher Education and Research, Mysuru, Karnataka	100.
B016	Wairagade Sakshi	Emerging Needs of Crushing Tablet Formulations in Head and Neck Cancer Patients	Anand Pharmacy College, Anand, Gujrat	101.
B017	Bundeliya Uday M.	Pharmacovigilance: An Overview	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	102.

Track	MOLECULAR PHARMACOLOGY			
Paper No.	**Author Name**	**Topic of oral presentation**	**Name of Organization**	**Page No.**
C001	Gavhane Yogesh Kumar	Anthelmintic Activity Of Chitosan And Chitosan Chlorhydrate Against Eisenia fetida And Eggs, Larvae And Adult Form Of Haemonchus contortous Isolated From Sheep In India.	Government College of Pharmacy Karad	104.
C002	Soni Ritu	Association between metabolic syndrome and Parkinson\'s disease	Nirma University	105.
C003	Dwivedi Durgesh	Involvement of Nrf2/ARE Pathway and NLRP3 Inflammasome Cascade in Alleviation of Diabetic Hepatopathy in Rats: A Comparative Study	Regional Ayurveda Reserach Institute, Gwalior	106.
C004	Patel Snehal	Hyperglycaemic Brain Insult and Ischemic Brain: Linked mechanisms and advanced therapeutics	Institute of Pharmacy, Nirma University	107.
C005	Garg Megha	Moderate Malnutrition Affects Expression of MRP2 And ABCC3 Transporters in Rat Liver: Implications for Doxorubicin Pharmacokinetics	TMC-ACTREC	108.
C006	Verma Srashti	Pharmacological Evaluation of PPAR ?/? Dual Agonist in the Modulation of Depressive-Like Behavior Co-morbid with Glucose Intolerance	Nirma University	109.
C007	Patel Shivangi	ER stress in diabetic peripheral neuropathy: The dawn of new therapeutic approaches	Bombay College of Pharmacy	110.
C008	Joshi Mit	The burning furnace: alteration in lipid metabolism in cancer associated cachexia	Nirma University	111.
C009	Hediyal Tousif	Role Of Renin Angiotensin System Modulators On Sleep Deprivation Induced Cognitive Dysfunction	JSS College Of Pharmacy Mysore	112.

C010	Patel Bhoomika	Effect of buspirone in endothelin-1 induced stroke cachexia	Institute of Pharmacy, Nirma University	113.
C011	Siddhi Bagwe Parab	Zebrafish model for Iron Induced Alzheimer's Disease	Shobhaben Pratapbhai Patel School of Pharmacy and Technology Management, SVKMS NMIMS	114.
C012	Yadav Ruchi	Role of WNT Pathway in Development of Diabetic Retinopathy	Nirma University	115.
C013	Dodiya Rohinee	Role of Immunotherapeutics in clinical practice	Ramanbhai patel college of Pharmacy	116.
C014	Saxena Bhagawati	Neuroprotective Effects of Taxifolin against Weight drop induced Traumatic Brain Injury in Rats	Institute of Pharmacy, Nirma University	117.
C015	Patel Shreya	Recent Perspective on Modern Analytical Techniques used in Metabolomics Analysis	Institute of Pharmacy, Nirma University	118.
C016	Kanzaria Sainika	Evaluation Of Protective Effect Of Nrf2 Activator Quercetin In Myocardial Ischemia	Faculty of Pharmacy, Dharamsinh Desai University, Nadiad, Gujarat	119.
C017	Rathod Jay Jigneshbhai	Dyrkl b as Emerging Target For Metabolic Syndrome	Anand Pharmacy College, Anand	120.
C018	Mili Ajay	In-silico Assessment of Sesamol Derivatives as an NRF-2 Activator	Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal, Karnataka	121.

Track	NATURAL PRODUCT PHARMACOLOGY			
Paper No.	**Author Name**	**Topic of oral presentation**	**Name of Organization**	**Page No.**
D002	Tambe Mukul	Evaluation of Calcium content and oral calcium bioavailability of some commonly used Ayurvedic bhasma	School of Pharmacy, Dr. Vishwanath Karad MIT World Peace University, Pune, Maharashtra	123.
D003	Juveria Usmani	Amelioration of immune function in murine model of sepsis: In-vivo and In-vitro analysis of ethanol extract of Carica papaya leaves.	Department of Pharmacology, School of Pharmaceutical Education and Research, Jamia Hamdard, New Delhi, 110062	124.
D004	Faldu Khushboo	Evaluating the efficacy of Celastrus paniculatus oil in social isolation and lead acetate induced attention deficit hyperactivity disorder in rats	Department of Pharmacology, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat, India	126.
D005	Ram Shraddha	Evaluation of Anti-Arthritic Activity of Poly-Herbal Sheetal Oil in Complete Freund's Adjuvant Induced Arthritic Rat Model	MIT College of Pharmacy, Pune, Maharashtra	127.
D006	Mane Priyanka	In-Vivo Screening of Anti-Diabetic Activity of Macrotyloma uniflorum on Albino Rats	Bharati Vidyapeeth College of Pharmacy, Kolhapur, Maharashtra	128.
D007	Patil Rashmi	Pterostilbene attenuates diabetes induced depression like behavior in rats	Department of Pharmacology, Poona College of Pharmacy, Bharati Vidyapeeth (Deemed to be University), Erandwane, Pune-411038, India	129.
D008	Jadhav Asha	Research Progress on Main Symptoms of Novel Coronavirus Pneumonia Improved by Traditional Indian Medicinal herbal syrup	Bharati Vidyapeeth College of Pharmacy, Kolhapur, Maharashtra	130.
D010	Zanwar Anand	Extraction and fractionation of bioactive lignan using solid-liquid extraction and evaluation of its toxicity	Centre for Innovation in Nutrition Health Disease, Interactive Research School for Health Affairs, Bharati Vidyapeeth (Deemed to be University), Pune-411 043	131.

D011	Akotkar Likhit	Evaluation of Mechanism of Action of Alpha Lipoic Acid in CUMS Induced Depression Like Behaviours, Cognitive Deficit and Cardiovascular Dysfunction in Wistar Rats	Department of Pharmacology, Poona College of Pharmacy, Bharati Vidyapeeth (Deemed to be University), Erandwane, Pune-411038, India	132.
D012	Pathan Asmatbanu	A Regulatory Perspective to Phytopharmaceuticals Regulation in India	Graduate School of Pharmacy-GTU, Gandhinagar, Gujarat	133.
D013	Mirza Anwarbaig	Protective Effect of Phenolic Acid on Diabetic Nephropathy in Streptozotocin Induced Diabetic Rats.	Department of Pharmacology, Institute of Pharmacy, Nirma University, Sarkhej-Ghandinagar Highway, Ahmedabad, 382481, Gujarat, India	134.
D014	Vaghela Khushboo	Developed and Evaluate Antituberculosis Novel Polyherbal Formulation; Microsphere	K.B. Institute of Pharmaceutical Education and Research, Nr. Gh-6 Circle, Sector-23, Gandhinagar-382024, Gujarat.	135.
D015	Surekha Yamgar	Nephroprotective activity of ethyl acetate fraction of Pithecellobium Dulce (Roxb.) Benth	Department of Pharmacognosy PDEA's Seth Govind Raghunath Sable College Pharmacy, Saswad, Pune, India	136.
D016	Farooqui Shagufta	Phytochemical and Antioxidant potential of leaves of Pongamia pinnata L. (Fabacea)	School of Pharmacy, SRTMU, Nanded	137.
D018	Sohi Shaheena	Pharmacognostic and biological evaluation of leaf extracts of Citrus reticulata Blanco var. kinnow	Department of Pharmacy, RIMT University, Mandi Gobindgarh, Punjab - 147301, INDIA.	138.
D019	Gunde Mahendra	Formulation and Characterization of Polyherbal Topical Gel Containing Jasminum grandiflorum, Cynodon dactylon And Andrographis paniculata	Datta Meghe College of Pharmacy, Wardha	139.
D020	Karanjkar	In-Vitro Antioxidant assay of Ethanolic Extract of Garcinia indica Leaves	Bharati Vidyapeeth's College of Pharmacy,	140.

			C.B.D. Belapur, Navi Mumbai, Maharashtra	
D021	Fathima Safur	In vitro antidiabetic activity of Yucca filamentosa flower abstract	ACS medical college, Tamil Nadu, Chennai	141.
D022	Kamde Akshay	Therapeutic Potential of Methanolic Extract of Lantana camara Linn. Leaves in Diabetic Nephropathy	Bombay College of Pharmacy, Mumbai, Maharashtra	142.
D023	Pingale Tanvi	Formononetin ameliorates cognitive impairment in Parkinson's disease	Shobhaben Pratapbhai Patel School of Pharmacy & Technology Management, SVKM'S NMIMS, V.L. Mehta Road, Vile Parle (W), Mumbai – 400 056, Maharashtra, India.	143.
D024	Jain Khushboo	Molecular docking of anti-depressant compounds of Indian herbs with hormone regulatory proteins: In silico control approach for postpartum depression	Department of Biotechnology, Vigyan Bhawan, Block B, New Campus, Mohanlal Sukhadia University, Udaipur – 313001, Rajasthan, India	144.
D025	Pratap Veeresh	Beneficial effect of methanolic extract of Pithecellobium dulce in the management of polycystic ovarian syndrome and obesity in rodent models	Department of Pharmacology, Gokaraju Rangaraju College of Pharmacy, Bachupally, Hyderabad, Telangana-500090	145.
D026	Mehta Jinit	Advancements in therapeutics to curb renin-angiotensin system mediated coronary heart disease progression	Department of Pharmacology, Shobhaben Pratapbhai Patel School of Pharmacy & Technology Management, SVKM's NMIMS, Vile Parle (West), Mumbai 400 056, India	146.
D027	Mohammed Mubashir	Adhatoda vasica, Nees: A Potential Herb to Fight Colon Cancer	Y. B. Chavan College of Pharmacy, Aurangabad, Maharashtra	147.
D028	Tripathi Nagja	Assessment of Photoprotective Activity of Herbal Extracts and its Formulation	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat, India	148.
D029	Sahal Vaibhav	Role of camphor for prevention of Covid-19	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	149.

D030	Singh Yatendra	Systematic Review on the Efficacy and Safety *Calotropis gigantea*	Pranveer Singh Institute of Technology (PSIT), Kanpur	150.
D031	Desai Ankita	Quercetin ameliorates diabetic nephropathy in a STZ-induced rat model by downregulating Nox4 expression	Faculty of Pharmacy, Dharmsinh Desai University, Nadiad, Gujarat, India.	151.
D032	Patel Anjali	Management of Urolithiasis by Novel Liquisolid Formulation of Saponin- A Future Potential Source of Therapeutics	Anand Pharmacy College, Anand, Gujarat	152.

Track	PHARMACEUTICS AND PHARMACEUTICAL TECHNOLOGY			
Paper No.	**Author Name**	**Topic of oral presentation**	**Name of Organization**	**Page No.**
E001	Aher Akash	Design and Evaluation of Lipid Based Quercetin Spherical Crystals	Dr. D.Y. Patil Institute of Pharmaceutical Sciences and Research, Pimpri, Pune, India.	154.
E002	Barot Harshit	Multifunctional Mesoporous Silica Nanoparticles for Drug and Gene Delivery	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat, India	155.
E003	Paliwal Himanshu	Influence of Surfactant Chain Length on Drug Release Kinetics of Microemulsion Loaded with BCS Class II Drug	Shree S. K. Patel College of Pharmaceutical Education and Research, Ganpat University, Mehsana. Gujarat	156.
E004	Athalye Mansi	Formulation Development and Evaluation of Lipid Drug Conjugated Nanoparticles for the Enhanced Delivery of Hydrophilic Drug to Brain	L. M. College of Pharmacy, Opposite Gujarat University, Navrangpura, Ahmedabad, Gujarat-380009, India.	157.
E005	Kumar Jahanvee	Drug delivery enhancement techniques in liposomal nanomedicine for cancer treatment	Institute of Pharmacy Nirma University, Ahmedabad, Gujrat	158.
E006	Choudhari Laxmi	Enhancing Loading of Water-Soluble Metformin HCl in Lipidic Nanoparticles for Repurposing in Cancer	Department of Pharmaceutical Sciences and Technology, Institute of Chemical Technology, Elite Status and Centre of Excellence (Maharashtra), N.P. Marg, Matunga (E), Mumbai, 400019, Maharashtra, India.	159.
E007	Vaja Payal	Development, Optimization and Evaluation of Mesalamine Containing Mucoadhesive Pellets to Treat Inflammatory Bowel Disease via Rectal Drug Delivery System by using 32 Full Factorial Design	School of Pharmacy, RK University Rajkot, Gujarat.	160.
E008	Thakkar Drashti	An Overview on PLGA Based Microspheres for Long Acting Parenterals	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	161.

E009	Bhandari Darshan	Thermodynamic Prediction of Excipients for Developing Lipidic Nanoformulation of Silymarin	Department of Pharmaceutical Sciences and Technology, Institute of Chemical Technology, Elite Status and Centre of Excellence (Maharashtra), N.P. Marg, Matunga (E), Mumbai, 400019, Maharashtra, India	162.
E010	Prajapati Parin	Micelles: An approach developed to improve bioavailability of Biopharmaceutical Classification System (BCS) class-II and IV drugs.	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	163.
E011	Rajashri	Incorporation of Diclofenac Sodium Loaded Ethyl Cellulose Polymeric Microsponges into HPMC E4M Inserts for Ocular Administration	1PDEA's Seth Govind Raghunath Ambikar Sable College of Pharmacy, Saswad, Purandar, Pune, Maharashtra, India.	164.
E012	Bhalodi Krishna	Development of Self-Micellization Solid Dispersion for Solubility Enhancement of Herbal Actives	Department of Pharmaceutical Analysis and Department of Pharmaceutics Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	165.
E013	Shyama S Kumar	Site Specific Oral Modified Release System of Furosamide Solid Dispersion	School of Pharmacy, RK. University, Rajkot, Gujarat-360020	166.
E014	Shah Bhavya D	An Overview of Evaluation of Polymeric Nanoparticles For Follicuar Drug Delivery	Institute of Pharmacy, Nirma University, S.G. Highway, Ahmedabad, Gujarat, India - 382481	167.
E015	Anne Boyina Sravani	Supramolecular Complex of Curcumin as a Treatment Modality for Urinary Tract Infections	Department of Pharmaceutics, Manipal College of Pharmaceutical Sciences, MAHE, Manipal, India	168.
E016	Chittam Suvarna	Novel floating agent Saccharomyces boulardii probiotic formulation based floating drug delivery system	PDEA'S Seth Govind Raghunath Sable, College of Pharmacy, Saswad, Pune, Maharashtra, INDIA.	169.

E017	Paryani Mitali	Applications of Biorelevant media for Lipid formulation: Case study of Lercanidipine Hydrochloride	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	170.
E018	Meet Patel	Probiotic Mouth Freshener- A promising approach for perennial oral hygiene	Ramanbhai Patel College of Pharmacy, Charotar University of Science and Technology, Changa, Anand, Gujarat	171.
E019	Sagar Bhor	Development and characterization of capsule dosage form of Gamma Oryzanol to improve Bioavailability	Institute of Pharmacy, Nirma University, Ahmedabad.	172.
E020	Dangre Pankaj	Development and Exploration on Flowability of Solid Self-Nanoemulsifying Drug Delivery System of Morin Hydrate	Department of Pharmaceutics, Datta Meghe College of Pharmacy, DMIMS (DU), Wardha-442 001, Maharashtra, India	173.
E021	Patil Deepak	Inhalation delivery of repurposed drugs through nano-carriers for lung cancer	Institute of Pharmacy, Nirma University, Ahmadabad, Gujarat	174.
E022	Bhatia Hemant	Herbosomes: Scientific Technique and Future Perspective in Phyto-medicines – An overview	Jayoti Vidyapeeth Women's University, Jaipur, Rajasthan	175.
E023	Prutha Patel	Design and optimization using QbD approach for prolonged release formulation using hot melt granulation technique for anti-depressant	Institute of Pharmacy, Nirma University	176.
E024	Jain Abhishek	Solubility enhancement of BCS Class IV compound having High Melting Point using Solvent-Aided Hot Melt Extrusion.	Kadi Sarva Vishwavidyalaya, Gandhinagar. Gujarat	177.
E025	Anushka Chanchlani	Development and Optimization of orally disintegrating tablet containing multi-unit pellet system.	Institute of Pharmacy, Nirma University	178.
E026	Kokaniwala Safinhushen	Development of Cationic Liposomes using Microfluidization approach.	Parul Institute of Pharmacy, Parul University, Vadodara, Gujarat, India – 391760.	179.
E027	Mewada Vivek	Development, Optimization and Evaluation of Buccal Film for Management of Pulmonary	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat.	180.

		Hypertension Using BCS Class I Drug		
E028	Gosavi Piyushgir	Development and Optimization of Paclitaxel Loaded PLGA Nanoparticle in Treatment of Cancer.	MET Institute of Pharmacy, Nashik, Maharashtra	181.
E029	Maiti Ritwik	Pulmonary Targeting Lipid Nanoparticle Drug Delivery System for Pneumonia	Institute of Pharmacy, Nirma University, S.G. Highway, Ahmedabad, Gujarat, India - 382481	182.
E030	Kanade Rupali	Nose to brain delivery risperidone nanosuspension: In-vitro and ex-vivo Characterization	MET'S Institute of Pharmacy, Nashik, Maharashtra.	183.
E031	Akolkar Tejas R	An overview of nanoparticle drug delivery system for anti – Hepatitis B virus therapy	Institute of Pharmacy, Nirma University, S.G. Highway, Ahmedabad, Gujarat, India – 382481	184.
E032	Gidde Prajakta	Preparation and characterization of Paliperidone nanosuspension.	Bombay College of Pharmacy (Autonomous), Mumbai, Maharashtra	185.
E033	Merai Khushboo	Solid Lipid Nanoparticles: Newer Approach for The Treatment of Glaucoma	Department of Pharmaceutics, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	186.
E034	Kuber Dinesh	Orally Disintegrating Tablets (ODTs) of model drug; Diclofenac Sodium using novel and natural Ocimum Basilicum Mucilage as a superdisintigrant.	MET's Institute of Pharmacy, Bhujbal Knowledge City, Adgaon, Nashik, Maharashtra, India-422 003	187.
E035	Mishra Kunalkumar	Design, Development and Optimization of Anti-Cancer Drug Tablet Using Roller Compactor	Department of Pharmaceutics, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	188.
E036	Barot Tularam	Drug-in-Adhesive Based Transdermal Patch of Atomoxetine Hydrochloride	ROFEL, Shri G. M. Bilakhia College of Pharmacy, Namdha road, Vapi, Gujarat, India	189.

E037	Sagar G. Surani	Development of Immuno-nanoparticles for Multiple Myeloma for Parentral delivery	Department of Pharmaceutics, Parul Institute of Pharmacy, Parul University, Vadodara, Gujarat , India -391760	190.
E038	Arti Mohan	Preparation, Statistical Optimization and In vitro characterization of Etravirine loaded solid lipid nanoparticles.	Department of Pharmaceutics, Arihant college of Pharmacy and Bioresearch Institute, Ahmedabad, Gujarat, India.	191.
E039	Patel Maitree	Development of Protein nanoparticles containing EGFR for the treatment of lung carcinoma	Department of Pharmaceutics, Parul Institute of Pharmacy, Parul University, Vadodara, Gujarat , India -391760	192.
E040	Garkal Atul	Design and Development of in-situ gelling sustained-release nevirapine suspension for treatment of HIV	Department of Pharmaceutics, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat, India-382481.	193.
E041	Gor Jeet	Development of micelles loaded mouth dissolving film	Department of Pharmaceutics, Parul Institute of Pharmacy, Parul University, Vadodara, Gujarat , India -391760	194.
E042	Kumari Pooja	Formulation and Evaluation of Topical Dosage Forms of Bio-Active Phytoconstituents for Acceleration of Wound Healing Process	Guru Jambheshwar University of Science and Technology, Hisar. Haryana	195.
E043	Vyasa Mudra	Nanotechnology in Cancer diagnosis: Current perspectives	Institute of Pharmacy Nirma University, Ahmedabad, Gujarat	196.
E044	Pooja Patel	Process optimization of ecological probe sonication technique for production of drug loaded niosomes	Parul Institute of Pharmacy, Vadodara, Gujarat, Parul University, Vadodara. Gujarat	197.
E045	Ray Vinayak	Self micro Emulsifying Drug Delivery System: Novel Approach For Treatment Of Ocular Uveitis	Department of Pharmaceutics, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	198.

E046	Nair Athira R	Implication of Solution Phase Behavior on the Co-administered Drugs: The Case of Rifampicin, Saquinavir and Darunavir	Manipal College of Pharmaceutical Sciences, Manipal, Karnataka	199.
E047	Dadhania Hemali K	Recent Trends and Challenges in Development of Medicated Shampoo	Department of Pharmaceutics, Institute of Pharmacy, Nirma University, S.G Highway, Ahmedabad, Gujarat, India – 382481	200.
E048	Bhatt Trishala	Electrospun Nanofibers as an Effective Alternative for Ocular Drug Delivery System	Parul Institute of Pharmacy, Vadodara, Gujarat	201.
E049	Jaiswal Devashish	Nano-emulsion loaded with Amphotericin B: A New Approach for the Treatment of Leishmaniasis.	Institute of Pharmacy, Nirma University, S.G. Highway, Ahmedabad, Gujarat, India – 382481	202.
E050	V Sai Krishna Anand	Investigating the influence of physicochemical interactions of co-administered anti-malarial and anti-retroviral medications	1Manipal College of Pharmaceutical Sciences, Manipal, Karnataka	203.
E051	Solanki Dhruvikumari Kiritsinh	Hydrogel Drug Delivery System for Effective Wound Healing.	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	204.
E052	Aliakbar Limdiwala	Micelles loaded hydrogel for ocular uveitis using QBD approach	Parul Institute of Pharmacy, Parul University, Vadodara, GUJARAT – INDIA	205.
E053	Vishwakarma Rajat Pradumna	Formulation Development and Evaluation of Floating Tablets of Zolmitriptan	Met Institute Of Pharmacy, Nasik . Maharashtra	206.
E054	Krishna K Patel	Nanosuspension Loaded Electrospinning Nanofibers for Sublingual Drug Delivery: Novel Approach	Parul Institute of Pharmacy, Parul University, Vadodara, Gujarat	207.
E055	Dani Lakshman Y	Screening of co-formers for the fabrication of co-amorphous systems: An In silico approach	Manipal College of Pharmaceutical Sciences, Madhav Nagar, Manipal, Karnataka.	208.
E056	Parmar Gayatri	Electrospun Nano scaffolds for Wound Healing	Department of Pharmaceutics, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat, India-382481	209.

E058	Krishna Sompura	Novel Pharmaceutical Composites for Tissue Regenration In Non Healing Diabetic Foot Ulcers	Parul Institute of Pharmacy, Parul University, Vadodara, Gujarat, India	210.
E059	Saha Sumit Kumar	Development and Characterization of the formulation containing Alectinib Hydrochloride for solubility and dissolution enhancement	Jamia Hamdard, New Delhi	211.
E060	Mr. Sarthik Dave	Development Of Cationic Polymeric Nanoparticle for Occular Drug Delivery	Parul Institute of Pharmacy, Parul University, Vadodara, Gujarat, India.	212.
E061	Muskan Joshi	Nanoformulations for the Treatment of Atopic Dermatitis	Department of Pharmaceutics, Institute of Pharmacy, Nirma University	213.
E062	Kawish, S.M	Ultrasonically Fabricated Borage Oil Nanoemulsion Containing Docetaxel for Improved Cancer Therapy: Development, Optimization, In Silico and In Vitro Investigation	Nanomedicine Research Lab, Department of Pharmacy, School of Pharmaceutical Education & Research, Jamia Hamdard, New Delhi, India	214.
E063	Shah Jigar N	A Comprehensive Review on Nano Formulations Loaded Microneedle for Transdermal Drug Delivery	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat.	215.
E064	Athar Shamim	Quality by Design driven fabrication of targeted Nano formulation of natural Peptidyl-prolyl isomerase-B inhibitors against Bacterial biofilm	Nanomedicine Research Lab, Department of Pharmacy, School of Pharmaceutical Education & Research, Jamia Hamdard, New Delhi, 110062, India	216.
E065	Mane Ashish	Study on Impact of Brexit for Drug Product Registration in European Region	Institute of Pharmacy, Nirma University, S. G. Highway, Ahmedabad, Gujarat	217.
E066	Upadhyay Uddeshya	Levothyroxine Sodium – Thyroid Hormone Replacement Therapy for Hypothyroidism: A Review of Patent Literature	Parul Institute of Pharmacy, Vadodara, Gujarat	218.
E067	Bangar Priyanka	Update on Hydroxypropyl β-cyclodextrin (HPβCD) as a stabilizer for protein and peptide-based Anti-VEGF formulations	Department of Pharmaceutics, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat, India-382481.	219.

E068	Ankita Yagnik	Microneedle Technology: An Insight into Recent Advancements and Future Trends in Drug Delivery	Faculty of Pharmacy, Parul University, Vadodara, Gujarat, India-391760	220.
E069	Hariharan Kartik	Development of lipidic nanovesicles containing anti-cancer drug using extrusion technique by changing One factor at a time (OFAT)	Institute of Pharmacy, Nirma University, SG Highway, Chharrodi-382481, Gujarat.	221.
E070	Shah Ripalkumar	Formulation, Development and Validation of RP-HPLC Method For Estimation of Lumefantrine In Nanosupension	Faculty of Pharmacy, Dharamsinh Desai University, Nadiad, Gujarat	222.
E071	Parikh Dhaivat	Challenges and Novel Approaches for Transungual Drug Delivery	Department of Pharmaceutics, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	223.
E072	Pisay Muralidhar	Characterization of Drug-Carrier miscibility in Amorphous Solid Dispersions	Manipal College of Pharmaceutical Sciences, Manipal. Karnataka	224.
E073	Jadiya Riddhi	Multifunctional Nano Sponge as A Carrier for The Treatment of Oral Cancer	Institute of Pharmacy, Nirma university, Ahmedabad, Gujarat.	225.
E074	Devadiya Hardik	Influence of Formulation Parameters on Dissolution Rate Enhancement of Eclipta alba Using Liquisolid Technique	Anand Pharmacy Collage, Anand, Gujarat	226.
E075	Sheth Dhwani	Current status of novel vaginal dosage forms for the treatment of trichomoniasis	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	227.
E076	Butani Shital	Self-emulsifying drug delivery system: An approach to deliver lipophilic drugs	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	228.
E077	Dattatraya Yadav	Thermal and in silico techniques for screening of appropriate Coformer in the manufacturing of Pharmaceutical cocrystal	Department of Pharmaceutical Chemistry, Institute of Pharmacy, Nirma University, Ahmedabad.	229.
E078	Maurya Dimpal	Statin Nasal Spray for Covid 19 Infection	Institute of Pharmacy, Nirma university, Ahmedabad Gujarat	230.
E079	Joshi Kanishk	Solid Dispersion: A Solubility Enhancement Strategy	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat.	231.

E080	Rathod Gaurav	Approaches for Targeted Drug Delivery in Treatment of Colon Cancer	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	232.
E081	Gadhavi Harshal	Development and Optimization of Oral Paediatric Suspension For Adjunctive Treatment of Epilepsy	Department of Pharmaceutics, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	233.
E082	Patel Charmy	Solid-Lipid Nanoparticles as Drug Delivery Carriers for The Treatment Of Breast Cancer	Institute Of Pharmacy, Ahmedabad, Gujarat Nirma University, Ahmedabad, Gujarat	234.
E083	Vinchhi Preksha	Natural Product-based Nano-Pharmacotherapeutics for Management of Chronic Wounds	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	235.
E084	Keta J. Patel	Formulation and optimization of Dispersible Tablet for the treatment of Pulmonary Arterial Hypertension	Department of Pharmaceutics, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	236.
E085	Khushboo Mathur	Development and Characterization of Telmisartan Immediate Release Tablets	Institute of Pharmacy, Nirma University	237.
E086	Dhuri Sonika	Surface functionalized Mesoporous Silica Nanoparticles in Drug Delivery: Future Perspectives	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	238.
E087	Joshi khyati	Regulatory requirements and life cycle management of parenteral products in ASEAN countries	Institute of Pharmacy, Nirma university, Ahmedabad, Gujarat	239.
E088	Thakker Prashant	Novel Technique for Taste Masking of Bitter Drug Levocetirizine Dihydrchloride	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat, India	240.
E089	Patel Jahanvi	Advances in iron based products for the management of malnutrition	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat.	241.
E090	Patel Kesha	Non-Oral Approaches in the treatment of Parkinson's disease	Institute of Pharmacy, Nirma University Ahmedabad, Gujarat	242.
E091	Shah Mohit	Recent Advances in Nasal Drug Delivery	Institute of Pharmacy, Nirma University, S. G. Highway, Ahmedabad, Gujarat, India	243.

E092	Sami Anam	Recent Advances and The Emerging Role of Electrospun nanofiber In Cancer Therapy	Institute of Pharmacy, Nirma Ahmedabad, Gujarat	244.
E093	Mahek Shah	Current Updates on Nano formulation for Gout Therapy-Opportunities & Challenges	Institute of Pharmacy, Nirma University, Sarkhej Gandhinagar Highway, Ahmedabad – 382481	245.
E094	Rani Monika	Formulation and Evaluation of Three Dimensional (3D) Mesoporous Silica Nanoparticles for Solubility Enhancement of Poor Aqueous Soluble Drug Luliconazole	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat, India-382481	246.
E095	Patel Mayur	Development and Characterization of Nano - Drug Delivery System for the Treatment of Tuberculosis	Department of Pharmaceutics, Institute of Pharmacy, Nirma University, Ahmedabad	247.
E096	Marques Shirleen Miriam	Novel Luliconazole Spanlastic Nanocarriers: Development and Characterisation	Goa College of Pharmacy, Panaji, Goa	248.
E097	Naga Thirumalesh Chevala	Multifunctional Surgical Sealant: A Surface Modified Fiber Reinforced Nanoporous Multifunctional Scaffold for Biomedical Applications	Department of Pharmaceutics, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal, Karnataka, India.	249.
E098	Joshi Shubham	Design and Development of pH-Sensitive In-Situ Ophthalmic Gel for Open-Angle Glaucoma	Institute of Pharmacy, Nirma University	334.

Track	PHARMACEUTICAL CHEMISTRY			
Paper No.	**Author Name**	**Topic of Oral Presentation**	**Name of Organization**	**Page No.**
F001	Muralikrishnan Amrita	Design of Some Benzimidazole Derivatives for Antifungal activity: An *Insilico* Study	National Forensic Sciences University, Gandhinagar, Gujarat	250.
F002	Patle Deepshikha	Design & identification of novel 2-benzoxazolinone derivatives as potential candidates for the management of Type-II diabetes through molecular docking studies	School of Pharmaceutical sciences, Lovely Professional university, Phagwara, Punjab	251.
F003	Vala Ruturajsinh	Antimicrobial study of dimethoxyphenyl substituted pyrazolo[3,4-b]quinolin-5-one	Department of Chemistry, Sardar Patel University, Vallabh Vidyanagar, Anand, Gujarat, India.	252.
F004	Das Subham	Design, synthesis, ADMET, Molecular dynamics, and biological evaluation of some PPAR-γ Partial Agonist as Insulin Sensitizers	Department of Pharmaceutical Chemistry, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal, Karnataka, India.	253.
F006	Damale Manoj	Design and Molecular modeling study of Novel Imidazole and Pyrimidine based Schiff Bases to find potential hits against fungal Biofilm	Department of Chemistry, Srinath College of Pharmacy, Aurangabad, India	254.
F007	Gnana Ruba Priya	Design, Molecular Docking, Microwave Synthesis of 2-Substituted Benzothiazole derivatives and study of their antioxidant and anticancer activities targeting DHFR Enzyme	Design, Molecular Docking, Microwave Synthesis of 2-Substituted Benzothiazole derivatives and study of their antioxidant and anticancer activities targeting DHFR Enzyme	335.
F008	Savjani Jignasa	AKT's Role and Significance in Cancer Treatment	Department of Pharmaceutical Chemistry, Institute of Pharmacy, Nirma University, Ahemdabad, Gujarat, India	255.
F009	Walhekar Vinayak	Molecular modelling investigation of inhibitors of PIM-1 kinase triazolo-pyridazines as anticancer agents: 3D-QSAR, molecular	Poona College of Pharmacy, BVDU (Deemed to be university), Pune, Maharashtra, India	256.

		docking and dynamics simulation studies		
F010	Chaube Udit	Discovery of Selective, Nontoxic CDK2 Inhibitor with the Aid of Ligand Based and Structure Based Drug Design Approach	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat, India	257.
F011	Shaw Suman	PI3K/Akt/mTOR A Novel, Prominent Oncological Pathway For The Treatment Of Triple Negative Breast Cancer: A Review	Department of Pharmaceutical Chemistry, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat, India	258.
F012	Modh Dharti	Insights into the structural features of anticancer 1,6-naphthyridines and pyridopyrimidines as FGFR inhibitors: 3D-QSAR, Molecular Docking and Dynamics studies	Poona College of Pharmacy, BVDU (Deemed to be university), Pune, Maharashtra, India	259.
F013	Jaiswal Payal	Computational Exploration, Synthesis and Screening of Glun1-1a/NMDA Antagonists: Potential Ligands to Treat Epilepsy	Patel Institute of Pharmaceutical Education and Research, Shirpur, Maharashtra, India	260.
F014	Dey Rajdeep	Heterocyclic Scaffold As Promising Telomerase Inhibitors For The Development Of Chemotherapeutic Agent: A Review	Department of Pharmaceutical Chemistry, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat, India	261.
F015	Jadhav Mrunal	Design of PLK Inhibitors as Potential Cytotoxic Agents	Department of Pharmaceutical Chemistry, SVKM's Dr. Bhanuben Nanavati College of Pharmacy, Mumbai, Maharashtra, India	262.
F016	Sankhe Kaksha	In-silico studies- new hits as potential AK inhibitors in cancer	Department of Pharmaceutical Chemistry, SVKM's Dr. Bhanuben Nanavati College of Pharmacy, Mumbai, Maharashtra, India	263.
F017	Gehlot Pinky	Guanidine-Based β Amyloid Precursor Protein Cleavage Enzyme 1 (BACE-1) Inhibitors for the Alzheimer's Disease (AD): A Review 2006-2021	Department of Pharmaceutical Chemistry, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat, India	264.
F018	Sadaf Fatima	Design, Synthesis, Anti-inflammatory Activity and	Nasimul Hoda, Syed Mansoor Ali, Sadaf Fatima	265.

		Docking Studies of Pyrimidine Derivatives	Department of Chemistry, Jamia Millia Islamia, New Delhi, India	
F019	Sharma Manmohan	A Review on Discovery of Novel Heterocyclic Agents as PfDHODH Inhibitors and Antimalarial Agents	Department of Pharmaceutical Chemistry, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat, India	266.
F020	Singh Satyam	A novel 4"-alkyl ether derivative of green tea polyphenol EGCG as potent and selective EGFR inhibitor	Department of Biosciences and Biomedical Engineering, Indian Institute of Technology Indore, Madhya Pradesh, India	267.
F021	Patel Bhumika	Modulating Wnt Signaling Pathway: Will it be a future therapeutic strategy for the treatment of Type II Diabetes Mellitus?	Department of Pharmaceutical Chemistry, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat, India	268.
F023	Chudasama Shrddhaba	A Review on Synthetic Account of 1,2,4-Oxadiazoles as Anti-infective Agent	Department of Chemistry, L.M College Of Pharmacy, Ahmedabad, Gujarat, India	269.

TRACK	PHARMACEUTICAL ANALYSIS AND QUALTIY ASSURANCE			
Paper No.	**Author Name**	**Topic of Oral Presentation**	**Name of Organization**	**Page No.**
G002	Bang Pratiksha	A comparative evaluation of LNB in Pharmaceutical Drug substances and Dosage forms using Green RP-HPTLC and Green NP-HPTLC methods	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	272.
G003	Chavan Mahesh	Development and Validation of Stability Indicating UV Spectrophotometric method for estimation of Levosulpiride in bulk and pharmaceutical dosage form	Amrut vahini collage of Pharmacy, Sangamner, Ahmednagar, Maharashtra	273.
G004	Jadav Zeel	Applications of Capillary Electrophoresis for Monitoring Environmental Pollutants	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	274.
G005	Patel Harsh	Indispensable role of β – Cyclodextrin in separation of enantiomers of pharmaceutical active ingredients	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	275.
G006	Patel Vishwa	Development and Validation of Analytical Method for Estimation of Aspirin and Dipyridamole in their fixed Combine Dosage Form	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	276.
G007	Patel Hetanshi	A Review on the Analytical Techniques for Different Poly-herbal Formulations and Bio-actives Used for Bone Tissue Regeneration	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	277.
G008	Makwana Isha	Implementation of QbD Approach to Analytical Method Development and Validation for Sunroid: An Overview	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	278.
G009	Gatlewar Bhagwati	Analytical method development and validation for impurity profiling of Sunpeptide and it's characterization by LC-HRMS	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	279.
G010	Shaikh Farhat	Development and Validation of Dissolution Method for Miglitol Tablets	Department of Pharmaceutical Quality Assurance, Amrutvahini	280.

			College of Pharmacy, Sangamner, Ahmednagar, Maharashtra	
G011	Kalariya Jeel	A review on LC-MS/MS analysis of selected drugs in oral fluid	Department of Pharmacetical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	281.
G012	Joshi Dhruv	Overview on Analytical techniques used for Metabonomics: Application to human health	Department of Pharmacetical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	282.
G013	Thakkar Rajvi R.	Data Integrity Remediation and CGMP Facilities	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	283.
G015	Patel Nrupesh	HPLC Method Development and Validation for Dissolution Study of Flucloxacillin Sodium Tablets	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	284.
G016	Patel Shruti	Overview of Quantitative NMR Spectroscopy & It's Applications	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	285.
G017	Mehta Priyanshi	Review on Forced Degradation Studies of Clopidogrel Bisulfate and Prasugrel Hydrochloride	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	286.
G018	Suhane Anshika	Impurity Profiling of Sacubitril Valsartan Complex using LCMS Compatible Analytical Method	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	287.
G019	Patel Avani	Development and validation of RP-HPLC method for Baclofen and its related substance in its tablet dosage form	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	288.
G020	Chandani Vikas	An Overview of Bioanalytical Techniques for Quantification of Biotherapeutics	Lupin Limited, Pune, Maharashtra	289.

G021	Desai Kashish	The development and validation of a stability-indicating RP-HPLC technique for the simultaneous estimation of Vildagliptin and Metformin in bulk dose form	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	290.
G022	Gajjar Saumitra	Importance Of Multi Attribute Method (Mam) in Post-Translational Modifications	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	291.
G023	Patel Sneh	Deep Eutectic Solvents and It's Applications	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	292.
G024	Lohare P. S.	Development and Validation of Stability Indicating UV Spectrophotometric Method for Fluticasone Propionate in Bulk and Pharmaceutical Formulation	Department of Pharmaceutical Quality Assurance, Savitribai Phule Pune University	293.
G025	Lunagariya Shreya	Modern Techniques For Extraction Of Herbal Drugs	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	294.
G026	Patel Manali	Review on in-depth understanding about drug-space radiation interaction and its evaluation model	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	295.
G027	Bhinde Khyati	QbD based development and validation of Green HPTLC method for the estimation of IRB drug substance and Marketed Tablet formulation	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	296.
G028	Ghodke Dhanashri	Method development and qualification of host cell protein impurities in SunmAb by ELISA	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	297.
G029	Bana Arpit	Protein Aggregation Analysis by Size Exclusion Chromatography Coupled to Multi Angle Light Scattering Detector	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	298.

G031	Modi Shely	A Review on The Regulatory Outlook For Peptide Therapeutics	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat, India	299.
G032	Patel Nipa	Development of LFIA based Sandwich-ELISA method for detection of Aflatoxin B1	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	300.
G033	Hariyani Heer	A Review on PEGylated Filgrastim Characterization	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	301.
G034	Modi Jeel	Analytical Method Development And Validation Of Teriflunomide By RP-HPLC	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	302.
G035	Shah Shikha	Development And Validation of HPLC Method For Estimation of Diroximel Fumarate	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	303.
G036	Parmar Dhanvi	Applications of Photoacoustic Spectroscopy	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	304.
G037	Shah Het	Review on Various Analytical Methods for the Estimation of Poly (ADP-ribose) polymerase1 (PARP1) Inhibitors: API, Pharmaceutical Dosage Forms, and Biological Samples	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	305.
G038	Barot Rutu	Overview on new trends in HPLC and an insight on Nano HPLC	Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	306.
G039	Patel Shikha	A review on forced degradation strategies to establish the stability of therapeutic peptide formulation	Department of Pharmaceutical Analysis, Institute of Pharmacy,	307.

			Nirma University, Ahmedabad, Gujarat	

Track	MODERN HEALTHCARE CHALLENGES AND OPPORTUNITIES			
Paper No.	**Author Name**	**Topic of oral presentation**	**Name of Organization**	**Page No.**
H001	Bhavsar Harshavi Palakbhai	Significance of Laboratory findings in novel SARS-CoV-2 disease Prognosis: A review.	School of Pharmacy, National Forensic Science University, Sector 9, Gandhinagar, Gujarat	309.
H006	Lakum Harmish	Combination Nanotherapies for TNBC Based on RNAi	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	310.
H008	Joshi Rushi	Artificial Intelligence-based Content Uniformity Detection: The Changing Paradigm of Pharmaceutical world	Ramanbhai Patel College of Pharmacy, Charotar University of Science and Technology, Changa, Anand, Gujarat, India.	311.
H009	Shaikh Farhan Maheboob	Development of More efficient and cost effective Virucidal Coated Face Masks to reduce spread of COVID-19 infection.	R.C patel Institute of Pharmaceutical Education and Research Shirpur (425405) Dist: Dhule.	312.
H010	Wagh Pradip	Preclinical evaluation of phloretin on cisplatin induced nephrotoxicity in peri-menopausal mouse model	R.C Patel Institute Of Pharamceutical Education & Research, Shirpur 425405 Dist- Dhule.	313.
H011	Kothari Charmy	Artificial Intelligence for Alzheimer's disease Diagnosis: A Boost in Accurate Prediction Approach	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	314.
H012	Gupta Nikita	Current Approaches and Emerging Novel Therapies for Idiopathic Pulmonary Fibrosis	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	315.
H013	G Haripraksh	Assessment Of Gaps Between Standard Diabetes Treatment Protocols Available In India And National List Of Essential Medicines And Who Essential Medicines- A Comparative Review Study.	Dept of Community Medicine, JSS Medical College, SS Nagar,	316.
H014	Parikh Karma	Regulatory Framework For Artificial Intelligence And Machine Learning Driven Software As A Medical Device (Samd)	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	317.
H015	Parikh Nandeeni	Experimental Acute and Chronic Pancreatitis Models: History, Current Status and Success	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	318.

H016	Rathod Hritik	Therapeutic advances in Dravet and Lennox-Gastaut Syndrome the devastating forms of Epilepsy: A targeted literature review	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	319.
H017	Udhani Raveena	A Comprehensive Study on Traditional And Cutting Edge Techniques For The Detection of the Vitamins and Minerals	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	320.
H018	Pathak Fagun	An Overview and Comprehensive Study of Current Emerging Trends in the Diagnosis and Treatment of Autism Spectrum Disorder	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	321.
H019	Varghese Rini	Network Pharmacology: A Novel Paradigm for Drug Repurposing and Synergism	Bombay College of Pharmacy, Kalina, Santacruz (E), Mumbai 400098	322.
H020	Kaur Rashmin	Nuclear medicine an opportunity or obstacle for health care system.	CT University, Ludhiana, Punjab	323.
H021	Padhye Mayuri	Microplastics: A threat to the terrestrial and aquatic ecosystem	Bombay College of Pharmacy, Kalina, Santacruz (E), Mumbai 400098	324.
H022	Panchal Zalak	Reducing Toxicity in Critically Ill Patients by using Therapeutic Drug Monitoring	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	325.
H023	Pekhale Mrunal Tanaji	Post Covid Opportunities in Pharmacy	MET, Bhujbal Knowledge City, Institute of Pharmacy, Adgaon, Nashik, Maharashtra	326.
H024	Kanani Surabhi	Regulations of 3D printed devices	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	327.
H025	Panchal Shital	Leaky gut syndrome: An emerging stress induced disorder	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	328.
H026	Diwane Shivani	Phloretin treatment prevent Arsenic Trioxide Induced Nephrotoxicity in Swiss Albino Mice	RC Patel, Institute of Pharmaceutical education and research, Shirpur	329.
H027	Shah Archi	Emergence of Immunotherapy to Combat Cytokine Storm in COVID-19	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	330.

H028	Kothari Manav	Effect of Covid-19 on Pregnancy and Related Outcomes	Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat	331.
H029	Desai Harsh	A Review on Nano-polymer formulation and Characterization for Drug Delivery System	Institute of Technology, Chemical Engineering Department Nirma University, Ahmedabad, Gujarat	332.
H030	Bhimani Sneha	Cardiorenal Syndrome: New Development in the Understanding and Pharmacological Management and diagnosis	Anand Pharmacy College, Anand, Gujarat	333.

TRACK-A

BASIC

PHARMACOLOGY

A001

Pharmacological Evaluation of Febuxostat in Experimentally Induced Breast Cancer in Rats

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Background: Breast cancer is a pathological condition in which breast cells abnormally divide to form a tumor. The main source of tumor formation is excessive generation of basal reactive oxygen species through various enzymatic sources which also includes xanthine oxidase. Febuxostat, a potent xanthine oxidase inhibitor may act as an inhibitor ROS production. Objective: Objective of the study was to evaluate the pharmacological action of febuxostat by estimating the mechanism of action. Methodology: Female Wistar rats were divided into five groups: normal control, breast cancer induced by single dose subcutaneous injection of 7, 12-dimethyl benz[a]anthracene (45 mg/kg) in the right pad of mammary gland, doxorubicin (4 mg/kg) treated, febuxostat (4.11 mg/kg) treated and combination of doxorubicin and febuxostat treated. Upon completion of 6 weeks treatment, excised tumors were subjected to assessment of tumor specific parameters, superoxide dismutase (SOD), glutathione reductase (GSH), TNF-α, IL-6 and IL-1β, PTEN, p53 genetic expression and histopathological and immunohistology expressions. Results: Expressions of SOD, GSH, TNF-α, IL-6 and IL-1β was increased in diseased animals due to higher oxidative stress and inflammation in tumor. Although SOD and GSH levels increased, malondialdehyde levels were reduced due to diminution in lipid peroxidation. Along with this, PTEN levels were increased in all treated animals suggesting inhibition of PI3K/Akt/mTOR pathway. Conclusion: Data suggested that febuxostat exerted reasonable anticancer activity against DMBA induced breast cancer model in rats due to moderate inhibition of oxidative stress and inflammatory parameters. Also, moderate PTEN expression suggesting that it might inhibit PI3K/Akt/mTOR pathway.

A002

Optimization of the Avian Embryo Chorio-Allantoic Membrane Model Protocol As A System for Screening of Angiogenesis Inhibitors

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Angiogenesis pays an important role in the pathology of diseases like macular degeneration and cancer. Thus, there is a persistent requirement for therapeutic approaches for establishment of new management strategies towards their treatment. The chick chorio-allantoic membrane (CAM) is a highly vascular biological testing membrane for reliable and reproducible pre-clinical assessment of efficacy, toxicity and kinetics of pro or anti-angiogenic drugs. The condensed procedure for CAM Assay is easy to understand but difficult to reproduce in the laboratory. To fill this gap, in the present research, a standardized and optimized CAM assay protocol has been proposed by using standard angiogenesis inhibitor, bevacizumab. The study proposes a standardized avenue for distinguishing anti-angiogenic molecules which may not support alternative vascularization pathway, that may have impact on future pro and anti-angiogenic drug development. High throughput screening of the anti-angiogenic compounds calls for refined animal models for the pre-clinical development and translation of effectual compounds to clinical practice. Considering this, the chick chorioallantoic membrane (CAM) model rationalizes the physiology and dynamics of angiogenesis, that cater for unambiguous research investigations along with compliance of 3Rs concept of animal ethics (reduction, refinement and replacement of animal models).The inclusion of CAM model in the pre-clinical development of compounds will ethically boost basic and translational angiogenesis research.

A003

Newer Targets for Cardiac Cachexia

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There is high prevalence rate of the cardiac cachexia leading to high mortality and morbidity. Patients with heart failure experience cardiac cachexia and such patients have the problems of skeletal muscle wasting, lean body mass, reduced appetite and poor quality of life. There is increase in levels of various cytokines like TNF-α, that leads to the proteasomal degradation through the ubiquitin system. Nrf2 and miRNA are other important target that affect the cachexia of the chronic heart failure patients. Murf-1 has also role for the up regulation of the expression that leads to the cachexia. Activation of RAS pathway leads to increase in reactive oxygen species, that produces muscle wasting and also increase proteolysis. RAS pathway also affects the AkT/Mtor pathway that inhibits protein synthesis. Also MCR4 present in melanocortin system that produces anorexia,appetite loss and elevated metabolic rate. Nrf2 is a transcription factor that regulates the antioxidant genes.Additionally, adiponectin has role in the cachexia patients for the prevention of heart failure. This review provides an over view of newer targets for cardiac cachexia.

A004

A short review on Pathogenesis, Diagnosis and Recent Herbal Treatments on Diabetic Nephropathy

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Diabetes is characterized by chronic hyperglycemia and is of major concern globally. It is associated with many complications and Diabetic nephropathy (DN) is one of the prominent ones. Currently, DN is a leading cause of end-stage renal disease characterized by hyperglycemia with disturbance in carbohydrates, fat, and protein metabolism which worsen with the progression of diabetes. If left untreated, it results in thickening of the glomerular basement membrane, glomerulosclerosis, glomerular hypertrophy, podocyte loss, expansion of mesangial cells, tubulointerstitial fibrosis, and ultimately kidney failure. Since the pathogenesis of DN is very complex and is still not fully understood, resulting in poor therapeutic outcomes. Standard therapy of strict blood glucose monitoring and blood pressure control fails to control the complication leading to end-stage renal damage and mortality. Understanding the key pathways such as oxidative stress, angiotensin II (Ang-II), and inflammatory processes involved in the progression of DN allows the identification of new potential targets. Recent herbal drugs such as Turmeric, Ginger, Berberine, Gardenia, Cinnamon, luteolin, for DN have paved their way to newer and safer treatment in complications of DN. The review highlights the mechanism and current therapeutic approaches of DN which will facilitate the early control and treatment of the complication.

A005

Role of Inflammation and Inflammatory Cytokines in Cardiac Cachexia

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Cachexia is the weakness and wasting of the muscle in the body due to severe chronic illness. The cachexia can be seen in cancer, COPD, kidney disease, CHF and AIDS. In, cardiac cachexia person usually suffers from the weight loss of the body along with change in body composition. The prevalence of cardiac cachexia is 5%-15% in CHF patient. The annual mortality rate of coronary cachexia is nearly 20%-40%. The mechanism of cardiac cachexia involves many factors such as catabolic anabolic imbalance, neurohormonal abnormalities, dietary deficiency. Protein synthesis is reduced, and protein catabolism is elevated, resulting in an accelerated loss of lean muscle tissue before adipose tissue. Patients with coronary cachexia may experience a loss of appetite due to changes in food smell and taste, pharmaceutical side effects, and fluid and salt restriction. The inflammatory cytokines such as Tumour necrosis factor alpha (TNF-α), Interlukin-6(IL-6), IL-1, IL-10, IFN-γ are increased in the plasma of coronary heart failure patients. The amount of bodyweight loss seen in cachexia patients is closely related to TNF levels and represents not only a decrease in lean muscle mass but also a decrease in fat and bone mass. Interleukin-6 is a multifunctional proinflammatory cytokine that plays a role in immunological and inflammatory responses. The level of proinflammatory cytokines elevated because of inflammation produced due to weight loss in the body. This elevated cytokine leads to coronary cachexia. This review will focus on pathophysiology of coronary cachexia and role of different inflammatory cytokines in cardiac cachexia.

A006

Clinical Evaluation of a Dental Gel Comprising Cranberry and Brindleberry for Prevention of Progression of Periodontitis

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The present study formulates and evaluates a polyberry gel comprising extracts of cranberry (*Vaccinium macrocarpon)* and brindleberry (*Garcinia cambogia*) in patients suffering from chronic periodontitis. The polyberry gel was evaluated for various physicochemical parameters, *in vitro* permeability and stability, and the active phytoconstituents were quantified by HPTLC. Estimation of phenolic content, total antioxidants, and ascorbic acid was carried out in the two extracts using *in vitro* assays. Patients suffering from chronic periodontitis with probing pocket depth of up to 5mm, with no systemic diseases from the age group of 30-50 years were divided into 3 groups of 21 patients each and treated with scaling and root planing (SRP) or SRP followed by subgingival placement of polyberry gel/tetracycline fibres (Standard). Plaque Index (PI), Gingival Index (GI), Probing Pocket Depth (PPD), Clinical Attachment Loss (CAL), and Aspartate aminotransferase (AST) and C-reactive protein (CRP) levels from saliva were recorded at baseline and after 1 month. A significant reduction in the periodontic disease parameters was observed in the standard and gel-treated groups between their baseline and 1 month time-interval readings. The polyberry gel treatment similar to tetracycline treatment significantly attenuated the periodontitis-elevated PI, GI PPD, CAL, AST and CRP levels when compared with SRP. The amelioration of periodontitis and gingival inflammation may be attributed to the potent antioxidant activity of the polyphenolic phytoconstituents of the gel. The polyberry gel may thus be used as a safe adjunct to SRP/tetracycline in chronic periodontitis.

A007

Skeletal Muscle Wasting in Cancer Cachexia

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Cachexia in Greek is kako= bad and hexis = condition. Cachexia can be defined as a complex syndrome which occurs as a secondary manifestation of a range of diseases, most commonly Cancer, Cardiac Heart Failure, Chronic Kidney Diseases and AIDS which leads to marked muscle loss in addition to weight loss which cannot be entirely reversed with nutritional supplement and exercise. Prevalence of cachexia in advanced stage cancer patients is of 50-80% approximately, and leading towards mortality rates of 20-30% associated with cancer. Decrease in quality of life and lower response to treatment is observed because patients experiencing weight loss would receive lower dose and have more toxicity which also effects survival intervals. Decrease in ability to move and reduced performance of respiratory and cardiovascular systems which relies on muscle system also out turns decrease in survival period. There are various mechanisms involved in cancer cachexia. One proposed mechanism is increased release of pro inflammatory cytokines when there is an increase tumor progression. Cytokines like TNFα, IL-6, IL-1 and IFN-ϒ shows metabolic disturbances. Skeletal muscle wasting leads to muscle atrophy which makes the patient's functionality to get impaired, fatigue and weakness. This phenomena is the result of when there is increased protein degradation and decreased protein synthesis. This review will focus on pathophysiology of Cancer Associated Cachexia and mechanisms acting on protein metabolism which causes wasting of skeletal muscle in Cachexia.

A008

Investigating the Role of Hypercoagulation in the Onset and Progression of High Cholesterol Diet Induced Neuropathology

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The mechanisms explaining the trigger of high cholesterol diet driven neurodegeneration are not well elucidated. Hypercoagulation followed by hypofibrinolysis mark the pivotal events in the advent of neurodegeneration in obesity. However, the contribution of coagulation mediators in obesity linked neurodegeneration remains unknown. In this study the role of hypercoagulation in obesity induced neurodegeneration in high cholesterol diet (HCD) fed wistar rats has been evaluated. Wistar rats were fed a high cholesterol diet (HCD) in three different concentrations for eight weeks. Analysis included quantification of: (i) body weight, lipid profile, oxidative stress, inflammatory response; (ii) the contribution of the coagulation mediators (PT, aPTT, fibrinogen) and fibrinolytic activity; and (iii) neuropathological changes, neurodegeneration and behavioural response. Parallel rise in body weight, cholesterol level and coagulation mediators was observed in HCD fed rats during 8 weeks of study. Significant increase ROS production and levels of inflammatory markers including TNF-α, IL-6, NF-kβ was observed in HCD fed rats. Our results also reflected those significant alterations in coagulation markers and fibrinolytic activity in HCD fed rats are suggestive of the potential link between obesity, hypercoagulation and neurodegeneration. Further, histopathological analysis, done through H&E and Congo red staining, demonstrated apoptosis and amyloidogenic effects in the hippocampus of HCD fed rats. Our findings highlight the potential contribution of hypercoagulation followed by hypofibrinolysis in the onset and progression of neurodegeneration in diet induced obesity.

A009

Repurposing of Anti-histamine Drugs for cancer therapy

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Cancer is the leading cause of death worldwide, accounting for almost 10 million deaths. The most prevalent are lung, breast, colorectal and skin cancer. Cancer does not follow the cell cycle which can lead to formation of tumors. The biogenic amine histamine synthesized by histidine. Increased amounts of histamine have been linked in regulation of several tumors. The receptors of histamine (H1, H2, H3, and H4) are distributed throughout the skin, where H1 and H2 are the main targets for drug therapy. Repurposing of the existing antihistamine drugs can be cost effective, safe medications and associated with lesser adverse effects. Researchers investigated Six H1-antihistamines (Cetirizine, clemastine, desloratadine, loratadine, ebastine and fexofenadine) in a nationwide wide cohort study of all Swedish patients with ten types of immunogenic (melanoma, bladder cancer, kidney, prostate, lung, pancreatic, colorectal, breast cancer and Hodgkin lymphoma) and six non-immunogenic (thyroid cancer, liver, ovarian, brain cancer and lymphoma) tumors. The study shows that Desloratadine and loratadine increased the survival rate for many tumors by inhibiting the growth tumors and promoting apoptotic cell death. The other H1 receptor antagonist Cloperastine knockdown FGF13 expression which is responsible for anticancer agent cisplatin-resistance and selectively kill HeLa cisR cells. Some findings believe that H1 receptor antagonist should be investigated in randomized clinical trials for immunogenic tumors. These drugs can be curative therapy for several tumors including those prognosis with limited treatment options.

A010

Central Histaminergic Transmission via H_1 and H_2 Receptor Modulates the Diazepam Induced Anxiolytic-like Behavior in Mice

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The present endeavor investigates the possible modulatory role of central histaminergic system in diazepam induced effect on anxiety-like behavior in mice. Diazepam has been reported to regulate the release of brain histamine which strengthens the premise that it might contribute or counter-regulate the anxiolytic effect of diazepam and could be novel approach in the treatment and management of anxiety. In this study, different doses of diazepam (0.5, 1, 2 mg/kg, i.p.) was tested for its effect on anxiety-like behavior on light and dark box test. Further the central administration (i.c.v.) of histaminergic modulators such as histamine (0.1, 10 µg), histamine neuronal releaser/H_3 receptor antagonist (Thioperamide: 0.5, 10 µg)/ agonist R-α-methyl histamine (0.5, 1, 2 µg), H_1 and H_2 receptor agonist (FMPH: 0.1, 6.5 µg; Amthamine: 0.1, 5 µg)/antagonist (H_1: Cetirizine 0.1µg) and (H_2: Ranitidine: 10 µg) or peripherally (i.p.) with histamine precursor (L-histidine: 250, 500 mg/kg) on diazepam induced axiolytic effect was studied. Results of our study showed that agents which enhances the histaminergic transmission was unable to modulate the diazepam induced anxiety related indices while the histaminergic pre and postsynaptic receptor agonist and antagonist respectively, significantly reverted the anxiolytic-like response of diazepam. Moreover, simultaneous injection of both postsynaptic antagonists to naïve mice increases the anxiety-like behavior but failed to alter the anxiolytic response following diazepam treatment. Therefore, involvement of both the histamine post synaptic receptor in mediating the effects diazepam is proposed and could play a plausible therapeutic role in managing anxiety.

A011

The Involvement of Acquired immunity in Alzheimer's disease.

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Dementia affects around 55 million people worldwide. The Amyloid Hypothesis is a crucial element of Alzheimer's disease (AD). This hypothesis is based on the role of amyloid beta protein, Neurofibrillary Tangles formation (NFT), and impairment in neuronal function in Alzheimer's disease. Acquired immunity plays an important role in amyloid plaque development, neuronal death, and memory loss in AD, it is really important to emphasise the role of acquired immunity in amyloid plaque formation, neuronal death, and memory loss. The use of acquired immune response in the therapeutic treatment area has generated a lot of interest. According to certain studies, many of these Alzheimer's patients have a genetic predisposition to the disease. Multiple risk factors also influence Alzheimer's disease progression through modulating microglia. Microglia can be a potential target for the treatment of AD.

A012

An Attempt to Fathom the Inhibitory Potential of Pantoprazole Sodium on Testosterone Induced Intraepithelial Neoplasia in Rats: Exploring the Role of TRPM7 Channel

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TRPM7 has been identified as a potential druggable target for prostate cancer therapy. The present study focuses to investigate possible link between pantoprazole and TRPM7. Molecular docking study was performed to evaluate the interaction of TRPM 7 with Pantoprazole followed by *in-vitro* study for assessing the effect of pantoprazole on TRPM7 expression in PC-3 cells. Further *in-vivo* study was conducted to study effect of pantoprazole (30mg/kg/day, p.o) on TRPM7 expression in prostate tissue of wistar rats after 8 weeks treatment as well as impact of pantoprazole in testosterone induced Prostatic intraepithelial neoplasia in rats. The study results demonstrated possible interaction of pantoprazole with TPRM7 kinase domain, which was reflected by decreased TRPM7 in both PC-3 cells as well as prostate tissue of rats treated with pantoprazole. Further, pantoprazole treated animal groups showed decreased level of serum testosterone and serum prostate specific antigen level. Converging all the results, pantoprazole showed a therapeutic potential for the treatment of prostate cancer by mediating inhibitory action on TRPM7 channel.

A013

Transient Receptor Potential Cation 6 (Trpc6): A Friend or Foe?

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TRPC6 is a non-selective receptor-activated cation channel that belongs to the "transient receptor potential canonical (TRPC) channel" family. TRPC6 is controlled by phosphorylation of tyrosine and serine, as well as phosphoinositides. TRPC6 is found in abundance in the placenta, heart, lungs, pancreas, kidneys, intrinsic cardiac ganglia, olfactory epithelium neurons, retinal ganglion cells, and several brain areas, including the cortex, hippocampus, substantia nigra, and cerebellum. Given its specific expression pattern, TRPC6 is likely to play a number of physiological roles which are confirmed by the analysis of a Trpc6 −/− mouse model. In smooth muscle Na+ influx through TRPC6 channels and activation of voltage-gated Ca2+ channels by membrane depolarization's the driving force for contraction. Permeability of pulmonary endothelial cells depends on TRPC6 and induces ischemia–reperfusion edema formation in the lungs. TRPC6 was also identified as an essential component of the slit diaphragm architecture of kidney podocytes and plays an important role in the protection of neurons after cerebral ischemia. TRPC6 channel is found to be overexpressed in the macrophages of COPD patients and also has a role in cardiac hypertrophy. It is also observed that TRPC6 plays an important role in the pathogenesis of various tumors like esophageal cancer, gastric cancer, prostate cancer, and renal cell carcinoma. TRPC6 channel is found to be overexpressed in head and neck squamous cell carcinoma cell lines and in Glioblastoma multiforme (GBM) patients. Recent studies concluded that TRPC6 blockers may be helpful in diseases with highly activated TRPC6 channel activity.

A014

Pre-clinical Safety Assessment of *Cassia tora Linn.* Stem.

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Toxicity testing is paramount in the screening of newly developed drugs before they can be used on humans. The essence of toxicity testing is not just to check how safe a test substance is, But also to characterize the possible toxic effects it can produce. The aim of the study was to assess the acute toxicity of the aqueous extract of *Cassia tora Linn*. Stem. It is presumed that Ayurvedic drugs have lesser side effects as compared to allopathic drugs. *Cassia tora Linn*. is a well-known plant widely distributed in India and other tropical countries. This medicinal plant reported to have, Immunomodulatory, Anti-inflammatory, Anti-cancer actions, Anti-diabetic and Wound healing activities are reported. In the present study, acute toxicity of *Cassia tora Linn.* was assessed in albino wistar rats as per OECD guidelines TG 425 up and down procedure to establish a safe dose for further animal studies to prove its medicinal properties. In the present study, mortality was not observed after treatment with aqueous extract of *Cassia tora linn.* stem during the study period. Parameters such as body weight, food, and water consumption did not show any significant changes the behavior of all experimental animals was found to be normal during the study. Based on the results obtained from the acute oral toxicity study it can be concluded that the drug was found to be safe, since there was no mortality observed at the dose of 2000 mg/kg.

A015

Pharmacology of SGLT2 Inhibitors Update on Decade of Progress

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Commercially a massive range of medication belonging to exceptional classes including biguanides, sulfonylureas, meglitinides and thiazolidinediones are available to govern and treat the type 2 diabetic sufferers. On the other hand, a long term usage of these drugs exhibits numerous side outcomes and headaches to one-of-a-kind organs of the body which in the end lead to cardiovascular issues, liver sickness, kidney disorder and weight gain too. Consequently, the development of a new pharmacological class of anti-diabetes agents targeting the kidney has provided new treatment options for the management of type 2 diabetes mellitus. Urinary tract and genital problems are very commonly seen via using gliflozins as non-stop use of those drugs will result in the urinary excretion of increasing amounts of glucose from the body. These complications or facet consequences are very typically seen in females than in males. Hypoglycaemia is a totally not unusual aspect impact when there may be a combinational use of insulin with SGLT-2 inhibitors. Consequently, its miles especially vital to be privy to the interaction of this combination. Drugs discovered in past decade for the treatment of diabetes consist of canagliflozin, dapagliflozin, and empagliflozin. Dapagliflozin (Farxiga) is approved on April 30, 2021 to reduce the risk of adverse kidney and CVD outcomes in patients with CKD who are at risk of progression with or without type 2 diabetes. Its miles hoped this study will inform us about pharmacological effects and development of formerly approved and different new drugs under SGLT-2 inhibitors.

A016

Plumeria acuminata: An Herb with Abortifacient Potential

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Background: An abortion, a healthy way of terminating pregnancy, is the ideal approach to control unintended pregnancy and world population. Plant *Plumeria acuminata*, of *Apocynaceae* family has exhibited several activities similar to abortifacient medicines. Objective: The aim for the present investigation was to study the abortifacient activity of ethanolic extract from *P. acuminata* leaves and roots in wistar rats. Methods: Ethanolic extracts of harvested *P. acuminata* leaves and roots were prepared through cold maceration process, subjected to qualitative phytochemical analysis and acute toxicity test. Based on the LD_{50} values, 100, 200 and 400 mg/kg dose of both extracts were determined for abortifacient activity in mated adult wistar female rats. Misoprostol was administered at 0.1 mg/kg, *p.o*, as standard abortion inducing drug. Standard and test-item treatments were given from gestation day (GD) 7 to 14. Morphological, hematological, hormonal, and histological examinations were performed on GD20 after euthanizing animals. Results: Administration of extracts significantly altered the hormonal levels up to ~20-30% i.e., decrease in estrogen and progesterone as well as increased PGE-1 and acetylcholine. Anatomical alterations in reproductive organs were confirmed by observing cystic follicle and atrophied squamous cells during histopathological evaluation. Visual observations of uterine horns confirmed ~25% live fetus, ~28% early resorption, ~30% late resorption resulting in ~75% post-implantation loss. Conclusion: Obtained abortifacient results can be attributed to presence of plumericin, sterol and lupeol triterpene groups of phytochemicals present in leaves and roots ethanolic extracts, making them potent candidate for natural abortifacient medicines.

A017

Pharmacological Evaluation of Olsalazine in the Treatment of Breast Cancer

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Objective: The objective of the study was to carry out pharmacological evaluation of Olsalazine for the treatment of breast cancer. Material and Methods: Breast cancer was induced by the administration of 7,12 Dimethyl Benz(α)Anthracene (DMBA) once at a dose of 45 mg/kg by subcutaneous route in mammary glands of rats. Following 16 weeks induction, treatment was given for 7 days. Blood was collected for biochemical analysis. In the end, tumors were isolated. Morphological parameters, immunohistochemistry and histopathology were carried out. In Xenograft model, $5*10^5$ cells were injected into the mammary glands of mice. Following 4 weeks induction, treatment was given for 7 days. Blood was collected for biochemical analysis. In the end, excised tumors were subjected to morphological assessment, histopathological and tumor specific studies. Results: Significant reduction in tumor volume in Olsalazine treated animals was observed. In DMBA induced breast cancer, reduced levels of tumor markers (LDH, CKMB, CRP, TP, SGPT, SGOT, and creatinine) was observed. In immunohistochemistry, low p53 levels were found in the Olsalazine treated group. In xenograft model, levels of LDH, CRP, Total protein, and SGPT levels were decreased in drug treated animals. Histological studies were suggestive of anticancer effects of Olsalazine. Conclusion: Olsalazine has potential in the treatment of breast cancer in both DMBA induced breast cancer as well as in Xenograft model.

A018

Short Review on Maternal Deprivation as Potential Animal Model for Early Life Stress

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Early life stress (ELS) induces long lasting consequences on stress responses and emotional regulations in humans increasing vulnerability to the development of psychopathologies. More than 50% of children worldwide are exposed to early stress. Early psychosocial stressors could result in neuropsychiatric disorders such as anxiety, depression, and post-traumatic stress disorder. While human depressive illness is indeed uniquely human, many of its symptoms may be modeled in rodents for the development of depression like symptoms such as anhedonia, memory impairment and neuroendocrine changes. Maternal deprivation (MD) is a widely used well established animal model of ELS. Chronic neonatal maternal deprivation during early childhood (PND 1-PND 10) is set to cause various alterations in the brain in adulthood which is said to resemble the conditions as that in humans. MD alters neurotrophins expression, serum cortisol level, changes in rat brains structure, cognition, and behavior which are the major factor responsible for stress in adulthood due to ELS in humans. This review highlights MD as a potential animal model which resembles ELS in humans based on existing evidence such as alterations in the expression of synaptic plasticity markers, such as the brain-derived neurotrophic factor (BDNF) and synaptophysin (SYN), impairment of olfactory bulb, alteration in parts of the brain such as Hippocampus, Amygdala and Prefrontal-cortex which are the major sites affected in stress.

A019

Chemokine Receptor CXCR4: A Systematic Review

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The CXCR4 has been established as a receptor for the functions of CXCL12, CXCR7 and for the regulation of CXCL12 gradients through high-affinity binding and rapid degradation. Therefore, extensive studies are needed to describe the precise role of the CXCR4-CXCR7-CXCL12 axes in cell migration. In addition, others have extensively studied the role of CXCR7 and CXCL12 in biology and disease. The binding of CXCL12 to CXCR4 initiates various downstream signalling pathways that result in a plethora of reactions including elevation of intracellular calcium, gene transcription, chemotaxis, cell survival and proliferation, which can be briefly mentioned here. Moreover, chemokine receptors are GTP-binding proteins that are sensitive to Gi-type pertussis toxin. Although initial studies focused on the role of CXCR4 in HIV infection of T cells, its association with cancer has been the subject of intense research, the discovery of its involvement in B cell transport and tissue localization in patients with chronic leukaemia, as well as the regulation of the Metastasis to specific organs in breast cancer models. CXCR4 is overexpressed in more than 23 different human cancers, including kidney, lung, brain, prostate, breast, pancreas, ovarian and melanoma, and contributes to tumour growth, angiogenesis, metastasis and therapeutic resistance. Targets of CXCR4 receptor in different types of peptide and non-peptide channels. This review provides a comprehensive overview of the biological involvement of CXCR4 in human cancers and other diseases. The current status of CXCR4-based therapeutic approaches, as small interfering RNA or microRNA in opposition to CXCR4, can function as an opportunity way of reducing CXCR4 expression to block the next invasion and metastasis. Increasing proof indicates that stem cells can also additionally play an important function in most cancers' progressions including tumour initiation, growth, and metastasis. Furthermore, many strategies aiming CXCR4/CXCL12 axis may have important clinical applications to inhibit cancer progression in numerous cancer types.

A020

Audit of Antibiotic Prescription in Suspected Neonatal Sepsis at an Indian Tertiary Care Hospital

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Introduction: Neonatal sepsis is one of the commonest causes of neonatal morbidity and mortality in the developing world. Rational use of antibacterials is a priority to prevent emergence of resistance and to reduce the burden of treatment failure. Materials and Methods: A prospective, cross-sectional study done by collecting data from 148 records of clinically suspected neonatal sepsis in a tertiary care hospital, between January 2017 and December 2017. The organisms isolated, prescribing patterns, approval status and listing of antibacterials in WHO Essential Medicines List/NLEM were analysed and presented as percentages, mean and standard deviations using appropriate tables & graphs. Results and Discussion: Of the 430 antibacterials analysed, single drug formulations were most commonly prescribed [400(93.02%)]; 298(69.30%) and 427(99.30%) were approved by DCGI and USFDA respectively; 275(63.95%) antibacterials were included in both WHO and NLEM. Most common organisms isolated were gram negative (64.1%). The most common class of antibacterials prescribed was Beta-lactams (ATC class: J01D and J01C) [251(58.37%)] followed by Aminoglycosides (ATC class: J01G) [124(28.84%)] irrespective of culture and sensitivity and almost 50% (216) of drugs were prescribed by their generic names. Regarding outcome 87.16% cases recovered well. In conclusion, the rationality of antibacterial drug usage in suspected cases of neonatal sepsis were followed the majority of times leading to better patient care and outcome.

A021

Gene Therapy as an Emerging Trend in Cardiovascular Diseases

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Cardiovascular diseases has one of the highest rate of morbidity. Several conventional treatments are used to treat cardiovascular diseases, but they have multiple limitations and numerous side effects associated with it. Gene therapy being a rapidly growing medical field, offers promising treatments for cardiovascular diseases. To achieve therapeutic effects, efforts are aimed at overexpression or suppression of key proteins of pathogenic importance in the blood vessel. . Gene therapy also intends to prevent restenosis after vascular intervention (such as stenting) and to prevent vein graft failure, percutaneous peripheral angioplasty, percutaneous coronary angioplasty and angiogenesis. The first human clinical trial paved the path for the novel cardiovascular gene therapy and established its feasibility and safety. However, several questions regarding its utility, safety and efficiency in treating cardiovascular diseases (CVD) still needs to be answered. Here we, discuss recent progress in cardiovascular gene therapy, various vectors used to develop the delivery system, and most promising therapeutic gene target for treating CVD in detail. Also we examine the recent clinical evidences in human trials. The innovative cardiovascular gene therapy's feasibility and safety were established in the first human clinical trial. However, various questions about its usefulness, safety, and efficacy in the treatment of cardiovascular diseases (CVD) remain unanswered. In this article, we go over the most recent advances in cardiovascular gene therapy, as well as the many vectors utilised to construct the delivery system and the most promising therapeutic gene target for treating CVD. We also look at the most recent clinical findings from human trials.

A022

In-silico Investigational Approach of Selected Phytochemicals Against Acetylcholinesterase, a Pesticide Target Protein: As an Ecopharmacovigilance Aid

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According to the WHO, "Ecopharmacovigilance is the research and actions related to the detection, evaluation, understanding, and avoidance of hazardous effects of pharmaceuticals in the environment". In the Aurangabad district of Marathwada, white flies, small caterpillars, aphids, spider mites, and nematodes are frequent pests that harm cotton, sugarcane, and papaya crops. On average, insect pests diminish the yield of essential food crops and cash crops by 15% to 20%. Carbamates and organophosphates were found to be commonly utilized conventional pesticides. We can see that, despite prohibitions and restrictions on the use of chemical pesticides, the use of organophosphates and carbamates continues. Moreover, medicinal herbs being therapeutically used also possess significant toxic, lethal, repellant, antifeedant, fumigant, growth control, and oviposition deterrent effects. Thus, new pest management strategies must be developed in order to prevent damage, save the environment, and enhance public health. As a consequence, a phytochemical database was used to choose the phytoconstituents and plants for the current study. After that, three phytochemicals, scoparone, ascorbic acid, and niacin, along with three botanicals, *Citrus limon*, *Acacia farnesiana*, and *Aspalathus linearis*, were chosen to be studied. Acetylcholinesterase Inhibitor (AChEI) pesticides constitute the majority of dangerous pesticides; thus, using phytochemical database and *in-silico* tools, an attempt has been made to detect action on this receptor and the desired impact, similar to that of traditional pesticides has been achieved. Conclusively, the plants *Citrus limon*, *Acacia farnesiana* and *Aspalathus linearis* that are rich in scoparone, ascorbic acid and niacin can emerge as promising pesticides.

A023

An Overview of Idiopathic Pulmonary Fibrosis (IPF) On MDM4 And MDM2 And Other Target

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Idiopathic Pulmonary Fibrosis (IPF) is a serious and chronic debilitating inflammatory lung disease. In Idiopathic Pulmonary Fibrosis it causes scar tissue to grow inside our lungs that leads to loss of elasticity that makes it hard to breathe. Idiopathic pulmonary fibrosis (IPF) is a progressive enfeeble lung disease with considerable morbidity. Heterogeneity in epidemiologic studies means the complete and visible impact of the disease is unclear. Basically IPF is known as a progressive, irreversible, and typically fatal lung disease. MDM4 is a very efficient and effective pathway in this advanced world. However, the exact mechanisms that link the IPF with aging remained unidentified till date but a number of changes concerned with aging revealed in IPF lungs. The p53 gene is a tumour suppressor gene that played a vital role in cancer and it is also known to have impact in fibrosis. MDM2 and MDM4 are the two vital inhibitors of p53. They only differ in their intrinsic E3-ligase activity and accelerate degradation of p53. MDM4 is a matrix stiffness -regulated negative regulator of p53 highly represented in fibrotic lesions of IPF. Some of the in vitro studies identified that MDM4-p53 pathway promoted lung fibrosis resolution in aged mice. This suggests that MDM4 can be one of the target against continual lung fibrosis associated with aging.

A024

A Study to Evaluate the Efficacy of Thanga Parpam in a Mouse Model of Parkinson's Disease

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Metal based drugs particularly gold based nanoparticles like Thanga parpam (TP) have shown potent anti-inflammatory and anti-oxidant potential. But there is no scientifically /experimentally validated data for the role of TP in Parkinson's disease (PD), so the present study aims to determine the efficacy and neuroprotective effects of TP mouse model of PD. In the current study, we evaluated the efficacy of prophylaxis treatment of TP for 5 days and then challenged with rotenone (30mg/kg, a neurotoxin) for 11days induced neuro toxic effects in mice focusing on neuro behavioral and bio chemical assessments. On day 13 to 16 behavioral assessments like Beam walk (Latency and number of foot slips) and NORT were evaluated. TP treated groups have shown significant improvement in the motor functions as evidenced through latency time and number of foot slips in the beam walk but failed to enhance the exploratory time for novel object indicating that TP at these dose levels failed to elicit behavioral alterations. We also analyzed corticosterone and Lipid peroxidation (TBARS) levels. Treatment with TP groups has shown reduction in the levels of corticosterone and TBARS levels as compared to positive control indicates role of TP in mitigating the HPA axis imbalance and oxidative stress. Based on these findings we propose that TP as the IV promising neuroprotective agent and can be of a choice as adjuvant or prophylactic agent in PD.

A025

A Review on Preclinical Studies on *Carica Papya* Leaf Extract for Antithrombocytopenic Activity

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Carica papaya (Caricaceae family) also known as pawpaw and papaya, is an evergreen herbaceous tropical and subtropical tree. *Carica papaya* leaf is well-known for its platelet enhancement activity and traditionally being used as immunomodulatory agent. In the Siddha and Ayurveda medicinal system papaya leaf juice is being used for increasing the platelet count. In the region of Srilanka, Malaysia and India papaya leaf juice is used as a folk medicine to increase the platelet count in patients with dengue fever. Preliminary phytochemical screening discovered the presence of carbohydrates, amino acids, saponin, glycosides, iridoids, flavonoids, phenolics, and alkaloids in *Carica papaya* leaf. This review paper includes the details of all the preclinical studies performed on *Carica papya* leaf extract for antithrombocytopenic activity in different thrombocytopenia model. This review highlights the role of *Carica papaya* leaf in treatment of thrombocytopenia.

A026

Neuroprotective Effect of Linagliptin, a DPP-4 Inhibitor Against Intracerebroventricular Streptozotocin Induced Neurodegeneration in Rat Model of Alzheimer's Disease

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Alzheimer's disease (AD) is the most devastated, progressive age-linked neurodegenerative disorder, characterised by extracellular deposition of amyloid beta (Aβ), intracellular deposition of tau protein, neuronal loss and cognitive impairment in brain. Precise etiopathology of AD is still unknown. Constant failure of clinical trials demands the utmost need to explore more therapeutic targets against AD. Pharmacological candidates like dipeptidyl peptidase-4 (DPP-4) inhibitors increases glucagon-like peptide 1 (GLP-1) level in the circulation which crosses blood brain barrier (BBB) and decreases the level of Aβ in the brain, have become valuable strategy against AD. The present study is hypothesised to evaluate the effect of linagliptin, a DPP-4 inhibitor in streptozotocin (STZ) induced rat model of AD. Male albino wistar rats were equally and randomly divided into seven groups. AD was induced by intracerebroventricular infusion of STZ in rat's hippocampus. After one week induction, rats were orally treated with linagliptin (3mg/kg) and reference standard donepezil (5mg/kg) for 8 weeks. Behavioral analysis was done by morris water maze (MWM) test to determine cognitive impairment. Following this, rats were sacrificed for biochemical parameters estimation and histopathological analysis. Results of our study reveals that linagliptin have significantly reversed cognitive impairment, augmented GLP-1 level and mitigated GSK-3β, soluble Aβ (1–42), AchE, TNF-α and oxidative stress level in hippocampus. Histopathological assessment, done through H&E staining of CA1 region of hippocampus have also demonstrated neuroprotective effect of linagliptin. Our study findings concludes preventive action of linagliptin against neurodegeneration and AD-related complications.

A027

The Cognitive Impact of Antiepileptic Drugs in Children

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Epilepsy is a central nervous system (neurological) disorder in which brain activity becomes abnormal, causing seizures or periods of unusual behavior, sensations and sometimes loss of awareness. Co-morbidities in epilepsy are very common and are often more problematic to individuals than the seizures themselves. Earlier studies have shown that classic and new generation antiepileptic drugs have potential to cause mixed effects on cognition and behavior. The current article focuses on the prevalence rate of various epilepsies in children. Moreover, it also emphasises on the various effects of different new classes of antiepileptics (Levetiracetam, Topiramate, Vigabatrin and Zonisamide) on cognitive function (memory) in childhood epilepsies. The findings proved to show that various classes of newer antiepileptic drugs have a different effect on the cognitive ability. Indeed, these results revealed that the most consistent evidence of widespread positive effects on cognition was found for levetiracetam, which may further verify to be particularly beneficial in cases with existing cognitive limitations. Despite these results, further investigations need to be carried out in the future to find out whether these effects on cognitive function are merely due to the impact of antiepileptic drugs or there occurs any role of etiologies in them. Hence, this may prove to be a promising approach for us to picturize the actual status of the drug therapies over cognitive function in case of childhood epilepsies.

A028

Therapeutic Potential of Chandraprabha Vati in Targeting Immuno-metabolic Target to Combat Obesity Induce Chronic Low-Grade Inflammation

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To evaluate Chandraprabha Vati's (CPV) potential to treat chronic low-grade inflammation associated with dyslipidemia in obesity. We explore the impact of CPV on primary clinical marker of chronic low-grade inflammation associated with dyslipidemia in model of obesity in rats. Rats fed with high fat, high-fructose diet (HFFD), for 8 weeks were followed by 4-week treatment with CPV 50 mg/kg, CPV 100 mg/kg *per se* and in combination with Metformin 500 mg/kg and Fenofibrate 100 mg/kg and compared with positive control and normal control rats. The impact of CPV on anthropometric parameters, blood glucose, lipid profile, liver parameter, serum insulin, TNF-α, and IL-6 were also evaluated. Compared with HFFD rats, rats receiving CPV 100 mg/kg showed significantly decreased body weight, food intake, water intake, BMI, Lee's index, and AC/TC ratio. Blood glucose, Serum levels of TG, total Chol, LDL, VLDL, non-HDL and atherogenic index were lowered in CPV 100 mg/kg treated rats than in HFFD rats. Concomitantly CPV 100 mg/kg *per se* and in combination with Met 500 mg/kg and Feno 100 mg/kg markedly reduced serum insulin, TNF-α, IL-6 as compared with HFFD rats. Obesity is the state of prolonged inflammation that cause decrease in immune defense, dyslipidemia & insulin resistance but CPV was found to be effective in treating hyperlipidaemia, insulin resistance, inhibition of cytokines TNF-α, IL-6 and increase in adiponectin. These findings are first of its kind in investigating immune metabolic targets. Thus, CPV was found to effectively attenuate obesity related metabolic disorder.

A030

Phycocyanin: A Marine Pigment with Anti-inflammatory, Anti-oxidant & Neuroprotective Activity.

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Now days there are various marine pigments like carotenoids, chlorophylls & phycobiliprotein etc has anti-oxidant, anti-inflammatory & immune-modulatory effects. Phycocyanin is polyphenolic marine pigment. PC is extracted from Spirulina plantesis, blue - green algae which has anti-inflammatory, anti-oxidant & neuroprotective activity. Phycocyanin has given anti-oxidant activity via scavenging alkoxyl, hydroxyl and peroxyl radicals and to react with peroxinitrite (ONOO-) and hypochlorous acid (HOCl). PC (Phycocyanin) also inhibits microsomal lipid peroxidation induced by Fe+2-ascorbic acid or the free radical initiator 2, 2' azobis (2-amidinopropane) hydrochloride (AAPH) in vitro & in vivo studies. PC has showed anti-inflammatory activity in more than ten models of inflammatory animal's modes by reducing histamine (Hi) release, myeloperoxidase (MPO) activity and the levels of prostaglandin (PGE2) and leukotriene (LTB4) in the inflamed tissues. These anti-inflammatory effects of PC can be due to its scavenging properties toward oxygen reactive species (ROS) and its inhibitory effects on cyclooxygenase 2 (COX-2) activities and on Hi release from mast cells. Phycocyanin Act via PI3-Kinase pathway and act on Aβ aggeration by binding with β-secretase which catalyzes the proteolysis of the amyloid precursor protein to form plaques in Alzheimer's disease & given neuroprotective activity. Even though molecular docking reports suggest that phycocyanin can easily cross blood-brain-barrier. PC also reduced the levels of tumor necrosis factor (TNF-alpha) in the blood serum in various animals' models of neurodegenrative diseases.

A031

Role of Central Histaminergic Transmission in the Endocannabinoid Induced Effect on Compulsive-like Behavior

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Cannabinoidergic system and histaminergic system co-exist in the thalamocortical pathway. These pathway are involved in the control of compulsive-like behaviors in humans and also in rodants..Therefore, the present study investigated the modulatory role of central histaminegic transmission on anandamide induced effects on compulsive like behavior. In this investigation, firstly we tested the effect of central (i.c.v.) administration of anadnamide (0.5, 5 µg/mouse) on behavioral despair in mice using MBB. Further, the modulatory response of pre i.c.v. treatment of histamine (0.1, 10 µg), histamine neuronal releaser/H_3 receptor antagonist (Thioperamide: 0.5, 10 µg), H_1 and H_2 receptor agonist (FMPH: 0.1, 6.5 µg; Amthamine: 0.1, 5 µg)/antagonist (H_1: Cetirizine 0.1µg) and (H_2: Ranitidine: 10 µg) or peripherally (i.p.) with histamine precursor (L-histidine: 250, 500, mg/kg) on anandamide induced effect on behavioral despair was studied. The preliminary findings showed that the i.c.v. administration of anadnamide to mice elicits anticompulsive-like behavior on MBB. Moreover, the experimental animals pretreated centrally/peripherally with agents enhancing as well as reducing the histaminergic transmission, potentiated the anticompulsive-like behavior exhibited by anandamide. On the other hand, simultaneous blockade of H_1 and H_2 receptor leads to further potentiation of anandamide induced anticompulsive-like effect on MBB, which may be due to activation of other central receptor of histamine specifically H_4 receptor. Therefore, it is speculated that central histaminergic transmission might positively modulate the anandamide induced anticomplusive-like effect via stimulation of both post synaptic $H_1$and H_2 receptor.

A032

Possible Therapeutic Targets for Idiopathic Pulmonary Fibrosis: Preclinical and Clinical Progress

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The Idiopathic pulmonary fibrosis is a chronic progressive lung disorder with highly associated morbidity and mortality. The therapeutic landscape has significantly changed in the last 20 years with two drugs currently approved that have demonstrated the ability to slow disease progression. Despite these developments, survival in IPF is limited, so there is a major interest in therapeutic targets which could serve to open up new therapeutic avenues. Various molecules, such as chemokines, cytokines, growth factors, adenosine, glycosaminoglycans, non-coding RNAs, and cellular processes including oxidative stress, mitochondrial dysfunction, endoplasmic reticulum stress, and hypoxia have been linked with IPF development. Importantly, strategies targeting these processes have been investigated to modulate abnormal cellular phenotypes and maintain tissue homeostasis in the lung. This review provides an update regarding the possible therapeutic targets, preclinical and clinical progress as well as therapeutic implication of IPF.

A033

To Formulate, Characterize and Evaluate the Brain and Systemic Bioavailability of a Novel Intranasal Formulation of Flurbiprofen

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The aim of the present work was to formulate novel intranasal thermosensitive based solid lipid nanoparticle (SLN)*in-situ* gel for nose to brain delivery and evaluation of brain and systemic bioavailability in rats.Solubility of drug was checked and components with high solubility were selected.Precirol ATO 5, Tween 80 and Poloxamer 188P were selected for formulation as lipid, surfactant and stabiliser respectively. The formulation was optimised by applying Quality by Design (QbD) approach using Design Expert Software. 2^3 factorial design was applied for optimising the formulation. The independent variable used in formulation were Drug:Lipid (D:L) ratio (X_1) and Surfactant concentration (X_2) while dependent variables were Particle size (Y_1), % Drug loading (Y_2) and %Entrapment efficiency (Y_3). Optimised formulation gave particle size of 138.69±3.8nm, %Drug Loading of 20.62±0.50 and %Entrapment Efficiency of 81.76±1.95 %. Further optimization of concentration of polymers for blank thermosensitive *in-situ* gel was performed using Poloxamer 188P and Poloxamer 407P and incorporated into SLN dispersion. This final formulation was evaluated for *in-vitro* and *ex-vivo* releasein comparison with Flurbiprofen marketed oral formulation. *In-vivo* study was performed and drug content was estimated using HPLC developed method. C_{max} of intranasal formulation in brain was found to be 490.3118 ng/ml while oral marketed formulation showed C_{max} of 145.0783ng/ml . C_{max} of intranasal formulation was found to be 2.5175 µg/ml while oral marketed formulation showed C_{max} of 3.4475 µg/ml. Novel intranasal formulation showed long residence time and sustained release of drug was observed as compared to marketed formulation.

A034

Role of Melatonin on Behavioural and Biochemical Paradigm in Gonadectomized Sleep-restricted Animals

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Chronic SR and gonadectomy have shown significant impairment on memory and neurochemical changes. The present study was designed to understand the effect of GD and sleep deprivation on cognition and KP, further the study was also designed to evaluate the efficacy of melatonin to improve cognition and normalize KP in Sleep-Deprived gonadal hormones depleted conditions. The protective effect of melatonin was measured in terms of cognitive functions (MWM, NORT). Our results suggest that following GD and SR there is impairment in the cognitive function and an elevation in the KYNA levels. Treatment with melatonin has alleviated the negative consequences induced by GD and SR. We also observed an increase in the testosterone and estradiol levels following melatonin treatment. The hormonal co morbidity aggravated the cognitive impairment and kynurenic acid levels in SD. Melatonin alleviated the behavioral and biochemical changes produced by gonadotropin hormone dysfunction in a sleep-deprived state. Further, studies are warranted in this line at a molecular level.

A035

Takotsubo Related to CNS

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Takotsubo is also known as stress cardiomyopathy, apical ballooning, or broken heart syndrome. It was recognized in Japan in 1990. The left ventricle bulges and takes a balloon shape. Which is similar in appearance to Japanese fisherman's means an octopus trap. It's Triggered by psychological or physical stress that includes subarachnoid bleeding, epilepsy, depression, amyotrophic lateral sclerosis, migraine, ischemic bleeding, clinically it mimics acute coronary syndrome. There is an elevation of cardiac biomarkers like troponin and pro-brain natriuretic peptide (pro-BNP) and predominance in post-menopausal women. It can be hereditary and non-hereditary central nervous system (CNS) disorders, which is directly or indirectly affect the heart (brain-heart disorders). Cardiomyopathy induced by hereditary CNS disease stress-induced myocardial dysfunction, known as Takotsubo syndrome (TTS). Heart failure is characterized by left ventricular dysfunction and mainly triggered by stress Awareness of the pathophysiological links between cardiovascular diseases (CVD) and CNS disorders are growing Joint efforts are required from cardiologists, neurologists, and psychiatrists for the advancement of pathophysiological knowledge and treatment strategies for CNS disorders in (CVD). In Takotsubo syndrome and peripartum cardiomyopathy, randomized multicenter trials are needed to generate better evidence for efficacy in applied treatments.

A036

Utility of Allometric Scaling Methods for Predicting Human Pharmacokinetics of Pan-JAK Inhibitor -Tofacitinib and Dose Extrapolation

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The main objective of this exercise was to evaluate utility of allometry scaling methods for an accurate prediction of pharmacokinetics of Tofacitinib (JAK inhibitor) in human from preclinical species. The simply allometry relationship was found to be satisfactory for the prediction of intravenous human clearance/volume of distribution for Tofacitinib. The volume of distribution (Vd) predicted by simple allometry (117 L) was found to be in 1.35 fold agreement with the reported value (86.6 L); clearance (CL) prediction by simple allometry was found to be at least 1.98 closer to the reported value (412 mL/min); CF were used to predict the clearance. Brain weight (B.W), maximum life span potential (MLP) and biliary correction factor predicted the CL with 27.4, 2.11 and 1.01 -fold difference. The application of monkey liver blood flow predicted CL with 1.48 fold which was also in reasonable agreement with reported value.The computational approaches with multiple linear regressions (MLR) method showed good prediction accuracy of human CL with fold difference of 0.85 fold. Overall, the simple allometry, biliary correction method, monkey liver blood flow, MLP method and computational approaches with multiple linear regressions (MLR) method showed excellent correlation with human. The time vs. plasma concentration simulated graph also showed the similar closeness with human profile. The retrospective analysis of tofacitinib dose were done as per FDA draft guidelines and observed that BSA-CF with monkey NOAEL based approach was found closer to actual human dose.

A037

Role of Interferon in Various Diseases

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Interferons are group of signalling proteins made and released by host cells in response to the presence of several viruses. IFNs belong to the large class of protein known as cytokines it uses the communication between cell to trigger the protective defences of the immune system. i.e., they are proteins that our body makes and works with our immune system. Interferons (IFN) are autocrine and paracrine family of anti-viral cytokines secreted by host cells in response to pathogens & viruses. There are different types of interferons – TYPE I (comprises α & β interferons and further sub divided into 17 types), TYPE 2 (IFN γ) & TYPE 3(λ1, λ2 and λ3). Interferon induces signaling transduction and transcription activation by jak/stat pathway in various diseases like viral infection – Covid 19, Pneumonia, Hepatitis A & B, HIV & Influenza. Cancer- hairy leukaemia, chronic myelogenous leukaemia, cutaneous T cell lymphoma, follicular lymphoma, multiple myeloma, kaposi's sarcoma, diffuse melanoma, renal carcinoma, carcinoid tumours, multiple sclerosis. Additionally, interferons shows anti cancer effect as second line therapy. This review provides an overview of interferons (IFN) in multiple disease treatment.

A038

Phytochemical Screening, Antioxidant Potential and Alpha Amylase Inhibitory Activity of an Antidiabetic Polyherbal Formulation

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The objective of this study was to evaluate the phytochemical profile, antioxidant activity and α- amylase inhibitory activity of an antidiabetic polyherbal formulation (PHF) that included *Eugenia Jambolana* L., *Gymnema sylvestre* Retz, *Momordica charantia* L, and *Trigonella foenum-graecum* L. Methods. Standard procedures were used to determine the total phenolic content, flavonoids, and flavonols in the formulation and to evaluate α- amylase inhibitory activity of the formulation. Total antioxidant activity, ferric reducing antioxidant power, and 2-diphenylpicrylhydrazyl (DPPH) assays were used to determine antioxidant potential. Results. The PHF contained 213.4 ± 0.72 mg gallic acid equivalent/g of total phenolic content. The PHF had 152.6 ± 0.45 mg quercetin equivalent/g of total flavonols and 126.2 ± 0.34 mg quercetin equivalent/g of total flavonoids. The reducing power of the PHF was 18.4 mg ascorbic acid equivalent/g. The total antioxidant capacity of 126.2 mg ascorbic acid equivalent/g was discovered. The PHF had a ferric reducing antioxidant power of PHP was 1024.4 (µM Fe (II)g). The formulation had a DPPH radical scavenging activity value was 1.8µg/mL for gallic acid and 2.6 µg/mL for the formulation. The IC_{50} value of α-amylase inhibition for water extract and hydroalcohol extract was found to be 8.425 and 10.242 mg/ml respectively Conclusions. The findings indicate that the polyherbal formulation has high antioxidant activity and could be a promising option for anti-diabetic research.

A039

Recent Advances in CAR T-Cell Therapy for Lymphoblastic Leukaemia

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The blood cancer is also known as lymphoblastic leukaemia arises due to the development of immature lymphocytes, mutation or uncontrolled growth of T-cells in bone marrow. White platelets which are able to fight against infections are also involved in pathophysiology of leukaemia. in healthy individuals, platelets develop and divide regularly as per body requirements but in diseased condition, bone marrow produces abnormal white platelets which are unable to perform their physiological functions. Due to the developments in the field of genomics and genetic engineering opens up the new possibilities for treatment of malignant cancer thus improving quality of life and increasing life span of the patient. Treatments like monoclonal antibodies and CD19 targeting chimeric antigen receptor (CAR) T-cells provide highly effective remedy for leukaemia. CAR-T Cell therapy, a gene therapy which is able to stop proliferation of cancerous cells and destroys them by targeting specific proteins associated with cancer cells. CAR is a Chimeric Antigen Receptor, a genetically modified molecule with an affinity for T- cells or lymphocytes and can target the mutagens. Newer generations of CAR-T therapy are beneficial over the previous generations by overcoming toxicity and improving efficiency by making modifications in T-cell structure. This review discusses different aspects of leukaemia and its treatment by CAR-T-cell immunotherapy and its future prospects.

A040

Neuroprotective Effect of Gossypetin Against Cognitive Dysfunction in Chronic Unpredictable Stress- induced Mice

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Chronic unpredictable stress (CUS) is a promising model for induction of cognition impairment. Stress induced memory dysfunction is linked to the activation of kynurenine (KYN) pathway. This pathway indicates that, chronic stress primarily promotes the release of excessive cortisol from the adrenal gland, which tends to activate microglia and further increases kynurenine and its downstream pathway, resulting in excessive quinolinic acid (QA), which further impairs brain derived neurotrophic factor (BDNF) levels and leads to neurodegeneration. Prior studies already established anti-oxidant and anti-depressant activity of gossypetin. This research study was mainly conducted to elaborate neuroprotective activity of gossypetin against CUS-induced cognition impairment via acting on kynurenine pathway. In this study, Swiss albino mice were exposed to various stressors for five weeks and then administered with gossypetin (5, 10 and 20 mg/kg, *i.p.*) from the 4th to the 7th week (from day 22 to 49). Several behavioral tests were carried out between days 36 to 49 (6th and 7th week) and further corticosterone, neurotransmitters, oxidative stress, and brain-derived neurotrophic factor (BDNF) levels were detected. Results state that CUS exposed mice showed significant improvement in the behavioral pattern after gossypetin treatment. Corticosterone levels and oxidative stress was also found to be significantly decreased in gossypetin (10 and 20 mg/kg, *i.p.*) treated mice when compared with CUS exposed mice. Whereas, serotonin, norepinephrine and BDNF levels were also found to be increased after gossypetin treatment. Hence, gossypetin can be considered as a neuroprotective agent against cognition impairment caused by chronic unpredictable stress.

A041

Therapeutic Potential of Naringenin with Special Focus on Neurodegenerative Diseases

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Neurodegenerative diseases (NDs) affect millions of people worldwide and are on the rise. As of 2021 report, the Alzheimer's Disease Association estimates that the number of Americans with Alzheimer's disease could be as many as 6.2 million and for Parkinson 1.2 million by 2030.The World HealthOrganization has predicted that NDs will become the second-most prevalent cause of death in the next 20 years. NDs are known as the gradual loss of neurons. Due to the complex pathophysiological mechanisms behind neurodegeneration, investigating effective and multi-target treatments has remained a clinical challenge.Natural derivatives are gaining critical attention in managing NDs due to the toxic effects of synthetic drugs. So, in recent years, several reports have introduced naturally-derived compounds as promising alternative treatments for NDs.Naringenin is a natural flavonoid possessing neuroprotective activities. Naringenin has been recently reported to possess anti-inflammatory effects by inhibiting leukocyte recruitment and reducing oxidative stress, boosting antioxidant capacity by activating Nrf2, which induces HO-1 expression and suppress activation of NF-κB in macrophages which causes the production of proinflammatory cytokines. In addition, naringenin inhibits the NF-κB signaling pathway by decreasing translocation and DNA binding of NF-κB.Moreover,our laboratory also documented that Naringenin exerts neuroprotective activity against rotenone-induced Parkinson in experimental rodents through Nrf2 mediated pathway. Inconclusion, naringenin is a promising compound for preventing and managing NDs. Derived from the results of several pre-clinical research, and considering the therapeutic effects of this compound, this review discussed the potential role of naringenin as pharmacological agent for the treatment and management of NDs.

A042

Role of Central Histamine H_1 and H_2 receptors in the antidepressant-like effect of endocannabinoids in mice

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The ability of endogenous endocannabiniod signaling system to release histamine from the histaminergic neuron originating from tuberomamillary nucleus in the brain leads to the speculation that central histaminergic transmission could possibly modulate some behavioral effects induced by endogenous CB1 receptor agonist, anandamide. Therefore, the present study investigated the modulatory role of central histaminegic transmission on anandamide induced effects on behavioral despair. In this investigation, firstly we tested the effect of central (i.c.v.) administration of anadnamide (0.5, 5, 10 µg/mouse) on behavioral despair in mice using Tail suspension test (TST). Further, the modulatory response of pre i.c.v. treatment of histamine (0.1, 10 µg), histamine neuronal releaser/H_3 receptor antagonist (Thioperamide: 0.5, 10 µg), H_1 and H_2 receptor agonist (FMPH: 0.1, 6.5 µg; Amthamine: 0.1, 5 µg)/antagonist (H_1: Cetirizine 0.1µg) and (H_2: Ranitidine: 10 µg) or peripherally (i.p.) with histamine precursor (L-histidine: 250, 500 mg/kg) on anandamide induced effect on behavioral despair was studied. The preliminary findings showed that the i.c.v. administration of anadnamide induced antidepressant-like behavior in mice on TST. Moreover, the experimental animals pretreated centrally/peripherally with agents enhancing as well as reducing the histaminergic transmission, potentiated the antidepressant-like effect exhibited by anandamide. However, the antidepressant-like response observed with anandamide in mice was completely reversed by the simultaneous injection of cetirizine and ranitidine in mice. This outcome delineates the plausible modulatory role central histaminergic transmission in mediating the antidepressant-like effect of anandamide via both H_1 and H_2 postsynaptic receptor activation.

A043

Dose Dependent Anti-inflammatory Effect of Zn^{2+}-curcumin Complex Inhibits Carrageenan-induced Paw Edema in Rats

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Curcumin is an active component in *Curcuma Longa.* Oral administration of curcumin exhibits multiple biological activities. However, its health-promoting potential is limited by its physical properties, low bioavailability and inability to detect curcumin in circulation or target tissues. To overcome this, a novel formulation of Zn^{2+}-curcumin complex was synthesized which has biological properties, including anti-inflammatory activity along with its better stability, solubility and pharmacodynamic effects than free curcumin. This study aims to evaluate dose dependent anti-inflammatory activity of Zn^{2+}-curcumin complex compared with free curcumin in a carrageenan-induced paw edema in rats. The experimental animals were treated orally with Zn^{2+}-curcumin complex (25, 50, 100, 440mg/kg) and saline (control group) and the reference group received 440mg/kg of Curcumin, after 1 hr edema was induced by subplantar injection of (0.1ml,1%) Carrageenan into left-hind paws of each animal. The results showed that the lowest dose(25mg/kg) of Zn^{2+}-curcumin complex treated group gave slightly inhibitory effect ($P<0.05$) and the intermediate(50-100mg/kg) and highest dose(440mg/kg) showed a significant reduction ($P<0.001$) in inflammation when compared with the control group and the reference group. The inhibitory effect of Zn^{2+}-Curcumin complexes began at 2 hr or later after the carrageenan injection. Depending on the dose administered, in the control group and reference group the inhibition of inflammation began at 3h or later. Present findings indicated that Zn^{2+}-curcumin complex produces an anti-inflammatory effect in carrageenan-induced paw edema in rat with higher efficacy compared to curcumin.

A044

A Study on the Safety and Neuroprotective Profile of Sesame Lignans and Nicotinamide Mononucleotide in Sleep-restricted Mice

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Sleep deprivation has shown a significant impairment of memory and neurochemical changes. The present study was designed to understand the effect of sleep deprivation on cognition and oxidative stress. The protective effect of sesame lignans and nicotinamide mononucleotide on sleep deprivation-induced cognitive decline was assessed. Results show that following sleep restriction there is an impaired cognitive function and elevated oxidative stress. Treatment with SL and NMN alone or in combination alleviated the consequences induced by sleep deprivation. When compared to individual administration SL and NMN combination treatment has shown highly significant results in reducing behavioural and biochemical changes produced by sleep deprivation.

A045

Pre-clinical Oral Glucose Tolerance Test of Garcinia Indica

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OGTT, which assess the ability to dispose of a glucose load, is used diagnostically to evaluate existing or impending diabetic conditions. In Epidemiological studies, fasting plasma glucose and glucose have been used as an index of β-cell function. *Garcinia Indica was* reported to have significant hypolipidemic and hypoglycemic activity. OGTT was developed to determine carbohydrate tolerance in the body. However, since the plasma glucose and the Insulin response during the test reflect the ability of the pancreatic β-cells to secrete Insulin and the sensitivity of the tissues to Insulin, the OGTT has often been used to elevate the β-cell function and Insulin resistance. Oral Glucose tolerance test was carried out using ethanolic extract of *Garcinia Indica* in freshly prepared 1% CMC solution at the dose of 200mg/kg and 400mg/kg body weight. The weight of the selected rats was between 180-200g. Female Wistar rats were used for this experiment. The rats were fasted overnight and the temperature was maintained between 25±2ºC along with humidity between 40-60%. The doses were calculated on the basis of Acute toxicity Study OECD 425 Up and Down Procedure. Based on the results obtained from the present study it can be concluded that ethanolic extract of *Garcinia Indica* at a dose of 400mg/kg was found to have Significant hypoglycemic activity as compared to a lower dose of 200mg/kg. It exhibits a time and dose-dependent decrease in blood glucose levels in normal rats.

A046

Involvement of Myeloperoxidase (MPO)-H2O2-Cl2 pathway in the pathogenesis of Traumatic Brain Injury (TBI)

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TBI is defined as traumatically produced structural injury to the brain and/or physiological disturbance of brain function as a result of an external force. According to the most recent CDC data, 1.6 million TBIs occur in the United States each year on average. Every year, 1.5 to 2 million people is injured in India, with approximately 1 million deaths. In the aetiology of traumatic brain injury, there are two stages: primary injury and secondary injury. Exicitotoxicity, Oxidative stress and neuroinflammation play the significant role in the Secondary Brain Injury. Exicitotoxicity is a key mediator in the Pathophysiology of TBI. Due to cerebral Hypoperfusion MPO is activate and release from the Neutrophils and damage the endothelial cell of cerebral blood vessels. Neuroinflammation also play major role in TBI. MPO activates the Microglia and release the Proinflammatory cytokines like IL-1ß and TNFα. It will leads to infiltration of leukocytes. Cellular excitotoxicity, Oxidative stress and activation of microglia cause the disruption of BBB. It will leads to edema. MPO is highly expressed in a number of inflammatory cells, including neutrophils, activated microglia, monocytes/macrophages, astrocytes, and neurons, as a heme-containing peroxidase. hypochlorous acid (HOCl) is a critical cytotoxic component that contributes to MPO-mediated oxidative damage. Activated MPO catalyses the reaction between Cl2 and H2O2 to produce HOCl, causing chlorinative stress. HOCl can covalently alter lipids and/or proteins, resulting in local tissue damage and inflammatory cascade amplification. MPO may be good therapeutic Target for the treatment of Traumatic brain Injury. It may be reduce the neuroinflammation and also may reduce the infiltration of Neutrophils.

A047

Assessment of Knowledge, Attitude and Practice of Self-Medication Among Undergraduate Medical Students in a Tertiary Care Teaching Hospital

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Self-medication is defined as the use of medication by a patient on his own initiative or on the advice of a pharmacist or a lay person instead of consulting a medical practitioner (WHO guidelines, 2000). Being future medical practitioners, (SM) has a special impact in medical students and they inevitably urge self-medication practice themselves and also for others as they are going through the professional course for their gradual acquirement of knowledge regarding different drugs and their proper use. Methods: The present study involved 276 2nd, 3rd and final year medical students in "Basaveshwara Medical College and Hospital, Chitradurga Karnataka. Study was questionnaire based, and the results were analyzed by descriptive statistical methods. Results: In our study 58% were females and 42% were males. 81.5% of the students were aware about OTC drugs. 97% of students had no knowledge on safety of SM, 69.5% did not prefer taking SM and 92% don't want to prefer SM for non medical persons. 67.3% practiced SM out of which 86.9% experienced side effects. 57% said they got source of information on SM from previous prescription and medical stores were the major (81%) of self medication and fever was the major symptoms for which students took SM. Paracetamol was most commonly used drug.. Conclusion: Conscientious self-medication can be promoted among both the medical students and the general public. From the present study we conclude that self medication is quite common among undergraduate medical students may be because of easy accessibility of drugs and information from text books and classroom teaching.

A048

Treatment of Diabetes by targeting Tyrosine Kinase Inhibitor

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Diabetes mellitus is a group of metabolic disorders which has an increased risk of macro and micro-vascular complications due to lipid dysfunction. Many PPAR-γ agonists were developed for the treatment of this metabolic dysfunction but shows significant adverse effects like weight gain, heart failure and edema. These adverse effects occur because of the drugs being full agonist of PPAR-γ receptors. The newer alternative of this full agonist are Selective PPAR-γ modulators which are partial agonist of PPAR-γ receptors, which shows less adverse effects with reserved insulin sensitization in animals. Tyrosine kinase inhibitors are proven for the treatment of various kinds of malignancies. This review summarizes the work carried out on Tyrosine kinase inhibitor on Diabetes. Tyrosine kinase inhibitors act as partial agonist of PPAR-γ receptors and results in anti-diabetic effect by improving insulin sensitivity and glucose disposal rate. Tyrosine Kinase Inhibitor's produces anti-hyperglycemic effects by acting on multiple targets such as EGF, PDGF, VEGF, HGF and IGF. It inhibits Abelson tyrosine kinase leading to the reduction in apoptosis of beta cells due to less activation of JNK and protein kinases-C delta. It also increases the insulin secretion by enhancement in expression of Nkx2.2 and glucose transporter type-2. Increase in ERK pathway regulation by phosphorylation leads to increase in insulin secretion by c-Abl inhibiton. Therefore it is hypothesized that Tyrosine kinase inhibitors like Imatinib, Dasatinib, Sunnitinib, Soratinib which are used for treatment of chronic myeloid leukemia and pancreatic cancers can be used in the treatment of patients affected with diabetic mellitus.

A049

MenSC: A newer approach towards mesenchymal cell derivation from human menstrual blood

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Stem cell as allogenic or autologous therapy is regenerative and repair treatment of damaged tissue. They are undifferentiated cells capable of differentiating into desired cells. Majorly, they are classified into Embryonic stem cells and Adult stem cells. Adult stem cells are known as mesenchymal cells or somatic cells. Isolation of adult stem cells through classical source like umbilical cord, adipose tissue, dental pulp, bone marrow has many limitations, like less amount of sample, invasive isolation methods, ethical issues. The regenerative ability of endometrium of fertile women during menstruating age is in sight of science. Extracting mesenchymal cells through endometrium cells from menstrual blood is novel approach as it shows high proliferation rate, less immunogenicity, noninvasive isolation method, quantity yield and less ethical consideration as compare to other sources. Being newer approach, menstrual blood derived stem cells (MenSC) are still under experiments for preclinical and clinical projects, giving promising hope for future regenerative medicine in diseases like liver cirrhosis, diabetes, neurodegenerative disease, wound healing, myocardial infarction, ovarian disease, autoimmune disease and many others which are still under investigation. This article will give overview about MenSC comprising in detail comparison of other source derived mesenchymal cells, isolation and characterization of MenSC and updates of available preclinical data for application of MenSC in various diseased conditions.

TRACK-B

CLINICAL RESEARCH AND PHARMACOVIGILANCE

B001

To evaluate the Attitude, Knowledge and Practice regarding Pharmacovigilance in Undergraduates Students & Postgraduates Residents at a Tertiary Healthcare Center – A Questionnaire based study

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Spontaneous reporting of Adverse Drug Reaction is a method of monitoring the safety of drugs and is the basic strategy for the post marketing surveillance of the suspected drugs. Despite its importance there is a very little reporting of ADRs by the healthcare professionals. The present study evaluates the knowledge, attitude, practice of undergraduates & postgraduates at a tertiary care center.1) Study design: Questionnaire based study 2) Site of study: Department of Pharmacology, Dr Vasantrao Pawar Medical College Hospital and Research Center, Nashik 3) Study participants: Undergraduates (2nd year) & Postgraduates medical students of all years. 4) Data collection instruments: Questionnaire for students; 5-point likert scale was circulated on a Google form to students after their consent. Only students willing to give informed consent will participate in the study and will be asked to fill the online form the data collected will be analyzed using appropriate statistical test. It is an ongoing study, the result of which is yet to be calculated.

B002

Antibiotic Sensitivity Pattern of Bacterial Isolates in Chronic Osteomyelitis in a Tertiary Care Teaching Hospital of North India

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Chronic Osteomyelitis is a debilitated disease and is characterized by persistent and prolonged infection of the bone and its management remained an increasing challenge to clinicians due to growing resistances to antibiotics. The proposed study was conducted to ascertain the antibiotic sensitivity pattern of bacterial isolates in chronic osteomyelitis patients. This descriptive study was conducted for a period of six months from June to Nov 21. A total of 80 samples of pus and other exudates were collected from all the patients ≥ 18 years of age with either gender and diagnosed with chronic osteomyelitis>6 weeks duration. The samples were sent for microbiological examination and culture. Various organisms were identified by standard methods. Antibiotic sensitivity pattern of detected microorganisms was also analysed. Patients with other form of arthritis, implant related osteomyelitis and who had antibiotic usage in last one week were excluded from our study. Out of 80 patients, 73 (91%) showed growth of microorganisms whereas remaining 7 (9%) samples were sterile. The commonest bone affected in the study was tibia 53 (66.3%). Staphylococcus aureus was the most common bacteria isolated in 57 (78%) of patients. Maximum antibiotic sensitivity pattern was noted for vancomycin and clindamycin (>90%) while maximum resistance was noted for penicillin in 22 (31%) of patients. Our study will thereby guide the clinicians in choosing appropriate antibiotics which not only contribute to better treatment but the judicious use of such antibiotics will also help in preventing emergence of resistance to drugs, which are still sensitive.

B003

Assessment Of Menstrual Patterns And Premenstrual Symptoms In Adolescents: A Cross-Sectional Study

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Introduction: Menstruation is a biological process experienced by adolescent girls & women, yet it isn't spoken about openly causing unnecessary embarrassment and shame. Menstruation is still a taboo in India. PMS affect the daily functioning of the individual experiencing it. Aim: To study menarche age, menstrual patterns and pre-menstrual symptoms (PMS) in adolescents. Methodology: It was a cross-sectional study carried out in adolescent girls studying in private college of Mehsana. Ethical approval taken for CRF contains demographics, questions regarding menstrual patterns, bleeding days, PMS symptoms. Collected data was described. Results: Total 102 girls were enrolled with age of 20.10±1.68 years. Menarche age was 13.29 ±1.46 years. Mother's menarche age was 14.33±1.41 years. 74% feel hesitation to discuss menstrual problems. 3% adolescent girls don't know about menstruation. Major source of information is social media and books. Most were using absorbent material, 8.8% uses clothes. 1% disposing it in drain. 30.4% girls were experiencing irregular menstrual-cycle. Most of girls (63.7%) were bleeding for 4-5 days. 54.5% adolescent girls experiencing PMS symptoms regularly, among them 80% experiencing for 1-3 days and 5% for 4-7 days. Girls were rated physical symptoms like backpain, dragging sensation, pelvic-cramps, acne followed by muscle-pain and headache. Emotional symptoms like depressed mood, anger without reason, mood swing. Conclusion: Menarche age of girls was less as compare with their mothers. Most of girls were experiencing PMS regularly. PMS symptoms affect routine activities and mental health. Need to plan for awareness program for adolescent girls related to hygiene and PMS.

B004

A Review on Renal Calculi: Its Types, Risk Factors and Comparative Treatment with Allopathic, Homeopathic and Ayurvedic Medicines

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Renal calculi disease is a crystal concretion formed within the kidney. The chemical composition of renal calculi depends on the abnormalities in urine composition of various chemicals and variations in minerals composition and pathogenesis. Renal calculi are classified into various types like calcium oxalate stone, calcium phosphate stone, uric acid, struvite, cystine stone, xanthin stone, drug induce stone, matric stone. The co-relationship between the occurrence of different risk factors such as hyperthyroidism, age, gender, variations in mineral composition and pathogenesis, lifestyle and dietary habit, disease and the fluid intake have been thought to be main etiological causes influencing the formation of different types of stones in urinary tract of human beings. Renal calculi is a recurrent disorder with life time recurrence risk reported to be as high as 50% by calcium oxalate crystals. Calcium oxalate occurred renal calculi is the most common stone reported in India. The patients detects higher lipid level in the blood may have tendency to develop renal calculi as compared to normal individuals. The patients have advice to take low fat diet and fibers of natural occurring plants and its herbal medicines. The combination of herbal medicines with allopathic treatment have a great idea to get rid all the complications related to renal calculi. Homeopathic can prove to be a boon for patients in whom surgery is a risky, hypertensive and diabetic or those who are in search of an alternative to surgery for economic or psychological reasons.

B005

Vaccines, Their Development, Importance and Mechanism of Action

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There are at least about 10,000 known diseases all over the world. The germs (pathogen) could be of any form like bacteria, virus, fungi, and parasites. Our immune system is the body's defense system against infection. Major protection is required for every individual against a threatening infection. Whenever a new pathogen enters the body, the antigen present on it makes the lymphocytes work to make antibodies which would help in protecting from the same pathogen again in the future. Nevertheless, the severity of the disease varies with age, so any person can't wait to get natural immunity. Hence, vaccines play an important role in providing immunity and further protection from pathogens. Pharmaceutical companies all over the world have developed lots of vaccines against various diseases. These vaccines could be of various types such as vector vaccines, mRNA vaccines, protein subunit vaccines, toxoids, etc. All of them have a slight difference in their components, the state of the pathogen, and its mechanism. Also, some of them require more than one shot at different durations. When injected into the body, the lymphocytes start making antibodies. The main three types of lymphocytes (Macrophages, B-lymphocytes and T-lymphocytes) help build this immunity and then the "memory" lymphocytes help in the future by protecting against the same. But every individual may not be able to take the vaccine, as a person can be allergic to some component of the vaccine or due to a chronic ailment they have. In that case, herd immunity plays a major role.

B006

Cost Effectiveness Analysis Among Different Oral Hypoglycemic Agents: A Review

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Introduction: Prevalence of Diabetes Mellites (T2DM) has been increasing explosively over the years. India is poised to become the diabetic capital of the world with a patient population of 69.2 million in 2015, which is projected to increase to 123.5 million in 2040. Proper glycaemic control is difficult to be achieved in half of the patients. T2DM treatment can be very expensive however, most patients used multiple agents for associated comorbidities. Total Cost is the key issue for managing patients, as India is a developing country. Newer agents are expensive, as compare to older agents. It is important to find the cost-effective treatment. Cost-effectiveness analysis (CEA) performed to found same between different combinations of the drug. Methodology: This review includes eight studies conducted Cost effective Analysis (CEA) between different classes as followed Metformin+SU and Metformin+DPP4i. Out of 8 studies, 2 studies were performed in India (UP & Karnataka), 2 studies were performed in UK, remaining 4 were done in different region like Ethiopia, China, US, Sweden. These were observational studies; patients were randomly enrolled. Author used different methods to calculate Cost-effectiveness in terms of CER & ICER like Markov model, UK Prospective Diabetes Study Outcomes Model, Cardiff Model, IMS-CDM. Result: CER was calculated in non-model-based studies, where ICER was calculated in model-based studies with using different glycaemic parameters HbA1c %, FPG (mg/dl), PPG (mg/dl). Conclusion: Four Studies concluded Metformin+SU is cost effective, remaining suggest Metformin+DPP4i. It leads to confusion what to choose so, such study would be performed in India.

B007

Design Implementation And Comparative Analysis Of Audio Visual Aids In Distance Learning Pharmacology In A Tertiary Care Hospital Before And After Covid 19 Outbreak.

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Utilization of audio-visual aids for online learning and teaching pharmacology among students and academicians is a known mode for understanding of abstract topics. The availability of effective educational videos and power point presentations on various online platforms have helped students in the covid era more than before. In this study we have analysed the use of power point presentations and youtube utilization of the pharmacology medical syllabus topics and compared them for number of views, downloads, actions taken, sources of online utilization and subscribers added in the same period. There were significant difference in the utilization pattern of power point presentations and youtube videos with significant p value (<0.005) on applying paired sample t test. The actions taken that is download and utilization was better with power point presentations. The number of views for each presentations, impressions, watch time and the subscribers added was more with the youtube videos. There is both scope for knowledge enhancement and knowledge retention by using youtube videos. There is a need to keep students motivated by giving introductory information videos, complete academic course ideas, inculcating basic ideas on core concepts in general pharmacology. Further such studies on use of audio visual aids in medical education is needed to enhance the use of youtube or teachers tube as a part of curriculum for better understanding of abstract subjects like pharmacology.

B008

Implications of 3D Spheroids in Breast Cancer: Current Challenges and Promises towards Precision Medicine

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Breast Cancer is a heterogeneous disease and is the leading site in females globally. The majority of research efforts have been put towards the identification of immunotherapies to increase progression-free survival. However, current management fails to solve problems like resistance/insensitivity to the therapy as the molecular mechanisms responsible for it are unclear. In the current Omics era, we are still relying upon the conventional approach to drug development and identifying targets using in vitro testing followed by in vivo studies and subsequent clinical trials. Even though, the drug fails to exhibit its effects and develop resistance/insensitivity.For the last three decades, in vitro testing has been widely used as a pre-clinical model. 2D cell-culture lacks to mimic tumor microenvironment and cell communication. Nevertheless, 3D spheroid models may suffice the need but there is still inadequate information regarding the protocols used to study the drug response in spheroids which deters the standardization and output of data analysis. 3D models in breast cancer research have brought a revolutionary change in mimicking properties of tumors including its tumor microenvironment. The efforts should be more towards creating 3D models, which will be beneficial in many ways. The 3D spheroids will be valuable (1) to identify the detailed drug-resistance mechanisms involved in the disease progression, (2) it will ease the process of drug-discovery by replacing in vivo studies which will save time and money, (3) it will offer a selection of tailored therapeutic regime to the patients which will lead towards the precision therapy.

B009

Role of Post Approval Clinical Trials For Drug Safety

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All medicinal products carry risks in addition to their possible benefits. For developing a new medicine, a decision can only be made if both benefits and risks are addressed. Identifying safety signals for new and/or existing drugs is a major priority in the protection of public health. Phase IV trials are often used to investigate drug safety after approval. Phase IV activities comprise the whole range of medical endeavors in order to fully develop and exploit the therapeutic potential of a drug once it has been approved. The aim is to deliver the maximum benefit to the patients and to reap the investments during development. The tools are clinical trials, observational studies, data mining, and the collection of outcome data and real world evidence. The latter provide the data for health technology assessments and provide as such the basis for the reimbursement schemes. There are two types of post-marketing safety reports: Individual case safety reports - submitted on an ongoing basis, and Descriptive information Referred to as "narrative information" or a "Periodic Safety Report"), which is submitted on a periodic basis. Prevalent practice patterns can generate leads that could result in further evaluation of a new indication via the RCT route or even a signal that may necessitate regulatory action. Disease registries are another option as are the large simple hybrid trials. Surveillance of spontaneously reported adverse events continues as long as a product is marketed. And so Phase IV in that sense never ends.

B010

Pharmacovigilance Activity on Immunotherapy in Cancer Patients in Tertiary Healthcare Setting

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Pharmacovigilance as a scientific discipline has a tremendous potential in data driven modern world since it is considered an arm of patient care and involves collection of authentic high-quality data. Effectively communicated information allows for evidence-based use of medicines, thereby preventing many ADRs. This is essential in cancer therapy as the conventional cancer therapies produce debilitating ADRs unlike, say antihypertensives, resulting in low activities of daily living (ADL). Immunotherapy is considered as an advanced treatment for cancer patients and are known to cause comparatively lesser and milder adverse reactions. The prospective study involved ADR monitoring activity on 37 patients diagnosed with advanced stage lung and H/N (Head & Neck) cancer with co-morbidities treated with immune checkpoint inhibitors (ICIs) as a palliative therapy. Observed ADRs were assessed for severity using CTCAE 5.0 scale and causality using WHO-UMC causality criteria. The conclusive results of the study found to support medical literature on these drugs. Common milder ADRs such as fatigue, cough, dyspnea and asthenia; and less common but severe ADRs such as pneumonitis, myalgia, rashes and peripheral sensory neuropathy were observed in 80% and 20% of patients respectively. Most ADRs were found to be "Possible" and "Probable" in about 60% and 20% patients respectively, during causality assessment. This makes it a viable option for performance status (PS) 2 patients. The study can serve a great deal in identifying ADR profile to a multidisciplinary health professional team treating cancer patients with immunotherapy to make better clinical decisions.

B011

Causative Factors, Diagnostic Testing and Management of Infertility

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Infertility is a disease of the male or female reproductive system defined by the failure to achieve a pregnancy after 12 months or more of regular unprotected sexual intercourse. Infertility is classified as primary and secondary infertility. Primary infertility is inability to have pregnancy and secondary is inability to have a pregnancy after previously successful conception. There are certain factors such as male factors, female factors, unidentified factors and other factors which are responsible for the cause of infertility. Moreover, there are some diagnostic tests available for testing both male and female infertility through which the actual cause of the infertility can be known. To deal with this disease various treatments and management are available such as pharmacological and surgical treatment. Also, there are some prevention strategies that can be explained to avoid the chances of infertility.

B012

Therapeutic Potential of Nutraceuticals and Dietary Supplements in Preventing Covid-19 and others Virus Related Complications: A Review

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Despite enormous scientific advancement, viral diseases still remain the leading cause of morbidity worldwide and their potential to spread is escalating, eventually turning into pandemics. As regards to the current corona virus pandemic, several nutraceutical actives have indeed been reported as being protective against some of the symptoms that are considered as manifestations of COVID-19 in infected patients. COVID patients if not managed appropriately, can rapidly progress towards acute respiratory distress syndrome (ARDS) with multiple organ dysfunction syndromes (MODS) and death. Some nutraceuticals used as adjuvant to pharmacological therapy, can be of use in preventing COVID-19 related complications, as prophylactic and capable of reducing burden and severity of diseases. In this scenario, the nonconventional therapy with vitamins, multi-nutrients, functional foods, nutraceuticals and probiotics can play a significant role to combat this rising threat. These agents are not virucidal in action but can boost the natural immunity and improve the physiological condition of human body making it difficult for the viruses to replicate inside the host body and decrease the severity of the symptoms. Clinical evidence has shown that numerous therapies based on nutraceuticals and antiviral agents might be reduce the duration, intensity of symptoms related to colds, flu and respiratory viruses in general, prevent the onset of current complications and also improve the body's immune defences. Purpose of this review is to provide evidence regarding the benefits of nutraceuticals and other dietary supplements in preventing COVID-19 and other virus related complications.

B013

Adverse Event Profiles of TCu380A and TCu200B IUCDs: a Retrospective Analysis

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Studies on Intrauterine Contraceptive Devices (IUCDs) conducted in India and globally show dissimilar results with respect to discontinuation rates of TCu200B and TCu380A devices due to AEs. There are no long-term community-based clinic studies on both devices emphasizing on AEs. In this retrospective analysis, we compared AE profiles of both devices for 5 years. Three-decade data records of attendees with TCu200B (n= 296) or TCu380A (n= 399) devices at Bone Health and Woman's health Clinic, ICMR (Mumbai), were studied focusing on device removals due to AEs/ SAEs while planning pregnancy and social reasons were not considered. Over 34% of TCu380A and 20% of TCu200B devices were removed due to AEs like expulsion, abdominal pain, bleeding and infection. Expulsion, low placement were the major reasons of removal in 44% of all AEs related removals of TCu380A whereas, much lower TCu200B devices were removed for these reasons. Accidental pregnancies and failed removal attempts were considered as SAEs which required hospitalization. Removal attempts were unsuccessful in 2 of TCu380A devices and 1 of TCu200B devices whereas, difficult removals were observed in additional 2 and 6 of the TCu200B and TCu380A devices respectively. Significantly high rate of discontinuation was observed due to AEs in users of TCu380A compared to TCu200B whereas, accidental pregnancies were observed in 1% TCu200B users while no cases were reported by TCu380A users. There is no mechanism for reporting of AEs of copper containing IUCDs, posing the need to have provision on reporting of AEs to the PvPI/ MvPI.

B014

Regulatory Requirements for Pharmacovigilance in Various Countries

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Pharmacovigilance system is a branch of pharmacological sciences dealing with reporting of Adverse Reaction Events which are caused by medicines and/or medical devices. After the sulphanilamide tragedy in 1937 and the thalidomide disaster in 1960, Drug Regulations have been improved as well as have become stricter. As a result Pharmacovigilance System has been established which deals with collection, detection, assessment, monitoring and prevention of adverse effects of pharmaceutical products. India has Pharmacovigilance system which is regulated by CDSCO, US pharmacovigilance system is regulated by USFDA, UK has MHRA in association with the Commission on Human Medicines (CHM) runs the yellow card system in the United Kingdom and Eudravigilance is an EU regulatory network system.The US, EU, and Japan constitute the largest pharmaceutical markets, and their regulations are some of the most stringent in the world. Currently, 86 countries participate in the programme, which is coordinated by WHO together with its collaborating centre in Uppsala, Sweden. The emerging trend in Pharmacovigilance is to link premarketing data with human safety information observed in the post-marketing phase. Good pharmacovigilance practice in the processes and procedures to help ensure regulatory compliance and enhance clinical trial safety and post-marketing surveillance that contribute to the assessment of benefit, harm, effectiveness, and risk of medicines, encouraging their safe, rational, and more effective use.

B015

The Drug Utilization Evaluation of Medications Used in Ischemic Stroke

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Stroke is the second leading cause of death and the third leading reason for disability. Ischemic stroke occurs due to occlusion of carotid arteries and leads to a hypoxemic state of the brain cells. There are several risk factors associated with stroke-like hypertension, diabetes, heart diseases. Due to the lack of awareness, the hospitalization of patients will be delayed and the disability will be irreversible. This study aims to understand the prescribing pattern of stroke medications, identify and report the DRPs, study the cognitive function in the patients. The study was prospective observational type conducted among 70 ischemic stroke in-patients aged from 20-90 years. The data based on demographic parameters, medication prescription patterns, and clinical profiles were documented from the patients and case sheets. The incidence of ischemic stroke was more in males (82.85%) compared to females (25.71%). The age group most affected by stroke was 51-70 years. The majority of the patients were prescribed Nootropics 21.71%, antiplatelet 8.55%, statins 6.57%, and combination drugs 17.10%. Helper and Strand Classification was used to identify the DRPs and overall, 98 DRPs were identified. The cognitive function of the patients was assessed using the MoCA Scale and the mean baseline and the follow-up assessment of MoCA score were 19.28±4.20 and 25.53±2.25 respectively, which showed a significant increase in the cognitive ability of the patient. The correlation of cognitive scoring will give the relationship between risk factors affecting cognitive ability. The occurrence of DRPs is common and Pharmacists should create awareness among other HCPs about the DRPs.

B016

Emerging Needs of Crushing Tablet Formulations in Head and Neck Cancer Patients

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Head and neck cancer is the epithelial malignancy that is developed inside the paranasal, nasal, verbal, larynx, lymph nodes, and salivary glands. Hence the oral cavity is the most frequent anatomical site for these cancers. In terms of severity H & N cancer got ranked 6 th worldwide, so with increased prevalence, the standard treatment option for patients with the oral metronomic chemotherapeutic treatment (OMCT) who are unableto swallow tablets is the serious causation and affects their treatment regimen. For geriatric, pediatric, and adult patients who are unable to take medication as the whole formulation, crushing tablet formulation givesan edge and longer & sustained treatment. Crushing tablets is common in real-time scenarios with a patient with a Nasogastric tube (to bypass the oral route, the tube inserted through the nose) in advanced H & N cancer. After the crushing process, the medication is dissolved in the water and dispersed well, and given tothe patient to swallow. There is a lack of information on crushing anti-cancer drugs in emergency cases andhow the drug Pharmacokinetic affects this existing fact. Crushing tablet formulation adds value to the currentclinical practice regarding crushing anti-cancers drugs with patients suffering from H & N cancer. This givesmore understanding to the physician for dose adjustment of drugs that will benefit the patient's overall condition.

B017

Pharmacovigilance: An Overview

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INTRODUCTION-Drug safety concern is now becoming the major concern. The thalidomide tragedy opened the eyes of drug regulators as well as other concerned systems to establish a way in order to ensure drug safety. In 1968, drug safety issues were strengthened and globalised after the establishment of World Health Organization (WHO) Programme for the International Drug Monitoring. OBJECTIVE-Every drug is associated with beneficial as well as undesirable or adverse effect. "Adverse drug reactions (ADR)" is the common clinical problem. The hospitalization due to ADRs in some countries is about or even more than 10%. In addition, it is estimated that 10-20% of hospital patients suffer from ADRs. APPROACH-*Pharmacovigilance* i.e., appropriate and effective monitoring of ADRs, is the only way to safeguard health of public. Spontaneous reporting system (SRS) is the first and most widely used method to report ADRs. It enables early detection of new, rear and serious ADRs and signal generation which is new possible causal link between a suspected ADR and drug; which was previously unknown. Disproportionality analysis is most commonly used method of data interrogation to figure out the association between drug and ADR of interest. The statistics of under-reporting of ADRs is very high. There are many factors associated with under reporting of ADRs; categorized as *personnel and professional* characteristics of healthcare professional. RESULT-In terms of ADR reporting, factors like knowledge and attitude of health professionals are strongly related. Thus, under-reporting can be significantly improved by appropriate educational intervention.

TRACK-C

MOLECULAR PHARMACOLOGY

C001

Anthelmintic Activity of Chitosan and Chitosan Chlorhydrate Against Eisenia fetida and Eggs, Larvae and Adult Form of Haemonchus contortous Isolated from Sheep in India

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Current study is designed to examine anthelmintic activity of Chitosan and Chitosan chlorhydrate (CCH) on Indian earthworm Eisenia fetida and eggs, larvae and adult form of Haemonchus contortus. Chitosan and CCH showed dose dependent activity in terms of mean paralyzing time and mean death time against Indian earthworm Eisenia fetida and adult and larval form of Haemonchus contortus compared to Albendazole and Mebendazole. ED50 for egg hatch inhibition was found to be 0.11 and 0.08 for Chitosan and CCH respectively. Maximum concentration required to induce 100% egg hatch inhibition was 2.5 and 4 µg/ml for CCH and Chitosan respectively. Against adult form of Haemonchus Contortous, highest 5% Chitosan produced paralysis in 13.9±0.86 min. while death in 25.3±1.65 min. 2.5% CCH produced paralysis in 17.1±1.2 min while death in 22.2±1.73 min. Chitosan-induced 82% mortality while half concentration CCH-induced 83% mortality. Variation between activities of Chitosan and CCH might be due to difference in water solubility resulting in easy CCH transcuticular absorption into parasite body.

C002

Association between metabolic syndrome and Parkinson\'s disease

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Parkinson's disease (PD) is an age-related neurodegenerative disorder which is progressive in nature. It mainly occurs due to degeneration of dopaminergic neurons in Substantia nigra Pars Compacta. However, many other factors are not only associated to it, but also responsible for onset of pathology. Metabolic syndrome is one such risk factor for PD. Metabolic syndrome is a cluster of disease mainly including diabetes, hypertension, obesity and hyperlipidaemia which pose a risk for developing cardiovascular disorders. All these disorders have their own pathological pathways which intertwine with PD pathology. This leads to alpha-synuclein aggregation, neuroinflammation, mitochondrial dysfunction and oxidative stress which are facets in initiating PD pathology. In this review, we aim to elucidate such molecular mechanisms involved in the association between them and pave way for potential repurposing of therapies.

C003

Involvement of Nrf2/ARE Pathway and NLRP3 Inflammasome Cascade in Alleviation of Diabetic Hepatopathy in Rats: A Comparative Study

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Approximately 70-80% type II diabetic individuals are suffering from diabetic hepatopathy/NAFLD. A combination of high-fat diet (HFD) and streptozotocin has been reported as well-established model to induce type II diabetes in rodents. Glibenclamide (GLB) possesses anti-inflammatory properties and inhibits NLRP3 inflammasome. Dimethyl fumarate (DMF) activates the Nrf2/ARE pathway and maintains the antioxidant status. The aim was to investigate, whether simultaneously targeting both NLRP3 inflammasome inhibition and Nrf2 activation (by administering combination of GLB and DMF) alleviate diabetic hepatopathy or not. High fat diet (HFD) was provided to rats for 17 weeks and streptozotocin (STZ; 35 mg/kg/day;ip) was injected once at third week. The intervention of GLB (0.5 mg/kg/day;po), DMF (25 mg/kg/day;po) GLB+DMF and metformin (MET; 200 mg/kg/day;po) were provided for last twelve consecutive weeks. Treatment with GLB, DMF and GLB+DMF significantly exhibited protection against STZ+HFD-induced diabetic hepatopathy by improving plasma levels of glucose, triglycerides, cholesterol, % HbA1c, and hepatic ROS, MDA, GSH, steatosis, NLRP3, ASC, caspase-1, IL-1β, NF-κB, Nrf2, SOD-1, catalase, IGF-1, HO-1, RAGE, and collagen-1 in diabetic rats. Simultaneous maintenance of antioxidant status by activating Nrf2ARE pathway and reduction of the inflammatory condition by inhibiting NLRP3 inflammasome cascade could be a rational strategy for improving liver recovery and to reduce the development of prolonged oxidative stress and inflammation associated diabetic hepatopathy.

C004

Hyperglycaemic Brain Insult: Linked mechanisms and advanced therapeutics

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Stroke is the recurrent morbidity and mortality among non-diabetics as well as diabetics. Diabetics have distorted endothelial function and impaired brain pathways which lead to various systemic metabolic complications. Diabetics have not only impaired neurotransmission but also have progressive neurodegeneration which leads to permanent neurological complications. Due to diabetic risk factors and altered physiology cardiovascular and cerebrovascular events are more common and also life-threatening which more often requires serious admissions. There is bi-directional linking of stroke and diabetes which worsens its outcomes. As diabetes is a metabolic syndrome, its systemic effects on human physiology are devastating. Hence, diabetic-stroke patients require specific dual-therapeutics which may provide dual-protection. Since the last few decades, scientific researchers have made excellent progress in diabetes-associated stroke and its therapeutics. In this review, we have briefly summarised the overall overview of diabetic brain and associated co-morbidities and recent advancements in stroke therapeutics.

C005

Moderate Malnutrition Affects Expression of MRP2 And ABCC3 Transporters in Rat Liver: Implications for Doxorubicin Pharmacokinetics

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Several studies from across India have reported malnutrition in cancer patients at diagnosis. Chemotherapeutic drugs used in cancer have a narrow therapeutic index. Pharmacokinetics of several drugs is known to change in malnutrition that can lead to toxicity. In this study, we wished to assess the underlying molecular changes that result in altered pharmacokinetics of doxorubicin in malnourished rats. We found minor and clinically insignificant differences in pharmacokinetic parameters of doxorubicin in malnutrition. However, we found that the concentration of doxorubicin in malnourished rat liver was significantly less compared to healthy liver. On further investigation we found that the protein and mRNA levels of MRP2 transporter that effluxes doxorubicin through bile-canalicular membrane was significantly decreased, while the levels of ABCC3 transporter were higher at both protein and mRNA level. This inverse relationship between MRP2 and ABCC3 is well documented in literature for other conditions like cholestasis and is responsible for rerouting the clearance of drugs from hepatic to renal route. Since the clearance of doxorubicin at the dose injected is not very different in malnourished rats, there may not be any direct clinical implication. However, clearance of the drug may be affected at higher doses or on repeated administration in view of altered expression of transporters in the liver, and consequently its toxicity. This requires further investigation.

C006

Pharmacological Evaluation of PPAR α/γ Dual Agonist in the Modulation of Depressive-Like Behavior Co-morbid with Glucose Intolerance

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In recent years, peroxisome proliferator-activated receptors (PPAR-α and γ) are emerging as promising targets for treating neuropsychiatric disorders and behavioral dysfunctions. Gallic acid can act on PPAR-α and γ that's why it becomes interesting to investigate it for anti-depressant activity. This study investigates the antidepressant effect of gallic acid on unpredictable chronic mild stress (UCMS) induced depression in hyperglycemic rats. Hyperglycemia was induced in rats using dexamethasone (2mg/kg i.p.) for 7 days followed by UCMS procedure for three weeks to produce experimental model of hyperglycemia-associated depression. Animals were administered with gallic acid (100mg/kg p.o.)/fluoxetine (2mg/kg p.o.)/metformin (140mg/kg p.o.) for 21 days. Behavioral paradigms like sucrose preference test, forced swim test, locomotor activity, novelty suppressed feeding, novel object recognition was performed. Biochemical estimation including glucose levels, oxidative stress parameters and neurotransmitter assay were performed. Gallic acid treatment showed significant antidepressant activity in behavioural parameters. Further, treatment with gallic acid also demonstrated better cognitive ability. Further, gallic acid has proved to improve the neurobehavioral parameters as compared to disease control which was comparable to fluoxetine treated group. Gallic acid treatment normalized the elevated blood glucose in disease control rats. The altered levels of anti-oxidant parameters and neurotransmitters like serotonin and dopamine were also improved after treatment. Histopathological evaluation of brain demonstrated increased neural density and restoration of normal neural morphology. Taken together, the result suggests antioxidant/neuroprotective effect of gallic acid via its action on PPAR-α and PPAR-γ, thus, helping combat depression associated with hyperglycemia.

C007

ER Stress in Diabetic Peripheral Neuropathy: The Dawn of New Therapeutic Approaches

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Diabetic peripheral neuropathy (DPN) develops and progresses in the peripheral nerve's heterogeneous environment, including a complex interplay between the nerve and its surrounding cells and tissues. ER stress role is being increasingly evaluated based on in vivo evidence confirming its function in the beginning and progression of DPN in both type 1 and type 2 diabetic rodent models. Furthermore, research into ER chaperone proteins, which aid protein folding in the ER by preventing freshly produced polypeptide chains and assembled subunits from aggregating into nonfunctional structures, is an emerging therapeutic strategy for restoring ER function. In Zucker fatty (fa/fa) rats, oral administration of trimethylamine oxide (TMAO), a chemical chaperone known to relieve ER stress, reduced protein expression of BiP/GRP78 in the sciatic nerve and enhanced nerve conduction velocities and behavioral responses to mechanical and thermal stimuli. When C57B6 mice on a high-fat diet (HFD) were given salubrinal, a drug that increases eIF2α phosphorylation, an improvement in neural phenotype was observed. The severity of neuropathy was also reduced in streptozotocin (STZ)-treated rats given TMAO. Finally, compared to wildtype STZ-injected mice, C57B6 Chop-/- mice injected with STZ showed enhanced nerve function and higher expression of the folding proteins BiP/GRP78 and GRP94 in peripheral nerves, implying a role for ER signaling in DPN formation. In this review, we therefore highlight how ER stress activates the UPR signaling pathway as well as how restoring ER function with chemical chaperones can improve peripheral nerve function in DPN.

C008

The Burning Furnace: Alteration in Lipid Metabolism in Cancer-Associated Cachexia

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Cancer cachexia can be defined as a complex metabolic syndrome characterized by weight loss, anorexia, and emaciation due to the wasting of adipose tissue and skeletal muscle. In the last decade, much research has been done to decipher the role of lipid metabolism in cancer cachexia. Tumors, as well as host-derived factors, cause major metabolic changes in the body. Metabolic changes lead to higher energy expenditure by the host. To meet the high energy demand, the host utilizes fat depots stored in adipose tissues by a process known as lipolysis. High catabolic and low anabolic response leads to loss of adipose tissue. A significant insight has been made regarding adipose tissue "browning" bestow on thermogenic activities of adipocytes that result in catabolic energy expenditure. Both lipolysis and WAT browning play an important role in exhaustion adipose tissue. The goal of this review is to summarise what is currently known about altered lipid metabolism and its utilization in cancer cachexia.

C009

Role of Renin Angiotensin System Modulators on Sleep Deprivation Induced Cognitive Dysfunction

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Sleep deprivation (SD) is a common condition that afflicts many people in modern life. SD interfere with cognitive abilities, motor performance, and emotional mood. Angiotensin II type 1 and 2 receptors of brain RAS plays opposite functions in CNS to each other. In the present, study was aimed to reveal the neuroprotective effects of AT1 and AT2 receptors in SD induced neurodegeneration. The study was performed in two phases viz., acute and chronic, 72 h and 8 h/day for 21 days, respectively and induction of SD was performed by modified multiple platform method. Cognition was assessed using Morris water maze (MWM) and step down latency paradigms. Biochemical parameters such as SOD, LPO, GSH, TBARS and plasma cortisol level were measured. AT1 and AT2 receptor elicit protective effect via PPARγ, we have approached selective blockade of PPARγ receptor using GW9662. Further, we approached selective antagonism/agonist of AT1 and AT2 R to unravel the clear mechanism of action. In MWM and step down latency, we found that C21 produced significant restoration of cognitive effect and restored the brain antioxidant properties significantly, compared to other groups. Both telmisartan and C21 showed an improved activity of SOD. C21 decreases the malondialdehyde content in TBARS and plasma costisol levels. C21 showed to improve the levels of GSH as compared with telmisartan, EMA200, GW9662. Based on behavioral and biochemical evidences AT2 R plays significant role when compare to AT1 R in reversing cognitive dysfunction in SD animals and this effect found to be independent of PPARγ pathway.

C010

Effect of buspirone in endothelin-1 induced stroke cachexia

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Stroke cachexia is associated with prolonged inflammation, muscle loss, poor prognosis, and early death of stroke patients. The present study aimed to evaluate the effect of a 5-HT1a agonist, buspirone on stroke cachexia. Wistar rats were injected with endothelin-1 to the bregma region of the brain to induce ischemic stroke followed by induction of cachexia after 4 days. Treatment with buspirone (3mg/kg *p.o*) was given for 4 weeks after confirmation of cachexia in animals. Disease control animals exhibited decrease in wire hanging time and increase in foot fault numbers compared to normal animals. Disease control animals also showed weight loss, decrease in food intake, increased serum glucose and lipid profile along with high serum levels of inflammatory cytokines – TNF-α, IL-6 and decrease in weight of skeletal muscle and adipose tissues. Treatment with buspirone improves behavioural parameters along with increases food intake and body weight, decreased inflammatory cytokines IL-6 and TNF-α and serum glucose levels with increase in lipid profile. Buspirone also increased the weight of adipose tissue and maintain the skeletal muscle architecture and function as depicted in histopathological studies. Our study suggests that buspirone produces beneficial role in stroke cachexia.

C011

Zebrafish model for Iron Induced Alzheimer's Disease

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Iron dyshomeostasis has been found to play a role in the genesis of brain-related disorders such as Alzheimer's disease (AD). In the brain MRIs of Alzheimer's patients, iron buildup has been detected also, it has been identified as a major contributor to the formation of Amyloid beta and Neurofibrillary tangles, which are hallmarks of AD. Microglial activation results in the production of cytokines, resulting in neuroinflammation and neuronal death. Inflammatory indicators such as IL-1 and TGF play a key part in the pathophysiology of Alzheimer's disease. Considering the significance of iron overload in the development of Alzheimer's disease and the lack of iron overload zebrafish models, the goal of this study was to develop an iron-induced zebrafish model for AD. The focus of this research was to see how varying iron concentrations affected zebrafish cognitive impairment. In this study, zebrafish were subjected to various iron concentrations for 28 days. Furthermore, the influence of iron overload on behavioral parameters (Y-maze, Novel tank test), oxidative stress parameters (MDA, GSH, Catalase), acetylcholinesterase levels, iron levels, and IL-1β levels in brain homogenate is investigated in this study. The behavioural and locomotory responses, specifically in animals exposed to iron for 28 days, suggest an increase in anxiety. The levels of reactive oxygen species significantly increased ($p<0.001$) with the increase in iron concentration. Iron concentration and IL-1β significantly increased ($p<0.001$) in the brain homogenate of the zebrafish.

C012

Role of WNT Pathway in Development of Diabetic Retinopathy

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Diabetic retinopathy (DR) is characterized by retinal vascular leakage, inflammation, and aberrant neovascularization, and is one of the most prevalent microvascular consequences of diabetes. In developed countries, DR has become the most common cause of blindness and loss of visual acuity among working adults, and the incidence is on the rise. Most patients with type-1 diabetes will eventually develop some degree of DR, and 50–80% patients with type 2 diabetes will develop DR with 20–25 years of diabetes. DR has a complicated pathophysiology. It's critical to gain a deeper understanding of the underlying mechanisms that cause DR in order to develop new treatments. The Wnt signaling pathway is an evolutionarily conserved pathway involved in embryogenesis and adult tissue homeostasis. Wnt signaling controls the expression of several genes involved in retinal development and eye organogenesis. It affects the formation and maturation of retinal vessels, as well as the establishment of synaptic structures and neuronal activity in the central nervous system. Mutations in Wnt/β-catenin signaling cascade components can cause serious retinal disorders, while Wnt signaling dysregulation can contribute to disease progression. Dickkopf homolog 1, a natural inhibitor of the Wnt pathway, ameliorated retinal inflammation, vascular leakage, and retinal neovascularization in the DR models. This review highlights recent progress in studies of Wnt signaling in DR and therapeutic potential of modulating Wnt signaling in DR.

C013

Role of Immunotherapeutics in Clinical Practice

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Immunotherapy has established itself as an important component of cancer treatment, improving the prognosis of many patients suffering from a variety of haematological and solid malignancies. Checkpoint inhibitors (CPIs) and chimeric antigen receptor (CAR) T cells are the two key factors underlying this progress. Current research on checkpoint blockade focuses on combinational methods, novel tumor entities, perioperative usage, toxicity control, response prediction, and use in specific patient groups. Recent investigations on CAR - T cells in patients with acute lymphoblastic leukaemia or diffuse large B cell lymphoma have verified their safety and efficacy. Various approaches to translating CAR's remarkable achievement. Immunotherapies can be injected into a vein, injected beneath the skin (subcutaneously), or injected into a muscle (intramuscularly). Immunotherapy can be given directly to the bodily cavity where the tumor is located in some cases.

C014

Neuroprotective Effects of Taxifolin against Weight drop induced Traumatic Brain Injury in Rats

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TLR4 is one of the Toll-like receptors (TLRs), which fall in the family of pattern recognition receptors. TLR4 is a key player in innate immunity and involved in the pathogenesis of traumatic brain injury (TBI). Targeting TLR4-mediated neuroinflammation provides a potential therapeutic opportunity for the treatment of TBI. Taxifolin is a phytochemical with potent anti-inflammatory activity. The present study aimed to investigate neuroprotective role of taxifolin against experimental models of TBI. Rats were assigned into four groups; control and TBI groups pretreated with vehicle, and two TBI groups pretreated with different doses of taxifolin (2 and 5 mg/kg/day, i.p., five consecutive days). Except for the control, all other groups were subjected to TBI using Marmarou's weight-drop method. 24 h after TBI, locomotor function was evaluated. Lastly animals were scarified and in addition to the TLR4 expression, estimation of lipid peroxidation, nitric oxide and myeloperoxidase in brain tissue, blood-brain barrier (BBB) integrity and brain edema were also estimated. Results of in-vivo studies showed that weight-drop induced TBI caused functional disability in the rats as indicated by impairment in locomotor activities. The TBI also resulted in augmented expression of TLR4 in rat brain. The results also showed disruption in the BBB integrity, increased brain edema, and increased nitric oxide, lipid peroxidation and myeloperoxidase in the brain of the rats exposed to trauma. Pretreatment with taxifolin (1 and 5 mg/kg) ameliorated neurochemical and behavioral consequences of trauma as well as attenuated the expression of TLR4. This study revealed that taxifolin can be considered as a potential candidate for managing the functional disabilities associated with TBI because of its TLR4 receptor inhibiting activity.

C015

Recent Perspective on Modern Analytical Techniques used in Metabolomics Analysis

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Metabolomics is the comprehensive assessment of endogenous metabolites and attempts to systematically identify and quantify metabolites from a biological sample. Small-molecule metabolites have an important role in biological systems and represent attractive candidates to understand disease phenotypes. Metabolites represent a diverse group of low-molecular-weight structures including lipids, amino acids, peptides, nucleic acids, organic acids, vitamins, thiols and carbohydrates, which makes global analysis a difficult challenge. The recent rapid development of a range of analytical platforms, including GC, HPLC, UPLC, CE coupled to MS and NMR spectroscopy, could enable separation, detection, characterization and quantification of such metabolites and related metabolic pathways. Owing to the complexity of the metabolome and the diverse properties of metabolites, no single analytical platform can be applied to detect all metabolites in a biological sample. The combined use of modern instrumental analytical approaches has unravelled the ideal outcomes in metabolomics and is beneficial to increase the coverage of detected metabolites that cannot be achieved by single-analysis techniques. Integrated platforms have been frequently used to provide sensitive and reliable detection of thousands of metabolites in a biofluid sample. Continued development of these analytical platforms will accelerate widespread use and integration of metabolomics into systems biology. Here, the application of metabolomics is discussed; furthermore, this review comprehensively highlights the role of integrated tools in metabolomic research.

C016

Evaluation of Protective Effect of Nrf2 Activator Quercetin In Myocardial Ischemia

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Myocardial ischemia occurred by obstructing blood flow to myocardium. In myocardium infraction Nrf2 maintain the level of antioxidant enzymes. The current study was designed to assess the cardio protective effect of quercetin via Nrf2 upregulation in rat model. The male Sprague Dawley (SD) (150–180 g) were randomly allocated to six groups (n=10). Except group I (normal control) & II(model control), Group II- VI animals were pretreated with 10 mg/kg, 25 mg/kg and 50 mg/kg Quercetin for 45 days. After finishing pretreatment group II and group II- VI animals were induced myocardial ischemia by Coronary Artery Ligation method. Animals were subjected to a 30 min LAD coronary artery ligation followed by a 2 h reperfusion. At the completion of the experiment, rats were sacrificed. After scarification anthropometric parameters, hemodynamic parameters, myocardial Infarct, serum parameters, antioxidant parameters were measured. The results were interpreted using ANOVA. Quercetin 50 mg/kg shown significantly improved hemodynamic parameters, increased antioxidant activity, also improved serum parameters. Results indicates quercetin could function as an effective therapeutic agent to attenuate the progression of myocardial ischemia by improving various parameters. Nrf2, Quercetin, LAD Coronary Artery Ligation, Myocardial Ischemia.

C017

Dyrk1b As Emerging Target for Metabolic Syndrome

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Dual specificity tyrosine- phosphorylation regulated kinase (DYRK1B) belongs to the Dyrk family of proteins, a group of evolutionarily conserved protein kinases that are involved in cell differentiation, survival, and proliferation. The encoded protein participates in the regulation of the cell cycle. Expression of the gene may be altered in number of tumor cells and mutation in this gene were found to cause abdominal obesity and metabolic syndrome. DYRK1B is a nutrient-sensing protein that inhibits the RAS–RAF–MEK pathway, which is widely recognized for its regulation of glucose uptake and glycolysis. DYRK1B level increased in patient with non-alcoholic steatohepatitis (NASH) and mice fed with high sucrose high fat diet. DYRK1B causes de novo lipogenesis (DNL) by activating mTORC2. Pathological DYRK1B results in enhanced expression of transcription factor PPAR-gamma, leading to increase adipogenesis. The expression of DYRK1B increases dramatically during adipogenic differentiation. Adipogenesis is a process of maturation of undifferentiated mesenchymal stem cells toward the adipocyte lineage. In addition, DYRK1B increases glucose-6-phosphatase, which is strongly associated with insulin resistance. Increased expression and activity of glucose-6-phosphatase are associated with elevated fasting glucose levels in patients with type 2 diabetes. Inhibition of DYRK1B enhances Treg differentiation and impairs TH17 differentiation without affecting known pathways of Treg/TH17 differentiation. As keramati et.al has shown role in adipogenesis, insulin resistance and atherosclerosis, which plays critical role in pathogenesis of metabolic syndrome, DYRK1B can be potential target for ameliorating metabolic syndrome.

C018

In-silico Assessment of Sesamol Derivatives as an NRF-2 Activator

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Drug-induced liver injury (DILI) is the injury caused to the liver by any drugs, xenobiotics, or their metabolites. DILI can simulate both chronic and acute liver failures. One of the reasons for DILI is the formation of reactive oxygen species (ROS), which leads to oxidative stress-induced organ failure by the drug or metabolite during their metabolism. Where the cellular antioxidant defense system is unable to contain the generated ROS. Activation of the Nrf-2 pathway can protect against oxidative stress-induced organ failure as it increases antioxidant gene expression. Sesamol is a significant constituent of sesame oil, and its pharmacological activity is linked to its antioxidant nature and the potential to alter the signaling-pathway like Nrf-2. The computational study was done in Maestro (Schrödinger) to find sesamol derivative as an activator of Nrf-2 signaling pathway using tools like Glide, induced-fit docking (IFD), MM-GBSA & Molecular dynamic simulation (MDs). Sesamol derivatives downloaded from databases (PubChem) were screened via glide tool in the protein PDB: 4L7D using High throughput virtual screening, subsequently standard precision, and extra precision. The top five compounds namely I) 2-[(1,3-benzodioxol-5-yloxy)methyl]-3-(4-chlorophenyl)quinazolin-4(3H)-one, II) 3-hydroxy-3-(6-hydroxy-1,3-benzodioxol-5-yl)-1-pentyl-1,3-dihydro-2H-pyrrolo[3,2-c]pyridin-2-one, III) 3',4',5-Trihydroxy-3-methoxy-7,8-methylenedioxyflavone, IV) 2-[2-[1-[3-(1,3-Benzodioxol-5-yloxy)propyl]piperidin-3-yl]ethyl]-6,7-dimethoxy-3,4-dihydroisoquinolin-1-one and V) 4-(5-Cyclopropylmethoxy-benzo[1,3]dioxol-4-yl)-5H-pyrrolo[3,2-d]pyrimidine-7-carboxylic acid (piperidin-4-ylmethyl)-amide were subjected to MM-GBSA, where three compounds (II, III & IV) were filtered out. The remaining two compounds: I & V, were subjected to IFD and MDs for 20 ns. Compounds I & V show interactions similar to that of activator present in 4L7D, with which we can postulate these derivatives will act as an activator.

TRACK-D

NATURAL PRODUCT PHARMACOLOGY

D002

Evaluation of Calcium content and oral calcium bioavailability of some commonly used Ayurvedic bhasma

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Bhasma are one of the commonly used dosage forms in Ayurvedic system of medicines for the management of various health ailments. They are also used as a natural source of calcium in Ayurvedic formulations. The current study was carried out to assess the calcium content and oral calcium bioavailability of three main sources of bhasma: animal origin, marine origin, and mineral origin. In the present study, we have selected six bhasma, two from each of above-mentioned sources. They were evaluated for percentage calcium content using Atomic Absorption Spectroscopy. The bhasma were then orally administered to Wistar rats at the dose of 300 mg/kg for eight days and evaluated for serum calcium levels. The calcium contents of Ajasthi bhasma, Kukkutandatvak bhasma, Muktashukti bhasma, Praval bhasma, Abhrak bhasma and Godanti bhasma were obtained to be 31.39%, 37.95%, 44.16%, 35.33%, 4.69% and 5.92% respectively. Bioavailability study showed highest calcium levels from Muktashukti bhasma with calcium Cmax of 36.05±0.25 g/dL and area under curve of 343.06 mg on day 1. On the other hand, Kukkutandatvak bhasma reported calcium Cmax of 41.56±0.25 g/dL and area under curve of 384.61 mg on day 8. From the statistical data evaluation, it can be concluded that for immediate action, Muktashukti bhasma has the highest rate of absorption whereas for chronic treatments, Kukutandatvak bhasma shows highest absorption amongst all bhasma.

Key words: Ayurveda, bhasma, bioavailability, calcium, serum level estimations.

D003

Amelioration of immune function in murine model of sepsis: In-vivo and In-vitro analysis of ethanol extract of Carica papaya leaves.

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Background: Plants have been used since time immemorial for the purpose to cure variety of ailments. Different parts of Carica papaya plant have many traditional claims for herbal medicine. The presence of numerous phytoconstituents in the leaves have shown significant antiiflammatory and immunomodulatory properties by moderating the release of various cytokines like interleukin-6 (IL-6), Tumor Necrosis factor-α (TNF-α), IL-10. Aims: (1) To perform a comparable qualitative and quantitative analysis of extracts of papaya leaves using ethanol, methanol and water solvents. (2) To determine in-vitro % cell viability of plant extract using MTT assay. (3) To induce and validate sepsis model by cecal ligation and puncture in rats. (4) To compare the effect of ethanol extract of papaya leaves and imipenem in sepsis model of rats. Method: Dried leaves sample (58g) were soxhlet extracted using different solvents (500ml). Phytoconstituent analysis, total flavonoids content, DPPH free radical scavenging activity were performed. HPTLC of ethanol extract analysed the separation of phytochemicals using toluene: ethylacetate: formic acid (8: 1.5: 0.5) as mobile phase. Peaks and Rf values were recorded at 254nm followed by FTIR to identify functional groups. Percentage cell viability of extract was analysed through MTT assay using J774 cells. Animals were divided into 4 groups as group 1 (Control; DMSO, i.p.), group 2 (Toxic group), group 3 (Ethanol extract; 100mg/kg, i.p.), group 4 (Imipenem; 120mg/kg, i.p.) which underwent cecal ligation and puncture induced sepsis. Drugs were administered 6 hours post CLP for 7 days after which animals were sacrificed and parameters were analysed. Result: The qualitative analysis of papaya leaves revealed maximum phytoconstituents and highest percentage yield (13.1%) in ethanol extract compared to methanol and aqueous extracts. Total flavonoid content in ethanol extract was calculated to be 1.905±0.002, DPPH assay value was 69.75%, FTIR

showed various peaks corresponding to O-H stretch (alcohols), O-H stretch (carboxylic acid), C=O stretch (aldehydes), C=O stretch (ketones). The percentage cell viability was highest at 25 µg/ml amongst different concentrations. Significant reduction in IL-6, TNF-α, IL-10 levels were observed in animals administered with ethanol extract (100mg/kg). Histopathological evidences showed the development of sepsis that was ameliorated by administration of Ethanol extract in comparison to other groups.

Conclusion: Ethanol extract of papaya leaves appeared to possess highest antiinflammatory and antioxidant phytocomponents by modulating inflammation and oxidative stress and reinforcing cell viability thereby protecting host cell from mortality of sepsis. Thus, the use of Carica papaya leaves in the management of clinically diseased conditions is justified.

D004

Evaluating the efficacy of *Celastrus paniculatus* oil in social isolation and lead acetate induced attention deficit hyperactivity disorder in rats

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To explore the pharmacological activity and mechanism of action of Celastrus paniculatus oil for the treatment of attention deficit hyperactivity disorder in perinatal rats. In the perinatal stage, the animals were either isolated or reared in eight groups. Lead acetate was administered to different groups to study the effect of environmental neurotoxicant on brain development. Atomoxetine served as the reference standard. The animal's behaviour was assessed through Y-maze, novel object preference, fear conditioning and resident-intruder aggression tests. Oxidative stress parameters, bioamine concentration (dopamine, noradrenaline and 5-hydroxytryptamine), nerve growth factor, interleukin-6, nuclear factor-κB and tumour necrosis factor α were estimated. And synaptophysin immunohistochemical assay was performed. The treatment with Celastrus paniculatus oil showed significant improvement in behavioural parameters in Y maze, novel object preference, discrimination index, fear conditioning and resident intruder aggressive test. The treatments showed increase in SOD, Glutathione and Catalase levels while the MDA levels in the treatment groups were found to be decreased. Celastrus paniculatus oil provided protection against oxidative stress. The levels of Dopamine and noradrenaline were increased while serotonin levels were restored by Celastrus paniculatus oil. Celastrus paniculatus oil increased nerve growth factor and decreased interleukin-6, nuclear factor-κB, and tumour necrosis factor-α. Synaptophysin immunoreactivity was improved by Celastrus paniculatus oil and reactive gliosis, degeneration, and vascular proliferation were alleviated. This research shows the therapeutic potential of Celastrus paniculatus oil for the treatment of ADHD.

D005

Evaluation of Anti-Arthritic Activity of Poly-Herbal Sheetal Oil in Complete Freund's Adjuvant Induced Arthritic Rat Model

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The Rheumatoid Arthritis is chronic autoimmune disease which mainly affects the larger joints and causes severe pain in patients. The conventional drugs shows efficacy against Rheumatoid arthritis with severe side effects, Extensive literature review showed some herbal plants possess antiArthritic activity. The present study was carried out to explore the anti-arthritic property of herbal marketed formulation 'Patanjali sheetal oil' (PMO). As a disease model for arthritic paw swelling, either sex Wistar rats were induced with Freundlich complete adjuvant (FCA). There were six rats in each of the three experimental and control groups. Through a 21-day feeding plan, the role of the PMO in illness amelioration was investigated using paw circumference and blood biochemical markers. The Salkowski test was used to look for the presence of anti-inflammatory chemicals using UV-visible analysis. FCA-induced paw swelling returned to normal, which served as a visible indicator of the experiment's success. The serum protein and enzyme levels in the treated mice were significantly higher. After therapy, the experimental rats' CRP, RA, and NO levels were estimated to be normal. UV-visible examination revealed the presence of at least four anti-inflammatory chemicals, including tannins, alkaloids, flavonoids, and 9-octadecenoic acid, all of which have been linked to anti-inflammatory and anti-arthritic effects. According to our findings, the PMO includes anti-inflammatory chemicals that could be employed as an anti-inflammatory/anti-arthritic drug.

D006

In-Vivo Screening of Anti-Diabetic Activity of *Macrotyloma uniflorum* on Albino Rats

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The prevalence of diabetes has risen dramatically worldwide, as the major cause of morbidity and mortality. In 2021, 537 million adults were suffering from diabetes. In 2019, diabetes was the ninth leading cause of death with an estimated 1.5 million deaths directly caused by diabetes. Allopathic treatment available in market has reported several adverse effects in diabetic patient.

The aim of this study is to formulate safe, effective and affordable herbal formulation for diabetes. The traditional indigenous plant Macrotyloma uniflorum(lam) also known as kulthi beans was selected and authenticated by botanist from Shivaji University, Kolhapur. Research protocol was approved by IAEC(CPCSEA) Bharati Vidyapeeth College of Pharmacy, Kolhapur. Seeds of Macrotyloma uniflorum were collected from local area of Kolhapur. Methanolic extract was prepared by Soxhlet extraction and phytochemical constituents were investigated as per official monographs. Diabetes was induced in albino rats by alloxan and in-vivo screening of anti-diabetic activity was completed as per the approved protocol in control, test and standard(glibenclamide) groups by measuring blood glucose level using glucometer. Daily oral administration of seed extract of Macrotyloma uniflorum (250 and 500mg/kg body weight) and Glibenclamide (10 mg/kg) showed beneficial effects on blood glucose level. Where 500mg/kg dose was more effective than 250 mg/kg ($P<0.001$).

The results of extract of Macrotyloma uniflorum shows promising decrease in blood glucose level in test and standard groups. The herbal extract is potent, effective and an alternative for allopathic means of treatment of diabetes. Henceforth, this project can be taken ahead for pre-clinical and clinical trials.

D007

Pterostilbene attenuates diabetes induced depression like behavior in rats

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Diabetes is considered as epidemic and is of major concern worldwide. Though hyperglycaemia is considered as a primary factor in the onset of diabetes, a bidirectional relationship between Diabetes and Insulin resistance, Inflammation exists. Persistent hyperglycaemia is associated complications of depression like behaviour which worsens with the advancement of the disease. Pterostilbene, a Resveratrol analogue through SIRT1 activation depict the antidiabetic potential. The animal experiment protocol consisted of STZ induced diabetic male Wistar rats, which were left untreated for 21 days. Post 21 days the rats were subjected to forced swim test (FST) and animals with increased immobility time were considered as depressed. The depressed animals were treated with vehicle or Pterostilbene (three doses-40 mg/kg, 20 mg/kg, and 10 mg/kg) or Metformin for 28 days. At the end of treatment schedule open field test (OFT),marble burying test (MBT),resident intruder test(RIT),sucrose preference test (SPT) paradigms were performed. It was followed by biochemical estimations for Lipid profile, Kidney function test (KFT), Liver function test (LFT), and antioxidant activity. The anti-inflammatory potential was estimated by Serum cortisol, nitric oxide (NO), interleukin-6 (IL-6) and interleukin-1β (IL-1β) levels. Persistent hyperglycaemia resulted in depression like behaviour and increased anxiety level in disease control group in comparision with Pterostilbene and Metformin treatment group. Based on results it was concluded that Pterostilbene helps in normalizing depression like mood and reduced the proinflammatory mediators.

D008

Research Progress on Main Symptoms of Novel Coronavirus Pneumonia Improved by Traditional Indian Medicinal herbal syrup

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Novel coronavirus pneumonia has become a massive threat to global public health. It is infectious and can be transmitted through respiratory droplets, digestive tracts, and contact. Coronavirus is from SARS-Co V family it mostly causes pneumonia either direct viral pneumonia or a secondary bacterial pneumonia. The World Health Organization (WHO) declared that COVID-19 can be characterized as a pandemic on March 11, 2020. Till March 2021 confirmed infections are 3.48Cr with 4.8L deaths across India. The current treatment aims to inhibit virus replication, mitigate the symptoms, increase survival and decrease mortality rate for that purpose mostly antiviral agents like chloroquine, hydroxychloroquine, remdesivir, tocilizumab are used which reported to have severe side effects like tachycardia, immune depression, trouble breathing stomach pain, continuing Seizures.An increasing mortality of the severely- affected patients, and a large-scale infection of medical staff indicating need of novel treatment for rendering anti-epidemic condition to the world so that a greater public health crisis can be avoided. Based on this objective our team has formulated safe, effective and stable herbal syrup by using traditional indigenous medicinal plants. The antitussive property was proved on a cough model induced by sulphur dioxide gas in mice. It has been observed that the herbal syrup has produced significant reduction in cough bouts at the dose level of 1, 2, 3 ml respectively after 1hr of drug administration. The highest dose of 3 ml was found to be more effective. The results showed that the formulated cough syrup exhibited significant antitussive activity in a dose dependent manner.

D010

Extraction and fractionation of bioactive lignan using solid-liquid extraction and evaluation of its toxicity

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Flaxseed is richest source of plant lignans. An important bioactive lignan present in flaxseed is secoisolariciresinol diglucoside (SDG) at a concentration of 1-3%. It plays important role in prevention and control of several metabolic disorders including diabetes, cardio-protection, hyper-cholesterolemic menopause, hypertriglyceridemia, reduction of atherogenic risks and regression of atherosclerotic plaques. The reported lignan extraction method from flaxseed are multi-step and yield of lignan is very less. Further current data available regarding the safety of linseed consumption is insufficient to evaluate its potential toxicity when the lignan component is extracted and administered in a concentrated form. Hence the objective of present study was to develop an efficient extraction method and evaluate its potential toxicity. Two step extraction methodology was developed using solid-liquid extractor (SLE-pilot plant unit). Initially hull fraction was separated from whole seed (richer fraction of lignan based on HPTLC analysis). Hull fraction was subjected for fat extraction using n-hexane using SLE. Defatted hull fraction was subjected to base hydrolysis and simultaneous extraction using ethanol was carried out using SLE. The filtrate was dried using vacuum oven. Further this crude extract was fractionated using alcohol-water and filtrate was dried. The lignan content in was 18.91% based on LC-MS analysis. Acute oral acute toxicity (OECD guideline 425) recorded no mortality after 48 hr. There was no gross clinical observations or toxic effect in rats were noted at the end of 14 days, indicating safety of lignan concentrate. Acknowledgement: Authors are thankful to DST-SERB (IRR/2018/000024) for financial support.

D011

Evaluation of Mechanism of Action of Alpha Lipoic Acid in CUMS Induced Depression Like Behaviours, Cognitive Deficit and Cardiovascular Dysfunction in Wistar Rats

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Depression is a neuropsychological disorder exhibiting behavioural distress due to reduced sensitivity of the serotonergic and dopaminergic systems. Alpha-lipoic acid (ALA) is a potent antioxidant exhibiting a myriad of beneficial effects such as cardioprotection, neuroprotection. Hence the present study was aimed to assess a possible antidepressant, cardioprotective and cognition enhancer effect of ALA in chronic unpredictable mild stress (CUMS) induced depression-like behaviours, cognitive deficit and cardiovascular dysfunction. Male Wistar rats were divided into 6 groups (n=8). Group I was vehicle control were kept under normal conditions, Group II was CUMS, Group III was standard subjected to CUMS treated with fluoxetine (FLX) (50 mg/kg p.o).Group IV, V and VI were subjected to CUMS with ALA treatment (50, 100, 200 mg/kg p.o for 42 days). The treatment for both FLX and ALA was from 1 to 42 days. The sucrose preference test (SPT), morris water maze (MWM), resident intruder test (RIT), marble-burying test (MBT), electrocardiogram (ECG) was performed on 0, 21 and 42 day. FST was conducted on 42 days of study. At the end of the study, animals were sacrificed, and the brain homogenate was studied for antioxidant and neurochemical parameters. Results led to the conclusion that ALA reverses CUMS induced behaviour deficits and improve cognitive functions by blocking 5-HT3 receptor. ALA up regulated DA, serotonin, antioxidant status and is a better and safer alternative to FLX.

D012

A Regulatory Perspective to Phytopharmaceutical Regulation in India

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PhytoPharmaceutical Products are gaining acceptance among people across the world due to rising awareness of lifestyle diseases and improper food habits. During the later part of the twentieth century, increasing interest in self-care resulted in enormous growth in the popularity of traditional healing modalities, including the use of Herbal remedies. Side effects caused by the use of modern medicines are driving consumers towards PhytoPharmaceutical and their supplements and this is driving the growth of PhytoPharmaceutical across the world. PhytoPharmaceutical, when sold commercially, should comply with country based regulations concerning safety, quality, and efficacy. At present regulations for PhytoPharmaceutical differ country-wise. Due to this, PhytoPharmaceutical companies cannot manufacture a standard product for the global market. Hence a concerted effort should be undertaken by global regulatory authorities and agencies like WHO to establish a uniform and harmonized regulation for herbal medicines. In this paper, we highlighted various challenges and constraints in manufacturing as well as the marketing of herbal medicinal products across the globe.

D013

Protective Effect of Phenolic Acid on Diabetic Nephropathy in Streptozotocin Induced Diabetic Rats.

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Diabetes and its complications are thought to be influenced by persistent hyperglycemia and oxidative stress. This study investigated the effects of phenolic acid (PA) on the renal biochemical and histopathological changes in neonatal diabetic rats which is well established and practiced model for type 2 diabeites mellitus (nSTZ). Streptozotocin (110 mg/kg i.p.) was given to neonates of Wistar rats in split form on 2nd and 3rd postnatal days. At adulthood, development of type 2 diabetes mellitus was confirmed by assessing fasting blood glucose levels, urine volume, food consumption, and water intake. The rats were then separated into 4 groups: non-diabetic rats, non-diabetic rats treated with PA (100 mg/kg), nSTZ diabetic rats, nSTZ rats treated with PA (25 mg/kg), nSTZ rats treated with PA (50 mg/kg), and nSTZ rats treated with Metformin (200 mg/kg). The treatment was started from 8th to 18th week postnatal. Biochemical markers in serum and urine were monitored throughout the study period to validate the development and progression of diabetic nephropathy. At the end, biochemical biomarkers were measured in urine and serum. Relative renal weight was calculated; antioxidant enzymes and Na+/K+ ATPase were estimated in renal homogenate; histopathlogical studies were carried out. Hyperglycemia, polydipsia, polyphagia, polyuria, and relative renal weight were all reduced after PA treatment. PA also decreased inflammatory indicators, biomarkers for renal damage, glycated hemoglonine, histpathological score, oxidative stress, and boosted Na+/K+ ATPase activity. These findings suggested that PA could play an important role in preventing kidney damage in nSTZ-diabetic rats.

D014

Developed and Evaluate Antituberculosis Novel Polyherbal Formulation; Microsphere

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Tuberculosis (TB) is a lethal epidemic, difficult to control disease, claiming thousands of lives every year. Global efforts are underway to eradicate TB using new drugs with new modes of action, higher activity and fewer side effects in combination with vaccines. The oral route is considered as the most promising route of drug delivery. This results in a significant fluctuation in drug levels. A well-defined controlled drug delivery system can overcome some of the problems of conventional therapy and it will enhance the therapeutic efficacy of a given drug. There are various approaches in delivering a therapeutic substance to the target site in sustained controlled release fashion using microspheres as carrier for drug. Administration of drugs in the form of microspheres usually improves the treatment by providing the localization of the active substances at the site of action & by prolonging the release of drugs. Hence, we have developed a novel polyherbal formulation; microsphere of herbal extracts of antitubercular plant. Microsphere were prepared using Emulsification-solvent evaporation method. Evaluation of Microsphere was done with the help of SEM, FTIR, Drug Release study and Mucoadhesive testing. *In-Vitro* Anti-tuberculosis activity of developed novel polyherbal formulation was screened against PATHOGENIC strain; *Mycobacterium tuberculosis H37Rv* using MGIT assay. On the basis of MGIT assay of selected plants extracts and prepared Microsphere, Extract and Microsphere relatively shows same percentage inhibition on pathogenic *Mycobacterium tuberculosis*. But here in Tuberculosis, Microsphere gives best effect due to its sustain release property and property of adhesion at the particular site of action. So it concludes that prepared novel polyherbal formulation; Microspheres shows potent antituberculosis activity.

D015

Nephroprotective activity of ethyl acetate fraction of Pithecellobium Dulce (Roxb.) Benth

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In genus Pithecellobium (Madras thorn), the phytochemical investigation of ethyl acetate fraction of methanol extract of bark of Pithecellobium Dulce (Roxb.) Benth family Leguminosae revealed the isolation and identification of catechol type of condensed tannins by using spectrophotometric and physicochemical analysis. Quantitative estimation of total tannins, flavonoids and phenolics contents were carried out for total methanolic extract. Biological activities of ethyl acetate fraction including nephroprotective activity was evaluated for the first time. The nephroprotective potential of Pd was evaluated in female rats with cisplatin induced kidney injury.

Quantitative estimation of total phenolics, flavonoids and tannins content in the total methanolic extract of Pd revealed high phenolics content (56.385 mg GAE /gm extract) in comparison with flavonoids content (6.287 mg QUE /gm extract) and tannins content (22.24/gm extract). The nephroprotective activity was studied using cisplatin as nephrotoxicant agent resulted in marked nephrotoxicity. While treatment of rats with ethyl acetate fraction of Pd significantly attenuated the nephrotoxicity through alteration of kidney biomarkers like serum creatinine, serum urea and albumin level improving the redox status of the tissue and so brought the serum biochemical parameters nearly toward the normal levels. Conclusion; The results suggested that Pithecellobium Dulce (Roxb.) Benth ethyl acetate fraction could be used in future therapy as nephroprotective drugs of natural source.

Key words: Pithecellobium Dulce, nephroprotective, serum creatinine, serum urea.

D016

Phytochemical and Antioxidant potential of leaves of Pongamia pinnata L. (Fabacea)

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Objective: The objective of this study was to carry out Phytochemical and Antioxidant potential of leaves of Pongamia pinnata L. (Fabacea).

Method: The present study provides pharmacognostic, phytochemical and quantitative details of the leaves of P. pinnata.

Results: The macroscopic study showed that the leaf was ovate or elliptic with smooth margins, short petiole, alternate imparipinnate, hairless, acuminate at apex, rounded to cuneate at base and slightly thickened. Microscopic study revealed collateral, closed vascular bundles, trichomes, paracytic stomata, xylem vessels and prismatic calcium oxalate crystals. Qualitative Phytochemical screening showed the presence of alkaloids, glycosides, carbohydrates, steroids and flavonoids and phenolic compounds in both the extracts. DPPH scavenging assay were performed to evaluate the antioxidant activity which was found maximum at 125 µg/ml concentration for both the extracts.

Conclusions: The results of this study can serve as valuable source of information for identification of this plant for future investigation and applications.

Key words: Pongamia pinnata L, DPPH, Antioxidant potential, 125 µg/ml

D018

Pharmacognostic and biological evaluation of leaf extracts of Citrus reticulata Blanco var. kinnow

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Context: Citrus species have a long history of use in traditional medicine for neurological conditions like insomnia, nervousness, mental exhaustion, headache and anxiety, but these claims have not been validated.

Objective: The objective of the present study was to establish pharmacognostic standards and evaluate leaf extracts of Citrus reticulata Blanco var. kinnow (Rutaceae) for anxiolytic activity.

Materials and methods: Leaves were subjected to macroscopic, microscopic and physio-chemical evaluation as per standard pharmacopoeial procedures. Leaf extracts of both the plants were prepared by successive solvent extraction using solvents in increasing order of polarity i.e. petroleum ether (60-80°C), chloroform, methanol and water. All the leaf extracts were subjected to preliminary phytochemical screening and TLC profiles were prepared. Swiss albino mice (20-30 g) were treated with different doses of leaf extracts viz. 100, 200 and 400 mg/kg orally. Anxiolytic activity was evaluated using elevated plus maze (EPM) with diazepam (2mg/kg p.o) as standard. The bioactive extract was standardised w.r.t total phenols and flavonoid content using Folin Ciocalteu's method and Aluminium Chloride method respectively.

Results: Pharmacognostic standards were generated for the leaves which may help in authentication of the plant for future use. Methanol extract at dose of 200 mg/kg exhibited significant anxiolytic activity comparable to diazepam. Findings of the study contribute to validate the ethnopharmacological claims about the plant and suggest that Kinnow mandarin may serve as a potential alternative in management of psychiatric illnesses after investigation of its toxicity profile.

Keywords: Citrus reticulata var. kinnow, anxiolytic, elevated plus maze, diazepam,

D019

Formulation and Characterization of Polyherbal Topical Gel Containing Jasminum grandiflorum, Cynodon dactylon And Andrographis paniculate

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Medicinal and aromatic plants and their combinations have been shown to have medicinal and cumulative effects in healthcare. In light of this, a polyherbal topical gel formulation based on plant extracts was developed to improve patient compliance, broaden the antibacterial spectrum, and improve cosmetic characteristics. The goal of this research was to develop and characterize a topical polyherbal gel for the delivery of active plant ingredients to treat skin disorders. For the formulation of topical gel, plant extracts of Jasminum grandiflorum (JG), Cynodon dactylon (CD), and Andrographis paniculata (AP) were used. Different formulation batches (F1 and F2) were created using carbapol-934 as a gelling agent at various concentrations. The pH, appearance, and homogeneity of the polyherbal gel formulation, as well as its viscosity, spreadability, and skin irritation tests, were all examined. All physicochemical parameters of the developed polyherbal cream were determined to be stable.

Keywords: - Jasminum grandiflorum, Cynodon dactylon, Andrographis paniculata, Polyherbal gel.

D020

In-Vitro Antioxidant assay of Ethanolic Extract of Garcinia indica Leaves.

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Oxidative stress is a phenomenon caused by an imbalance between the production and accumulation of Reactive Oxygen Species (ROS) in cells and tissues and the ability of a biological system to detoxify these free radicals. Oxidative stress plays a major role in pathophysiology of diseases such as Alzheimer's disease, Parkinson's disease, Cancer, and Diabetes Mellitus. According to the mechanism of oxidative stress in heart disease, increased ROS leads to decreased nitric oxide availability and vasoconstriction, causing arterial hypertension and leading to the number of cardiovascular diseases such as hypertension, atherosclerosis, and stroke. Garcinia indica (Kokum) is an Indian spice whose fruit rind is used in cooking, cosmetics, and has a variety of medicinal uses. Garcinia indica has been reported to have anti-cancer, anti-oxidant, and anti-obesity properties. Leaves of Garcinia indica consist of Hydroxy citric acid, Garcinol, and Iso garcinol which are potent antioxidants. The In-Vitro study was carried out to evaluate the antioxidant activity of Ethanolic extract of Garcinia indica leaves. The following parameters were used to determine the activity: DPPH Assay, Reducing Power Assay, and Hydrogen Peroxide Scavenging Activity. Method of Govindarajan et al. was used to test in-vitro DPPH radical scavenging activity (2003). According to the method of Oyaizu Reducing power Assay of the extract was determined. The method of Ruche, Cheng, and Klaunigk was also used to determine Hydrogen Peroxide Assay. When compared to the ascorbic acid standard, the results of the study showed that ethanolic extract of Garcinia indica leaves has significant free radical scavenging potential.

Keywords: Oxidative stress, Reactive Oxygen Species, Garcinia indica, Antioxidant, Hypertension, In-vitro, DPPH Assay, Reducing Power Assay, Hydrogen Peroxide Assay.

Abbreviations: ROS- Reactive Oxygen Species, DPPH-2,2-diphenyl-1-picrylhydrazyl.

D021

In vitro antidiabetic activity of Yucca filamentosa flower abstract

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Objective: In vitro analysis of the anti-diabetic effect of various extracts of the medicinal plant yucca filamentosa.

Methods: Extracts of the plants were prepared by cold percolation. They were then tested for inhibition of α-amylase activity and α-glucosidase activity.

Results: Inhibition of amylase and glucosidase enzymes involved in digestion of carbohydrates can significantly decrease the post prandial increase of blood glucose after a mixed carbohydrate diet and therefore can be an important strategy in management of blood glucose. The hydroethanol extract of yucca filamentosa flowers showed strong inhibition of α-amylase and α-glucosidase.

Conclusions: The findings indicate that all the extract of the plant possess antidiabetic properties too varying degrees. They can be used to develop natural drugs which may be used in lieu of commonly used strong allopathic drugs which possess a number of harmful side effects

D022

Therapeutic Potential of Methanolic Extract of Lantana camara Linn. Leaves in Diabetic Nephropathy

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Diabetic Nephropathy (DN) is a predominant collateral disorder associated with long term diabetes and here we aimed to explore the potential of Methanolic Extract of Lantana camara Linn. (MELC) leaves in diabetic nephropathy. Evaluation of the therapeutic potential of MELC in comparison with the standard drugs Metformin and Valsartan in a model of diabetic nephropathy in rats was carried out. Rats were randomized into 7 groups (n=8) and given 10% fructose solution in drinking water till 14 days (except vehicle group) along with standard rat chow. Except vehicle group, rats from other groups were administered with streptozotocin (STZ) 50.0 mg/kg i.p. on day 15.17th day OGTT was performed for confirmation of disease, followed by 4-week treatment with metformin 500 mg/kg, valsartan 15 mg/kg, Metformin + Valsartan, MELC 200 & 400 mg/kg respectively. The effect of MELC on blood glucose was measured using glucometer, biochemical and urine parameters was measured using commercially available kits. Histopathological study of kidneys was investigated using H & E stain. Increase in body weight, food intake, total protein levels and decrease in kidney weight, kidney weight/body weight ratio, fructose water consumption, blood glucose, OGTT, serum creatinine, blood urea nitrogen, urine albumin, urine output was observed. H & E reveals recovery in damage to kidneys when compared with the positive control group. The present study reveals that MELC may be a novel therapeutic agent protecting against STZ induced diabetic renal damage.

D023

Formononetin ameliorates cognitive impairment in Parkinson's disease

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Now a days in early stages 30%- 40% people affected mild cognitive impairment in Parkinson's disease. Depending on their severity risk of cognitive involvement in Parkinson's disease converted to dementia. The aim of the study is to understand the mechanism of mild cognitive impairment in Parkinson's disease. Currently there is no clinically effective drugs available for the treatment of cognitive impairment in patients with Parkinson's disease. Previous study suggested that phytoestrogens can be useful for the treatment of cognitive impairment in Parkinson's disease. In this study, intraperitoneal Formononetin at the dose of 5, 10 & 20 mg/kg administered in the mice with Parkinson disease for 28 days. During the study animals were evaluated for improvement in biochemical and behavioral parameters. Significant improvement was observed in behavior of animals with Parkinson after formononetin administration. Rota rod and catalepsy improved after treatment with formononetin. After 28 days, formononetin elevated the levels of antioxidant such as glutathione reductase and SOD in mice with Parkinson showing its protective effect in brain. Furthermore, formononetin also reduced the elevated levels of inflammatory biomarkers such TNF-alpha, IL-1beta and IL-6. Study findings suggest that formononetin shows improvement in cognitive impairment associated with Parkinson disease.

Keywords:

Formononetin, cognitive impairment, Parkinson's disease, TNF-α, catalepsy.

D024

Molecular docking of anti-depressant compounds of Indian herbs with hormone regulatory proteins: In silico control approach for postpartum depression

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The postpartum phase is a very difficult phase for a mother where she faces physical, mental and emotional changes. Postpartum depression is one of the major depressive disorders that occurs within the first month after childbirth and can last up to several months. It occurs in 10–15% of childbearing women, and is accompanied by headache, exhaustion, mood swings, irritability, anxiety, and anhedonia. In severe cases, the mother can harm herself or her baby or may attempt suicide at times. Based on the experimental and clinical evidence imbalance in estrogen, Progesterone, oxytocin, melatonin and triiodothyronine (T3) and thyroxine (T4), is a major cause of the development of postpartum depression. To keep this in mind present study was focused on the control of these secretory hormones through anti-depressant agents present in the Indian spices. For the current study three herbs Anethum graveolens (Dill), Trachyspermum ammi (Ajwain), Linum usitatissimum (Flax) were selected. Based on the previously published researches anti-depressant compounds present in these herbs were selected and antidepressant chemical drugs were docked with hormone regulatory proteins. Results revealed that anti-depressants present in the herbs has more binding efficiency with hormone regulatory proteins and have the ability to control their regulation. A higher negative docking score was observed in the case of herbs as compared to chemical drugs. Further, the current finding can be used to formulate a drug to control postpartum depression.

D025

Beneficial effect of methanolic extract of Pithecellobium dulce in the management of polycystic ovarian syndrome and obesity in rodent models

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Background: Some of the potential factors may contribute to the development of the polycystic ovarian syndrome (PCOS). Over the past few decades, several animal models have been developed in an attempt to understand the potential contribution of exposure to excess steroids on the development of this syndrome. In the present we examined the effects of methanolic extract of Pithecellobium dulce (MEPD) on PCOS like symptoms in female rats.

Methods: PCOS symptoms were induced in rats by Dihydroepiandrosterone (6mg/100g bd. wt. s.c) treatment for 4 weeks developed PCOS condition, assessed the hormonal levels (progesterone and estradiol), lipid levels (total cholesterol, triglycerides and HDL) and biochemical parameters like SGOT &SGPT. Letrozole (1 mg/kg bd.wt/p.o) treatment for 45 days in female rats developed PCOS condition, evaluated luteinizing, follicular stimulation hormone, lipid levels (total cholesterol, triglycerides and HDL) and biochemical parameters like SGOT & SGPT.

Result: Treatment with MEPD significantly reduced the LH, progesterone and estradiol level, an increase in FSH level, and reduction in ovary weight, reverted back the uterine weights significantly reduced both SGOT & SGPT decreased serum TC, TG while increase HDL levels were observed. Histological changes in cystic vacuoles, corpora lutea, and increased thickness of the thecal cells were observed in the PCOS group; remarkably reverse alteration can be seen after treatment with MEPD

Conculsion: Above results suggest that MEPD extract possess the inhibiting properties of PCOS symptoms by regulating the imbalanced hormonal, lipid and biochemical parameters as well as irregular follicules.

D026

Advancements in therapeutics to curb renin-angiotensin system mediated coronary heart disease progression

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Coronary heart disease (CHD), which is the atherosclerotic plaque formation in the coronary arteries, is a major cause of morbidity and mortality arising from cardiovascular diseases. In the past few decades, various risk factors have been identified that act synergistically with sedentary lifestyle to worsen CHD progression. Of the many risk factors involved, renin-angiotensin system has been investigated thoroughly for its direct as well as indirect effects that exacerbate endothelial dysfunction via inflammatory and oxidative stress pathways rendering higher vulnerability to the coronary arteries for plaque deposition. The intensifying situation from coronary diseases needs immediate attention with novel therapeutics to address the situation and prevent or decelerate disease progression. Although allopathic medications have been beneficial at end-stage disease control, they face many limitations such as severe side effects and medication induced gut dysbiosis which may result into long term harmful outcomes. Therefore, addressing this issue from an early stage of life with a holistic approach is required on an urgent basis. This includes finding novel therapeutics which have fewer to no side effects which also have a higher patient compliance and minimal medical interventions. Therefore, the aim of this review is to report new phytochemicals, natural foods (or food substances), and nutraceuticals in the management of CHD which are also inexpensive and affordable for the larger community.

D027

Adhatoda vasica, Nees: A Potential Herb to Fight Colon Cancer

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The incidence of colon cancer is most common in developed countries; Epidemiology study has shown that people on high fat diet are more prone to colon cancer. The complexity, side effects and costly treatment associated with the allopathic medicines have caused both the health care practitioners and the majority of world populations to turn towards alternative therapies. A variety of herbal medicines are having chemical constituents showing potent anticancer activity. Adhatoda vasica is a widely used medicinal plant in herbal medicine belonging to family Acanthaceae. Alkaloids, tannins, saponins, phenolics, and flavonoids are among the physiologically active phytochemicals found in its leaves. Pyrroquinazoline, alkaloids such as vasicine, vasicol, vasicinone, and peganine, as well as other minor elements, make up the majority of it. Leaves of vasaka from local Marathwada region of Aurangabad were extracted and analysed for the presence of these phytoconstituents with HPLC-MS. The plant has a spectrum of pharmacological characteristics, including anti-spasmodic, antibiotic, expectorant, and antipyretic properties, and is used to treat a variety of ailments such as influenza, tuberculosis, bronchitis, and gastric ulcers. Other activities have been documented, including radio modulation, hypoglycaemic effect, cardiovascular protection, antitubercular, antiviral, hepatoprotective, and antioxidant activity. Thus, this herb has been underwent in-vitro parameters to evaluate its potential on colon cancer cell lines and ex-vivo action on isolated chick colon for estimation of its effect on this tissue. Thus it was proved that the extract used shows presence of essential phytochemicals and possesses a potential against colon cancer.

D028

Assessment of Photoprotective Activity of Herbal Extracts and its Formulation

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Due to depletion of ozone layer and more penetration of the UV rays there is an increase in the cases of hyperpigmentation, premature ageing and skin cancer. Due to these harmful effects of UV radiations there is need to develop sunscreen formulations to heal and prevent sun burn, suntan, skin cancer and to block UV rays and increase the level of protection from the UV-rays. Flavonoids and phenolic compounds have good capacity to absorb UV rays in UV-A region and possess good antioxidant activity. Present study was conducted to develop herbal formulation for photoprotective activity. Liquorice and Pomegranate were selected because they contain phenolics and flavonoids in abundance. Total phenolic content was found higher in hydro-alcoholic extract of Pomegranate peel and total flavonoid content was found higher in methanolic extract of Liquorice. IC50 value of pomegranate peel methanolic extract was 64.5 µg/ml, and it showed good anti-oxidant potential. IC50 value of liquorice hydro-alcoholic extract was 53.7 µg/ml, so hydro-alcoholic extract showed good anti-oxidant potential. Methanolic extract of both herbal drugs showed good photo-protective activity as compared to combined Hydroalcoholic extract so methanolic extracts were selected for incorporation in the herbal formulation. It was observed that by increasing the concentration of extract from 2% to 8%, the SPF value increased. The herbal formulation showed good physical characteristics and optimum photoprotective activity.

D029

Role of camphor for prevention of Covid-19

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With every new variant of covid-19 there is a need to bring on some new drugs or ways to treat it as the older system to treat may or may not work for the new variant or upcoming ones. So it's always better to have prevention rather than searching for the cure so one of the very promising substance for this is camphor. The present review includes the compilation of role of camphor in COVID. Camphor is a volatile terpene that is obtained from the dried bark of the Camphora L plant cinnamomum. Family: Laureaceae. Camphor has many therapeutic importance such as: Camphor oil works as nasal decongestant and cough suppressant. Further camphor has been suggested for reduction of pain and inflammation of bronchus, pain of rheumatism, sprain and muscle pain. For prevention its various pharmacological actions can be used like antiviral, antibacterial, and antioxidant effects of camphor. There were various studies conducted to test these actions. It is also known to increase oxygen levels, and decrease respiratory distress. Various formulations are present in market which can help this cause; steam distilled hydrosole camphor water, camphor spirit, and pure camphor spray.

D030

Systematic Review on the Efficacy and Safety Calotropis gigantea

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Ancient sage monks had very vast knowledge of traditional Indian medicine. But this knowledge is obsolete in the present scenario due to lack of clinical evidences. Calotropis gigantea is one of them, which is found in description of many traditional Indian books such as the Shiva Purana. It is an easily available Indian medicinal herb that is applied in numerous conventional medicines to manage many chronic diseases. Traditionally, it is very good anthelmintic and carminative and capable to cure cough, leprosy, and asthma. To compile this review article, we carried out a rigorous exercise to search literature related to safety and efficacy of Calotropis gigantea on PsychInfo, PubMed, Science Direct, and PLOS databases. Currently traditional and botanical application of herbal bioactive, mainly which are derived from natural source, had acquired substantial interest because of their therapeutic values and minimal toxicity to human health. Herbal flora have been described to have therapeutic potential attributable to their bioactive such as terpenes, steroid, glycosides, tannins, saponins, flavonoids, alkaloids, and many more. This review examines efficacy and safety Calotropis gigantea along with their phytoconstituents.

Key-words: Calotropis gigantea, efficacy, safety, toxicity, phytoconstituents

Key Messages: A combination of traditional knowledge with current research findings open a new perspective to treat the patient with minimum toxicity. Calotropis gigantea is a folk Indian herb that can certainly be helpful in the management of many incurable diseases if clinical safety and efficacy are well established.

D031

Quercetin ameliorates diabetic nephropathy in a STZ-induced rat model by downregulating Nox4 expression

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Diabetic nephropathy (DN) is a kidney disorder marked by structural and hemodynamic changes that result in lower GFR, detectable glomerular lesion, urine albumin excretions, and microalbuminuria. In diabetic kidneys, the NADPH oxidase pathway, via upregulation of the NOX-4, eventually worsens the production of AGEs (advanced glycation end products), ROS, and the development of DN. The current study was designed to assess the Reno protective effect of quercetin via NOX-4 downregulation in a DN rat model. The healthy male Sprague Dawley (SD) rats were divided into three groups (n=6): normal, model control (Streptozotocin (STZ 60 mg/kg) i.p), and treatment (STZ 60 mg/kg i.p + Quercetin (QUE 80 mg/kg p.o.) for 70 days (10 weeks). Food and water intake were recorded on a daily basis, and body weight was calculated on a weekly basis. At the end of the experiment, hemodynamic, biochemical, and antioxidant parameters were all evaluated. Hematoxylin and eosin staining was used to examine kidney sections histologically. Real-time PCR was used to determine NOX-4 expression in the kidney. The results were interpreted using ANOVA, followed by a post-hoc Dunnett's test Quercetin (80mg/kg p.o.) significantly downregulated the expression of NOX-4 and oxidative stress as evidenced by low MDA levels, high GSH and SOD levels, improves renal function by mitigating changes in kidney function parameters, glucose level, lipid profile, and pathological changes when compared to model control rats, indicating that QUE could function as an effective therapeutic agent to attenuate the progression of renal injury by reducing ROS via downregulation of NOX-4.

Keywords: - AGE, Diabetic Nephropathy, NADPH oxidase, NOX-4, Quercetin, ROS

D032

Management of Urolithiasis by Novel Liquisolid Formulation of Saponin- A Future Potential Source of Therapeutics

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Saponins have presented a plethora of pharmacological activities and has been reported in number of plants. By tradition, Bryophyllum pinnatum is used in ethnomedicinal practices for various diseases. This study aims to investigate anti-urolithiatic potential of saponins rich extract and its novel Monoherbal formulation in experimental renal stone. Phytochemical analysis of extract was tested by UV, HPTLC, HPLC, and GC-HS. A novel formulation was developed using liquisolid technology. Pre- and post- formulation parameters were evaluated. Ethylene glycol (EG-0.75%, 28 days) induced urolithiasis rat model was used to study the effect of extract and Monoherbal formulation (20 mg/kg). Cystone (750 mg/kg) was used as standard drug. After treatment, Biochemical parameters in urine and serum along with Antioxidant parameters were evaluated. Histopathological examination of a kidney was also examined. Present investigational study revealed the presence of steroidal and triterpenoidal saponins (Total saponin content 10.4875 %). The presence of β-sitosterol, stigmasterol, and Lupeol was confirmed by HPTLC fingerprint profile. β-sitosterol 1.61% was quantified in extract. The residual solvent concentration was found to be 1483.22 ppm in extract. Liquisolid formulation comprising carrier/coat ratio (32:1) and 88 % liquid medication, showing superior dissolution properties. Treatment with extract and formulation exhibited significant protection against EG induced alterations by reducing stone promoters and increasing levels of stone inhibitors in a comparable manner with Cystone. Also, improved histopathological changes. This effect possibly through hindering biochemical parameters involved in calcium oxalate formation, along with its diuretic and antioxidant potential, hence supporting folkloric information to use in treatment of urolithiasis.

TRACK-E

PHARMACEUTICS AND PHARMACEUTICAL TECHNOLOGY

E001

Design and Evaluation of Lipid Based Quercetin Spherical Crystals

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Quercetin, a wonder flavonoid despite of numerous pharmacological actions has limited clinical applications due to solubility and permeability issues and additionally having shorter biological half-life. The objective of the current study was to design and optimize lipid-based spherical crystals of Quercetin, so as to improve its oral bioavailability. Anti-solvent precipitation method was employed to prepare Quercetin spherical agglomerates using ethanol and distilled water as good solvent and bad solvent respectively. As bridging liquid chloroform, dichloromethane, hexane and gelucire 43/01, compritol 888 as lipid carrier were screened. The effect of drug to lipid polymer ratio and stirring speed were optimized using a 3-level, 2-factor, factorial design. Numerical optimization function was employed to identify the optimum level of independent variables. Spectroscopic, micromeritic, surface morphology, size distribution, saturated solubility, *in-vitro* dissolution, *in-vivo* pharmacokinetic and stability studies were performed. The surface morphology studies indicated the agglomeration of Quercetin needle like fragments into spherical shape which further showed smooth surfaces due to deposition of lipid carrier. The spherical agglomerates of Quercetin showed 4-fold enhancement in aqueous solubility compared to pure drug and showed 92.13% drug release in 8 hours. The *in-vivo* pharmacokinetic study conducted in male Wistar rats indicated 3.44-fold increase in relative bioavailability of optimized formulation compare to the marketed preparation. The obtained lipid-based spherical crystals of Quercetin with enhanced bioavailability could be effectively used for its various potential pharmacological applications. The designed system can also be utilized for delivery of other phytochemicals having poor bioavailability due to limited solubility and permeability.

E002

Multifunctional Mesoporous Silica Nanoparticles for Drug and Gene Delivery

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Mesroporous silica nanoparticles (MSN) are solid structures which have a distinctive and well laid honey-comb like structure with numerous empty channels which can be greatly exploited to achieve loading and delivery of several drug molecules and biological materials like genes. Modulation of pore size, expansive surface area, narrow and uniform size distribution with favorable thermal and chemical properties make this a realty. MSNs are capable of effectively overcoming the shortfall of mammalian cells to engulf macromolecules by means of endocytosis. Co-condensation, grafting, and molecular imprinting with several organoalkoxysilanes imparts functionalization which allows it to circumvent few short comings such as inducing an immune response, allows targeted delivery of therapeutic agent. This is essentially beneficial as the MSN have an inherent negative charge and is hostile towards negatively charged DNA, nucleic acid. Thus metal-cation co-delivered vector, amination, and cationic functionalization are some of the techniques to circumvent the problem. It is advantageous to have provisions for "gate-keeping" agents which include the likes of supramolecular-assemblies, nanoparticles, and organic molecules. Their main aim is to govern encapsulation into the MSN and subsequent release "at-will", giving superb control on location and timing of release. This principle can be achieved by incorporation of photochemical gated, redox active, and pH responsive mechanisms. Notwithstanding extensive research, critical issues need to be addressed to aid further development in the area, namely; pharmacokinetic parameters, biocompatibility, in-vivo, in-vitro performance.

E003

Influence of Surfactant Chain Length on Drug Release Kinetics of Microemulsion Loaded with BCS Class II Drug

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The chain length of surfactant systems in microemulsion based drug delivery systems can play a vital role in governing the release of the drug. Therefore, this work involved studying the influence of chain lengths of surfactants representing different chain lengths (C8, C12 and C18) were chosen and their effect of stability and drug release was studied. The selection of excipients was done on the basis of the solubility of model drug (Rosuvastatin calcium) in various oils, surfactants, and co-surfactant. Capmul MCM and PEG 400 were selected as oil phase and co-surfactant for the formulation, while three surfactants chosen were labrasol, Tween 20 and Tween 80 representing C8, C12 and C18 chain length type surfactants. Pseudo ternary diagrams were constructed to find out the optimum combination of excipients. The formulations were characterized for drug release and physicochemical characteristics such as % transmittance, particle size, zeta potential, viscosity, and drug content. The results of the physicochemical study showed that the stability of the formulations with Tween 80 was significantly higher than labrasol and Tween 20. The in vitro release of Tween 80 containing microemulsion was optimized formulation displayed ~95% release in 120 minutes. The study stresses upon the effect of carbon chain length of surfactant on stability of on stability and solubilization capacity of microemulsion to improve the release characteristics.

E004

Formulation Development and Evaluation of Lipid Drug Conjugated Nanoparticles for the Enhanced Delivery of Hydrophilic Drug to Brain

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For many years, the lipidic nanoparticles such as liposomes, solid lipid nanoparticles, nanostructured lipid carriers etc. have been explored for the brain targeted drug delivery successfully. Though, all these formulations are most suitable for lipophilic drugs and not for hydrophilic drugs as it show insufficient drug loading, poor entrapment efficiency as well as drug leaching which affects the therapeutic effectiveness of the formulation. Therefore, in the present research work lipid drug conjugated nanoparticles(LDC-NPs) were formulated wherein the hydrophilic drug, Levetiracetam was conjugated to the fatty acid, which makes it adequately lipophilic for the effective delivery to the brain. The different lipids were screened using Chemdraw® software based on the defined criteria and the lipid-drug conjugate(LDC) was synthesized using stearic acid through covalent linkage like amide bond via NHS-DCC (N-Hydroxysuccinimide-N,N'-dicyclohexylcarbodiimide) coupling mechanism. The LDC was evaluated by FTIR, NMR, Mass spectroscopy, DSC and XRD. The LDC-NPs were prepared by solvent injection method using Polysorbate 80 as stabilizer and to improve brain targeting. The LDC-NPs were evaluated for particle size, size distribution, zeta potential and loading efficiency as well as by DSC, XRD and TEM. The lyophilized formulation exhibited the uniform, spherical particles with the size <200 nm suitable for brain targeting. It also indicated desired drug release profile in *in-vitro* diffusion study. Thus, it can be concluded that lipid drug conjugated nanoparticles can be the promising approach for the effective targeting and delivery of hydrophilic drug to the brain.

E005

Drug delivery enhancement techniques in liposomal nanomedicine for cancer treatment

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Cancer is characterised by the evolution of anomalous cells that multiply unruly and are liable to invade and damage normal body cells. The second leading cause and contributing to 1 in 6 deaths worldwide. Cancer treatment is yet a global medical challenge due to lack of drug specificity, high toxicity, hydrophobicity, short half-life. Application of nanosized drug delivery systems (DDS) i.e., nanoparticles, especially lipid-based liposomal approach, overcomes the drawback of conventional DDS. The three basic criteria of anticancer drug designing, are; increasing drug accumulation in tumours cells through enhanced permeability and retention (EPR) effect, reducing nonspecific uptake by the reticuloendothelial system (RES), nano delivery platform based on both the principles.

Liposomes are biocompatible compartmented (outer-polar hydrophilic head and inner-nonpolar hydrophobic tail) microcapsules (100-150 nm-sized) surrounded by multilayer structures (small or large uni and multilamellar) consisting of phospholipids or cholesterol (maintains fluidity). The complications of clinical development of liposomal formulation are; 1) Non-specific uptake by the RES, which can be rectified by active targeting, wherein the specific surface ligand of nanoparticles interacts with the particular tumour cell, 2) Rapid clearance which can be deciphered by passive targeting, 3) Opsonization which can be solved by PEGylation (reducing the clearance rate) e.g. Doxil (PEGylated liposome) comprising the active component of Doxorubicin (anthracyclines chemotherapy drug class). Administered via i.v. route, the formulation comprising of HSPC, cholesterol and DSPE-PEG2000 is used to treat ovarian and breast cancer, HIV-related Kaposi sarcoma, multiple myeloma. These techniques show great potential in enhancing Liposomal DDS in anticancer treatment.

E006

Enhancing Loading of Water-Soluble Metformin HCl in Lipidic Nanoparticles for Repurposing in Cancer

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Metformin an antidiabetic drug is repurposed for activity against pancreatic, colon and breast cancer. The aim of our study is development of Solid-Lipid Nanoparticles (SLN) of Metformin HCl (MH), for lymph mediated oral targeted delivery for breast cancer. Such lymph mediated targeting by absorption through Peyer's patch dictates the need for lipidic nanoparticles. However, metformin HCl a very water-soluble drug poses significant challenges in loading in hydrophobic SLN. The objective of the present study is development of SLN with desired size (300-400 nm) and good entrapment efficiency of MH (>70%), to ensure good drug loading. MH-SLN using glyceryl monostearate as lipid were prepared by nanoprecipitation, wherein GMS was in THF and MH with surfactant was in the aqueous phase. The three approaches investigated to enhance %EE were; Inclusion of an anionic agent Docusate sodium (AOT), Part replacement of aqueous phase with isopropyl alcohol, Addition of sodium chloride in the aqueous phase. MH SLN with GMS revealed very poor EE (<5%). Concentration dependent enhancement in %EE was observed with increasing concentration of AOT attributed to ionic interaction. Replacing part of the aqueous phase with IPA enabled enhancement of EE to ~50%. However, adding NaCl to the aqueous phase enhanced EE to >70% due to common ion effect. Furthermore, inclusion of sodium chloride enabled reduction in size to the desired range.MH-SLN with desired size and high entrapment efficiency, which could ensure high drug loading were successfully developed.

E007

Development, Optimization and Evaluation of Mesalamine Containing Mucoadhesive Pellets to Treat Inflammatory Bowel Disease via Rectal Drug Delivery System by using 3^2 Full Factorial Design

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Background: Inflammatory bowel diseases (IBD) are group of inflammatory conditions in which body's own immune system attacks parts of digestive system. High amount (400 mg, 800 mg) of Mesalamine (MSL) is required as normal dose for the effective treatment of IBD. In contrast to unit dosage forms like tablet and capsule, Multiparticulate systems have less chance for dose dumping. As Mesalamine is locally GI active drug, lower doses of the drug can be administered intrarectally to obtain good therapeutic effect as that attained with a higher dose of oral formulation. Current research was carried out to develop, optimize evaluate MSL mucoadhesive pellets which were further incorporated in Suppositories for intrarectal administration. Pellets were prepared by Extrusion Spheronizer. 32 factorial design was applied for optimization and batches were evaluated for different parameters.

Result: By using design expert 6.8, optimized batch was prepared and measured for Mucoadhesion strength, % swelling index, % cumulative drug release (% CDR) at 06 hours in 7.4 pH phosphate buffer and % cumulative drug release(%CDR) at 15 hours in 7.4 pH phosphate buffer. Result were found to be 0.143 Mucoadhesion strength, 50.50 % swelling index, 44.45% CDR at 06 hours and 75.26% CDR at 15 hours. The mucoadhesive sustained release pellets were incorporated in cocoa butter Base to formulate suppository.

Conclusion: Mucoadhesive Pellets were successfully developed by Extrusion Spheronizer method and incorporated in suppository for rectal route. In-vitro study revealed the release which is sufficient for once in a day administration. Mucoadhesion will ensure the local delivery of MSL. Further in-vivo comparative investigation is required to scientifically prove the efficiency of formulated preparation.

E008

An Overview on PLGA Based Microspheres for Long Acting Parenterals

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Although not very patient friendly, parenteral route of administration is unavoidable for the treatment of certain diseases. To improve patient compliance- by reducing and the dosing frequency, the parenteral controlled drug delivery can be developed. Many approaches are there under particular, from which microsphere is a most commonly used because of its site-specific targeting, improved release kinetics and improved bio distribution of both hydrophilic and lipophilic drugs. It is formed by matrix in which the API is dispersed. Different kinds of polymers can be used for this purpose. However, amongst them, PLGA Poly (lactic-co-glycolic acid) is only approved in marketed products. This is because of its biodegradability due to ester linkage and safety. As synthetic polymer, we can also modify its chemical and other properties by varied chain length. PLGA composed of glycolic acid and lactic acid, however both having very limited application for controlled release individually. Higher glycolic acid content leads to increased degradation time. As per the requirement microspheres are formed to release drug from several weeks to months and method used based upon whether the drug is hydrophilic (double emulsion) or lipophilic (single emulsion). The most remarkable point is, it can carry large molecules like proteins and peptides. Major applications are for the treatment of neurological disorders, cancer, ocular diseases, pulmonary diseases etc. Although it is challenging to develop long acting parenterals using PLGA.

E009

Thermodynamic Prediction of Excipients for Developing Lipidic Nanoformulation of Silymarin

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Silymarin is a BCS class II drug that is effective against hepatocellular carcinoma. Silymarin suppresses the growth of hepatocellular carcinoma cells by down-regulating the slit-2/Robo -1 pathway. This slit-2/Robo-1 pathway is involved in many processes like cell proliferation, angiogenesis, cell invasion, metastasis, etc. Silymarin exhibits poor solubility and bioavailability. Targeting silymarin to the tumor cells is necessary to increase the efficacy and reduce side effects. Silymarin is hydrophobic and can be easily entrapped in a lipidic nanocarrier system. In the present study, we report an innovative approach, namely, thermodynamic screening of excipients to develop novel lipidic nanoformulation of silymarin. Excipients included lipids, surfactants, and pharmaceutically acceptable solvents. The thermodynamic affinity parameters, namely Δδ total (total solubility parameter), ΔMixing Enthalpy, and ΔPolarity were determined using standard equations. The Δδ total, ΔMixing Enthalpy, ΔPolarity denotes the affinity of two solute components, with a low Δδ total, ΔMixing Enthalpy, and ΔPolarity reflecting greater affinity. Among various pharmaceutically acceptable vehicles evaluated, the prediction revealed high affinity of Silymarin and Polyglyceryl-6-distearate for Dimethylacetamide. This was validated by solubility experiments of silymarin and lipids which confirmed the prediction. The thermodynamic approach being in-silico could significantly reduce the number of experiments for screening of excipients. Our study proposed that thermodynamic affinity parameter evaluation is a promising approach for screening and selection of optimal excipients while developing nanoformulations.

E010

Micelles: An approach developed to improve bioavailability of Biopharmaceutical Classification System (BCS) class-II and IV drugs.

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Nearly half of the newly discovered drugs face problem of low dissolution rate in the gastro-intestinal fluids which ultimately restricts their bioavailability. Additionally, drug encounters several challenges like poor permeability, first pass metabolism, change in pH and gives side effects which are the significant issue in drug development today. Hence micelles as a nano formulation in the past couple of years have acquired enormous consideration attributable to their positive applications in expanding the bioavailability of poorly water-soluble drugs. Polymeric micelles as novel drug vehicles specifically are inclined as they provide numerous benefits like thermodynamic stability, enhanced biological barrier penetration, protection of drug in GI tract, hindrance like efflux pumps, minimizes cytotoxicity, prevents renal filtration and reticuloendothelial system (RES) uptake. The structures of polymeric micelles are generated as a result of self-assembled of amphiphilic block co-polymers at critical micelles concentration. US FDA approved and biodegradable polymers like Pluronics (PEO-PPO-PEO), Poly lactic-co-glycolic acid (PLGA), Poly caprolactone (PCL), or mixer of them are widely used. Further types, general properties, preparation, characterization techniques, challenges and their applications have been discussed. The polymeric micelles enable hydrophobic drug loading in micellar core via hydrogen bonding, metal complexation and electrostatic interactions and has shown wide area of applications in oral, transdermal and parenteral administration. Currently polymeric micelles can be employed as 'advanced drug carrier' as the co-polymers gives opportunity for controlled release by modifying or by external stimuli like pH-temperature change, can make targeted drug delivery by ligand base and Immunomicelles.

E011

Incorporation of Diclofenac Sodium Loaded Ethyl Cellulose Polymeric Microsponges into HPMC E4M Inserts for Ocular Administration

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Hydroxypropylmethylcellulose (HPMC E4M) polymeric ocular inserts, containing Diclofenac sodium (DS) loaded microsponges were prepared. Microsponges gave controlled release and with insert formulation residence time could be improved. With varied polymer: drug ratio DS loaded microsponges were prepared with Ethyl cellulose polymer by quasi solvent diffusion method. Microsponges evaluated for particle size, entrapment efficiency, drug content, in vitro drug release, Fourier Transform Infrared Spectroscopy (FTIR), Differential scanning calorimetry (DSC) and Scanning electron microscopy (SEM). The microsponges formulation that showed the requisite particle size (below 10 µm) and; with slower drug release rate was incorporated in HPMC E4M polymeric ocular insert. Selected formulation of microsponges and ocular insert were subjected to Stability studies. Microsponges formulation EC4 having particle size 8.69 µm, production yield 71.25%, drug content 83.33%, entrapment efficiency 67.86% and cumulative drug release 65.43% up to 6 h; was incorporated into ocular insert. All the inserts showed the acceptable folding endurance of >300, thus ensures flexibility of formulated inserts. The drug content (%) in all formulations varied between the ranges of 96.25±2.36% to 98.95±2.69% indicating uniform distribution of drug throughout the polymeric inserts. The surface pH of the inserts ranged between 7.23 to 7.49 hence have less potential to irritate the eye. EC4 followed Higuchi kinetic release model with non Fickian diffusion. Inserts showed a biphasic DS release pattern with initial mild release followed by a more gradual sustained release of 80.72% for 10 h. Outcome from studies indicated that microsponges loaded ocular insert have potential scope for ophthalmic delivery.

E012

Development of Self-Micellization Solid Dispersion for Solubility Enhancement of Herbal Actives

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The pharmaceutical industry's unending challenge is related to the poor solubility of maximum drugs. Various technologies have been developed to overcome this problem, but none appears to be a promising one. Solid Dispersion (SD) is one of the oldest and most widely used techniques can be defined as a distribution of active pharmaceutical ingredients as an amorphous molecular particle and/or in the microcrystalline state as a carrier matrix-like polymer. Therefore, selecting a suitable polymer is crucial for developing a productive solid dispersion system. Self Micellization Solid Dispersion (SMSD) employs amphiphilic block co-polymers as a carrier material, which is beneficial for enhancing not only solubility but also of the oral bioavailability of poorly water-soluble compounds because they form micellar structures when dispersed in water. The bioactive herbal molecule, a natural yellow isoquinoline alkaloid, has promising action on Alzheimer's disease. However, herbal actives have drawbacks such as poor bioavailability, P-glycoprotein subtracts due to re-excretion of drug in the blood, resulting in decreased oral absorption. Therefore, a suitable amphiphilic polymer and surfactant for developing of an SMSD system were selected based on solubility. PEG 6000 and Pluronic 407 were used from the initial screening for their potential improvement in solubility and stability. Further, the SMSD was prepared using a simple melt mixing technique and investigated for dissolution studies. The dissolution rate was faster when compared with free drugs. The result demonstrated the SMSD strategy as a promising way to overcome the biopharmaceutical limits of herbal actives with improved physicochemical properties.

E013

Site Specific Oral Modified Release System of Furosamide Solid Dispersion

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BCS class IV drugs need a tailor made drug delivery system in order to overcome poor solubility and permeability issues. Moreover molecules like Furosamide (FURO) with pH dependent solubility create additional challenge for formulation development as it further restricts absorption window. Current study is aimed at formulating a modified release drug delivery platform of model drug FURO to overcome these challenges. In order to overcome solubility problem of drug, solid dispersion (hot melt) technique was utilized. While pH dependent solubility was addressed by adding a pH modulator forming a third generation solid dispersion. Composition of solid dispersion with highest solubility was further developed as a plain mucoadhesive tablets to improve contact area, to keep tablet surface in close proximity of GI tract surface for maximize absorption probability and to keep it retained into stomach which is the major absorption site. Drug release from this site specific modified release system was further optimized by applying central composite design. Solubility studies of prepared solid dispersions clearly demonstrated that basic pH modulators can increase solubility of drug very significantly by increasing micro environmental pH. Solid dispersion prepared by Drug: PVP K-30 ratio of 1:0.5 increased FURO solubility in 0.1N HCl up to 0.3 mg/ml. While in presence of basic pH modulator, above solid dispersion showed further 10 times increase in solubility. Optimization formulation derived from the experimental design showed an extended release profile up to 24 hr. with sufficient adhesive strength to retain the dosage form in stomach. All in vitro experimental results were found at par with the objective of the study.

E014

An Overview of Evaluation of Polymeric Nanoparticles for Follicuar Drug Delivery

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Follicular route proved to be advantageous in topical delivery for penetration of polymeric nanoparticles targeting diseases of follicular region. Hair follicle serves as a potential reservoir for nanoparticle which results into controlled release of drug to the follicular region. Nanoparticle of size less than 500nm retain in the infundibulum of hair follicle and sebaceous gland serves as reservoir for lipophilic moieties. Particle size measurement is an important parameter for characterization of nanoparticles. Particle size can be determined from scanning electron microscopy, transmission electron microscopy and its modification transmission mode of scanning electron microscopy gives more precise and accurate results, having ability to identify less than 10nm size particles. Photon correlation spectroscopy (PCS) is based on Brownian motion of the particles and measures hydrodynamic diameter of the particle. Moreover, if any aggregates are present in the solution can also be determined by PCS. Encapsulation efficiency is used to determine actual drug encapsulated or attached to nanoparticle and can be modified by change in polymer concentration and method of synthesis. In vitro methods for determination of nanoparticles retained in hair follicle are discussed in detail. Various approaches have been developed for preparation of the skin to study in vitro permeation to nanoparticles through hair follicle which includes comparative study with follicle free or blocked follicle skin. Franz diffusion cell followed by centrifugation or differential stripping method and punch biopsy method which include application of pilosebaceous unit of skin are the methods for invitro permeation study.

E015

Supramolecular Complex of Curcumin as a Treatment Modality for Urinary Tract Infections

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Urinary tract infections (UTIs) are one of the most common infections worldwide and around 95% of the uncomplicated UTI cases in women are due to Gram-negative bacilli *E. coli*. The growth of resistance to antibiotics has complicated the treatment of UTIs. Plant derived compounds used to treat various diseases, constitute an alternative to antibiotic resistance. Curcumin (CUR), a natural polyphenol compound obtained from *Curcuma longa* has gained diverse medicinal properties. But its clinical use is limited due to its poor solubility and bioavailability. CUR-SC (supramolecular) inclusion complex was prepared using co-precipitation method. The inclusion ratio and binding constant showed the successful formation of inclusion complex with 1:1 ratio. The *in silico* docking studies supported *in-vitro* and wet lab experiments, revealed that methoxy group and OH group of CUR interacting with cyclodextrin (CD) formed a stable complex. Fourier transform-infrared spectroscopy (FTIR), differential scanning calorimetry (DSC), X-ray diffraction (XRD), Proton nuclear magnetic resonance (^{1}H NMR) and two dimensional Nuclear Overhauser Enhancement Spectroscopy (2D NOESY) of inclusion complex confirmed the formation of CUR-SC complex. *In vitro* release study in simulated vaginal fluid (SVF) showed increased drug release from CUR-SC complex (approx. 49.4%) than pure CUR (approx. 13.4%) at the end of 48h. The prepared complex investigated with disc diffusion method showed anti-microbial activity with zone of inhibition (ZOI)13mm against *E. coli* and 11.5mm against *S. aureus* whereas CUR alone did not showed any ZOI. The prepared CUR-SBE-β-CD inclusion complex improved solubility and demonstrates a promising alternative for treatment of UTIs.

E016

Novel floating agent *Saccharomyces boulardii* probiotic formulation based floating drug delivery system

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Saccharomyces boulardii, is the unique yeast probiotic that has been effectively used as a good biotherapeutic agent. In aerobic respiration it produces CO_2 and H_2O and in anaerobic alcoholic fermentation, it generates ethanol and CO_2. In present investigation this property of yeast is used to generate carbon dioxide in floating tablet. Valsartan is a highly selective and orally active antihypertensive drug belonging to the family of angiotensin II type 1 receptor antagonists. It is a weak acidic drug has absorption window in the acidic environment of stomach. It is rapidly absorbed orally but only have 23% bioavailability, hence it is selected as model drug for the development of a floating drug delivery system. Floating tablet prepared by direct compression using *Saccharomyces boulardii* probiotics formulations as floating agent due to its ability to generate carbon dioxide gas and its safety. Different grades of hydrophilic polymers are used as matrix formers. Calcium hydroxide is used as pH modifier which enhance solubility of valsartan and also maintain integrity of matrix. Sodium Lauryl Sulfate SLS as solubilizing agent.

Study indicate that *Saccharomyces boulardii* is a promising floating agent in 0.1N HCl solution (pH 1.2) and the formulation containing this novel floating agent is suitable for gastro retention and it increases bioavailability of valsartan. it's very easy to prepare tablet using this novel floating agent in combination with different hydrophilic polymers.

E017

Applications of Biorelevant media for Lipid formulation: Case study of Lercanidipine Hydrochloride

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Dissolution rate is considered as rate limiting step for poorly soluble drugs. It is majorly affected by change in pH, solubilization, ionic strength, presence of food components and surfactants. Using compendial dissolution media to predict the IVIVC behavior of poorly soluble drugs in lipid formulation is inadequate. Decade ago, biorelevant medias were developed which exhibited reliable IVIVC by considering most physiological conditions and simulating body fluids. Here, Lercanidipine Hydrochloride lipid-formulations using short chain, medium chain and long chain triglycerides were prepared and evaluated in biorelevant media. Different biorelevant medias were prepared for simulating distinctive body fluids taking fed and fasted state in consideration. The objective of this study is to evaluate lipid-based formulation in biorelevant media for understanding the interaction between GI environment and different length triglycerides. Here, use of biorelevant media ease the determination of robust formulation by exhibiting unique attributes of phospholipid components, food content, bile salt which influence the in-vivo release of lipid systems. It also represent the dynamic environment of GI tract and its effect on the percentage release of LCH establishing reliable IVIVC.

E018

Probiotic Mouth Freshener- A promising approach for perennial oral hygiene

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Probiotics have been proven beneficial for treating various health disorders to the host if consumed in adequate amounts and proven beneficial for treating various oral disorders and maintaining overall health hygiene. Thus, Mucoadhesive approach will be helpful in colonizing good bacteria, oral pH modulation, inhibition of bone resorption, reduction in inflammatory makers along with inhibition of bone resorption, reduce chances of oral cancer. As across the globe 45 % suffers from the superficial infection and 19% suffers from moderate infection and 5% suffers from serve infection due to various factors thus leading to oral disorders like dental caries, periodontitis etc. From the literature review market survey and along with various clinical studies carried out it can be said that mouth freshener is widely been used across the world and most common in India so why not to have probiotic mouth freshener. Fennel, Cinnamon, Clove, Cardamom, Stevia, menthol, Peppermint oil, Pan, Kesar flavour, Gelatine (30%) were utilized as mouth freshener. Mucoadhesive probiotic powder was prepared using Xanthan gum and HPMC. *Bacillus coagulans* and *subtilis* were selected as probiotic strains which have proven impact over oral disorders. The lyophilisation cycle and mucoadhesive to probiotic carrier ratio was optimized for product performance. SEM analysis of bacterial strain and mucoadhesive powder, ex vivo mucoadhesive studies, enumeration and preformulation studies at various levels were performed. Better mucoadhesive strength was achieved along with effective colonization in the oral cavity and maintaining oral health hygiene.

E019

Development and characterization of capsule dosage form of Gamma Oryzanol to improve Bioavailability

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The primary aim of the work was to prepare a formulation of gamma oryzanol for maintaining the blood cholesterol level and antioxidant properties. Gamma Oryzanol has been used as a nutraceutical owing to its lipid-lowering property. Due to poor aqueous solubility, there are hurdles in achieving the higher bioavailability of gamma oryzanol. The main focus of the formulation is to enhance the aqueous solubility and achieve higher bioavailability. The preliminary study was carried out to check the solubility of gamma oryzanol in the various oils, surfactants and co-surfactants. Based on higher drug solubility, oil, surfactant and co-surfactant were selected. The role of various excipients such as Microcrystalline cellulose (MCC), Croscarmellose sodium (CCS) and PVP was determined. Preliminary batches were formulated by changing the concentration of ethyl oleate, Tween 80, propylene glycol, CCS and MCC. The optimisation was done with the help of design expert software by applying the Simplex Centroid design. All suggested batches were prepared and evaluated to obtain the optimised batch. The optimised batch was selected and prepared based on the Overlay Plot. The suggested batch showed required drug release profile, flow properties, globule size and zeta potential. The prepared formulation possesses the self-micro emulsifying property and has better drug release as compared to the marketed formulation.

E020

Development and Exploration on Flowability of Solid Self-Nanoemulsifying Drug Delivery System of Morin Hydrate

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The presented work endeavours the design of a solid self nano-emulsifying drug delivery system (S-SNEDDS) of Morin hydrate (MH) to elicit its solubility and bioavailability also, the investigation of powder flow behaviours employing powder flow tester (PFT). MH is a promising flavonoid and possesses a diverse range of biological activities; unfortunately, it finds limited clinical application due to its low water solubility. Herein, we developed SNEDDS employing Labrafil M 1994 CS, Cremophor RH 40, and Transcutol HP and carried out solidification by physical adsorption using Neusilin US2 and Aerosil 200. The S-SNEDDS of MH was thoroughly investigated for flow function test, wall friction angle, and internal friction angle employing PFT. The S-SNEDDS prepared using Neusilin US2 exhibits excellent flow properties and their solid-state characterization by DSC, PXRD, and SEM exhibited transition of crystalline to the amorphous state of MH resulting in improvement of dissolution and bioavailability. The stability studies also showed excellent physical and chemical stability with an estimated shelf life of 27.5 months. In brief, the solidification of S-SNEDDS and investigation of flow behaviors by PFT could be found attentions in the pharmaceutical and food industry for commercial purposes.

E021

Inhalation delivery of repurposed drugs through nano-carriers for lung cancer

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Cancer is a serious health concern and the second foremost cause of mortality worldwide. In 2020, international agency for research on cancer estimated around 3 million new cancer cases and almost 10.0 million cancer deaths globally. Among these cancers, lung cancer is observed to be the foremost cause of mortality of which non-small cell lung cancer consists large number of cancer cases (85%) while small-cell lung cancer comprises (10–15%) cancer cases. Drug repurposing (DR), is an approach to identify new therapeutic indications of an already approved drug here for lung cancer. DR is an alternative approach to classical pharmacology which offers various benefits such as proven pharmacology, track-record of safety, less investment and shorter time frame. Drugs like celecoxib (cell proliferation), atorvastatin (apoptotic), bedaquiline, itraconazole (cytotoxic), metformin, etc are some repurposed non-oncology drugs (RNOD) used for lung cancer treatment. RNOD when loaded on Nanocarriers and administered through inhalation route by nebulizer, drug powder inhaler it gives anticancer activity in lungs on cell lines like A549, H460, H1299. Mostly lipophilic Nanocarriers (liposomes, steresomes, nanomicelles) are used because it shows maximum retention of formulation in lungs. The ideal aerodynamic diameter of the particles to be deposited deep into the lungs is in the range of 0.5-5 μm. The purpose of using RNOD with nanocarrirers over anti-cancer drugs is to overcome the side effects caused by anticancer drugs. The nanotechnology-based approach is suitable to modify the physicochemical characteristics of repurposed drugs, and to overcome the anatomical challenges of the respiratory system.

E022

Herbosomes: Scientific Technique and Future Perspective in Phyto-medicines –An overview

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Herbosome is a Modern hypothesis in herbal drug delivery technology that is universally used to prevent and treat disease and disorders by the formation of a combination with phospholipids for better action such as absorption, penetration, Bio-availability. With this novel drug delivery technology, more drugs are released or available at the site of action (heart, liver, kidney, etc). Herbosomes act as a bridge between novel drug delivery and traditional drug delivery system. Preparation of Herbosome composition with true or substitute of synthetic phospholipids with pharmacological active phytoconstituents extracted from the plant in a suitable solvent system in a ratio of 1:1 or 1:2 by using one of the methods out of these such as rotary evaporation, anti-solvent precipitation, Solvent evaporation, Ether-injection, Anti-solvent precipitation method, and its evaluation includes spectroscopic and microscopic examination, drug release profile, zeta potential, size, etc. This article includes advantages, disadvantages, application, methods of preparation, and evaluations. Herbosome technology has been effectively used by Pharmaceutical Industry due to its effectiveness and safety such as silybinphytosome, ginkgophytosome, ginsengphytosome, curcuminphytosome, centellaphytosome, grapeseedphytosome, and many more used commercial available. This paper includes an update about technology, preparation, properties, applications, and marketed formulation of herbosomes that would be helpful for research-based drug delivery systems.

E023

Design and optimization using QbD approach for prolonged release formulation using hot melt granulation technique for anti-depressant

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Prolonged release drug delivery system is widely explored for the treatment of depression because patients are not ready to accept that they are suffering from the depression. Hot melt granulation is the new technique for the manufacturing of the wax-based extended-release matrix tablets. Tablets were prepared using carnauba wax as extra fine powder and polyvinyl pyrollidone (PVP K-30) as release retardant polymers. A 2^3 full factorial design was applied to systemically optimize the drug release profile. Amounts of Carnauba wax (X_1), Polyvinyl pyrrolidone (X_2) and Magnesium stearate (X_3) were selected as independent variables and release after 0.5 h (Y_1), 1.5 h (Y_2), 4 h (Y_3) and 8 h (Y_4) were selected as dependent variables. Furthermore, because the wax-based matrix tablet exhibits high mechanical strength, the drug release rate was controlled effectively. Therefore, it can be concluded that the hot melt granulation technique is a suitable platform for developing direct compressible high-dose prolonged-release solid dosage forms.

E024

Solubility enhancement of BCS Class IV compound having High Melting Point using Solvent-Aided Hot Melt Extrusion.

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Bioavailability for a poorly soluble active pharmaceutical ingredient (API) is limited due to its solubility and permeability related concerns. Amorphous solid dispersions (ASDs) of API in Polymer are highly effective method of increasing solubility and thereby improving bioavailability. Large scale manufacturing of Polymeric ASDs can be achieved by spray-drying and hot melt extrusion (HME). HME is more suitable and cost effective technique where, API melting is essential to facilitate mation of a fully homogeneous amorphous system by Molecular dispersion in polymer matrix. But for compounds with high melting point (MP), processing below the MP renders the system more susceptible to residual crystalline content; hence, conventional HME is not suitable for such APIs. In this work, Alectinib was used as a model API with possessing properties of high melting temperature (Approx. 260°C). A modified solvent aided HME has been developed where, ASD prepared using HME with incorporation of solvent in formulation during extrusion and removal post-processing. Dimethyl sulfoxide (DMSO) solvent was mixed with API : Polymer mixture using high sheer granulator and extruded using a twin-screw extruder at temperatures below the MP of API. The incorporation of solvent allowed a significant reduction in processing temperatures due to its increased mobility, while also driving the conversion of the API to its amorphous form and solvent was removed through a secondary drying using a Fluidized bed dryer. Potential for processing of high melting and thermally labile APIs via HME has been demonstrated.

E025

Development and Optimization of orally disintegrating tablet containing multi-unit pellet system.

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MUPS are multi-particulate pellet formulations that, easily administered as tablets, disintegrate into their subunits directly after swallowing, across the stomach and the small intestine. The rationale for the study was to develop MUPS of delayed release with desired physical properties and unaltered drug release profile from pellets even after compression into a tablet. Formulation of multi-unit pellet system is done by drug layering using Wurster process where different layers of coating is applied on pellets such as drug layering, seal coating, delayed release and film coating followed by compression into tablets using appropriate excipients. The batches were prepared to optimize ratios of binder and disintegrant. The full factorial 23 design was used with various factors like property of pellets to be compressed, coating level, the composition of tableting excipient and ratio of drug-loaded pellets to tableting excipients were identified and optimized. However, acid resistance should be less than 10% in gastric whereas more than 80% in colon region. The desired dissolution studies were obtained in F8 batch and the required drug release was achieved. Henceforth, the compressed tablets were characterized for acid resistance, disintegration time and for dissolution studies. The developed MUPs tablet can be consider as a patient friendly approach to deliver the proton pump inhibitors.

E026

Development of Cationic Liposomes using Microfluidization approach.

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Cationic liposome are structures that are made by positively charged lipids and are increasingly being researched for use in gene therapy due to their favourable interactions with negatively charged DNA and cell membranes. Liposome can deliver tumour antigens to while cells remain active. In aim to develop techniques that decrease the number of steps, and time-consuming processes involved in the current production protocols. The use of microfluidics systems in liposome production might overcome these major challenges. The mechanism involves forcing the coarse particle through microchannels to the particular area by pneumatically powered pump by pressurizing compressed air and the different passes lead to different sizes. The major advantages of the techniques include higher stability with a smaller particle size, higher scale production of nanodelivery systems with higher reproducibility.

E027

Development, Optimization and Evaluation of Buccal Film for Management of Pulmonary Hypertension Using BCS Class I Drug

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The primary aim of the work was to design an immediate release mucoadhesive buccal film for the management of hypertension. Sildenafil citrate is provided very prominent result in pulmonary hypertension. The bioavailability of sildenafil citrate is approximately 43 % when administered orally in the form of tablet with a dose of 20 mg. which is much lesser than the other hypertensive agents. So, keeping in mind the pharmacokinetics profile of the sildenafil citrate, an alternate site of administration had to be designed. The main focus of the formulation is to increase the bioavailability of the molecule. The Preformulation study was carried out to check the purity and compatibility of the sildenafil with both the polymers (Proloc and Methocel E5 LV). The FT-IR and DSC graph proved that drug and polymers are good compatible with each other. The films were prepared using solvent casting technique. The preliminary trials batches were formulated by changing the concentration of polymers and plasticizers with a different ratio. The optimisation was done with the help of the design expert software by applying 3^2 full-factorial design. All the batches were evaluated for the various parameters like; thickness, disintegration time, tensile strength, elongation, swelling index, content uniformity, dissolution test, SEM, DSC, in-vitro drug release profile, in-vitro permeation profile and satisfactory results were obtained for all parameters. The research proved that the immediate release buccal film of sildenafil citrate possesses good bioavailability as compared to the marketed oral tablet formulation and has good market potential.

E028

Development and Optimization of Paclitaxel Loaded PLGA Nanoparticle in Treatment of Cancer.

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Paclitaxel is one of the most effective chemotherapeutic drugs and is active against a broad range of cancers, such as metastatic ovarian, breast carcinoma, small cell lung cancer. The encapsulation of paclitaxel can protect the body from toxic side effects of the drug thereby lowering its toxicity, increasing its circulation half-life, exhibiting improved pharmacokinetic profiles, and demonstrating better patient compliance. Present study focused on development of paclitaxel loaded PLGA (NPs) by O/W emulsion solvent evaporation method followed by spray drying. NPs were characterized by Particle Size, Drug Entrapment Efficiency, Surface Morphology, *In Vitro* Drug Release, Zeta Potential. Drug excipient compatibility was studied by FTIR. Particle size of nanoparticle gets affected due to high speed homogenization implemented during the formulation process. The drug entrapment efficiency of different batches of nanoparticles was found in the range of 23.05 % to 69.85 %. SEM photographs revealed spherical and smooth surface of nanoparticles. In vitro drug release was found to be in sustained release pattern with attributed to the drug adsorbed on the nanoparticles. Most formulations were following korsmeyer peppas kinetic model. Effect of Temperature and Humidity on stability of optimized formulation was studied for the period of one month with no significant changes in entrapment efficiency and drug release pattern.

E029

Pulmonary Targeting Lipid Nanoparticle Drug Delivery System for Pneumonia

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The lipid colloidal particle is extensively under investigation as a drug carrier for the application in pneumonia via nasal administration. The lipid carrier system such as liposomes, solid lipid nanoparticles, and nanostructured lipid carriers has been under investigation for a long time for various pulmonary infections. The pulmonary administration of nanoparticles serves as an alternate route to target Active pharmaceutical ingredients (API) as a local delivery against pulmonary disease. The pulmonary route serves as an advantage as it circumvents first-pass metabolism and possesses surplus vascularization which has huge potential for drug targeting through nebulization. The protein buffer system which pre-exists in the alveolar surface reduces the surface tension and enhances the effect of formulation. The challenges in colloidal delivery of lipid nanoparticles are usually in controlling the physicochemical characteristic while nebulization of colloidal particles. The review covers each lipid particle formulation and characterization. In addition, a summary of marketed drugs is also being discussed.

E030

Nose to brain delivery risperidone nanosuspension*: In-vitro* and *ex-vivo* Characterization

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Risperidone (RIS) is an atypical antipsychotic agent with low aqueous solubility, low bioavailability due to extensive first-pass metabolism and high protein binding. It is the drug of choice in the treatment of schizophrenia and showed minimal extrapyramidal side effects and favourable clinical effects. But due to physiological hurdle of the BBB (blood brain barrier), effective brain targeting of risperidone is the major challenge in development of optimised formulation. The present work was designed to explore the efficacy of risperidone by intranasal administration of optimised nanosuspension containing poloxamer and surfactants. Optimised formulations were characterized by particle size analysis, saturation solubility, drug diffusion study using goat nasal mucosa, surface characteristics by SEM, nasal ciliotoxicity. Formulation AP5 showed 26 folds increase of aqueous solubility of risperidone, nanometric size range (153.3 nm) with high drug loading. Histopathology study on goat nasal mucosa showed no adverse effects of formulation on nasal tissues. Thus it can be concluded that optimized nanosuspension of risperidone by intranasal administration would be promising approach for brain targeting.

E031

An overview of nanoparticle drug delivery system for anti – Hepatitis B virus therapy.

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Hepatitis B is an infectious disease caused by the Hepatitis B virus (HBV), which belongs to the family of hepatophilic DNA viruses and is prevalent worldwide. HBV is spread by contact with blood or body fluids of an infected person. There is no specific treatment for acute hepatitis B. Oral treatments like tenofovir and entecavir are recommended by WHO as they are the most potent drugs to suppress hepatitis B virus, they are simple to take and have limited side effects. In recent years several novel anti hepatitis B drugs have been developed on the basis of life cycle of virus and host immune mechanisms. Anti-HBV nucleoside drugs, especially Lamivudine and Adefovir Dipivoxil, are associated with long treatment cycles, a high rebound rate after drug withdrawal, and a high rate of drug resistance. Several nanoparticle delivery systems for traditional nucleoside analogues (NAs) have been developed which can reduce dosage and toxicity and improve the therapeutic index. Polymeric nanoparticles, solid lipid nanoparticles, multiple lipid nanoparticles, albumin nanoparticles were loaded with Lamivudine, Adefovir Dipivoxil, and Entecavir. Ultrasonication, hot homogenisation, solvent diffusion, ionotropic gelation, and dialysis are the various methods used for preparation of nanoparticles. These drug delivery systems have exhibited increase in the accumulation of drug in the liver, reduced cytotoxicity, improved cellular uptake, and reduction in dosing frequency.

E032

Preparation and characterization of Paliperidone nanosuspension.

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Paliperidone is a second-generation antipsychotic drug and it is indicated for the management of schizophrenia in the short and long term. Paliperidone belongs to BCS class II owing to low solubility which results in reducing the bioavailability. Thus, the objective was to formulate nanosuspension of Paliperidone to improve the bioavailability. Paliperidone nanosuspension was prepared by using nanoprecipitation technique and the concentration of the excipients were optimized using Quality by Design (QbD) approach using factorial design. Poloxamer 407 as a surfactant and Polycaprolactone as a polymer were found to be efficient for preparation for Paliperidone nanosuspension. Optimized nanosuspension was lyophilized using trehalose as a cryoprotectant and it was evaluated for particle size, zeta potential, % entrapment efficiency, drug content, *in vitro* dissolution study, stability study and characterized by Scanning electron microscopy, Powder X-ray diffraction, Differential scanning calorimetry and Fourier transform infrared spectroscopy. The optimized nanosuspension showed particle size of 167 nm and zeta potential of -27.7 mV. The % entrapment efficiency was found to be 70 % and the drug release was found to be 78.5 % at 24 hrs and followed Korsemeyer-Peppas release kinetic model. The optimized nanosuspension was found to be stable up to 3 months. Thus, the Paliperidone nanosuspension can be a convenient alternative to the commercially available dosage forms of Paliperidone.

E033

Solid Lipid Nanoparticles: Newer Approach for The Treatment of Glaucoma

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Glaucoma is a neurodegenerative disease indicated by the gradual loss of retinal ganglion cells and their axons. Variety of drugs currently being used for the treatment of glaucoma comprises Prostaglandin analogues, β-Blockers, Carbonic anhydrase inhibitors, Adrenergic agonists, and Parasympathomimetics. The conventional dosage form for treating glaucoma currently available in the market includes solution, suspension, eye drops, gel, ointment, cream, etc. The major bottleneck of the conventional formulations includes limited bioavailability of the drug at the site of action, non-specific tissue distribution, and non-predictable drug release kinetics resulting in highly variable therapeutic effects. Moreover, few of the formulations may exhibit ocular irritation, drug leakage, burst release, particle aggregation, etc. The solution to above-mentioned issues lies in the nano-formulations, whereby several research groups have explored various approaches including liposomes, nano-particles, NLCs, SLNs, micelles, dendrimers, etc.; however, the promising results were obtain using Solid lipid nanoparticles (SLN), which has proved edge over above for ocular region. SLNs are colloidal carrier systems composed of a high melting point, biodegradable lipid as a solid core coated by aqueous surfactant and the drugs, with more predictable drug release and improved local bioavailability. Methods for preparing SLN include High-pressure homogenization, Ultra-sonication, high-speed homogenization, Solvent evaporation Method, Solvent emulsification-diffusion method, etc. Evaluation of ocular SLN involves Human Cornea Construct (HCC) and Drug Permeation, Ex-vivo transcornea penetration study, Corneal hydration level, IOP measurement / Intraocular pressure-lowering effect, Ocular tolerability assessment, and Ocular histology study. This review will comprise of approaches and challenges in development and evaluation of Ocular SLNs.

E034

Orally Disintegrating Tablets (ODTs) of model drug; Diclofenac Sodium using novel and natural Ocimum Basilicum Mucilage as a superdisintigrant

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Swallowing of tablets and capsules pose a real problem in paediatric and geriatric patients. Orally Disintegrating Tablets (ODTs) would be an appropriate choice for these patients but appropriate disintegration time and dissolution rate of the ODTs can be achieved with an important excipient; superdisintigrant. By considering the cost and related side effects of synthetic superdisintigrant, present study focused on novel and natural origin gum; Basil Seed (Ocimum basilicum L.) Mucilage. Mucilage was isolated from *O. basilicum* seeds and ODTs were prepared to investigate the superdisintigrant potential of Basil seed mucilage (BSM). ODTs were prepared by direct compression technique using Avicel PH 102, BSM,mannitol,magnesium stearate and talc using model drug diclofenac sodium. Tablets were evaluated for weight variation, wetting time/ water absorption ratio, hardness, friability, drug content, disintigration time and *in vitro* dissolution test**.** From obtained results, it was concluded that BSM exhibited good disintegrating potential and increase in concentration of mucilage showed faster disintegration of tablets. Tablets formulation consisting 8 % of BSM showed faster disintigration of diclofenac ODTs within 30 seconds. Optimised formulation of ODTs complied all evaluated parameters as per the standard specifications. Thus BSM would be a better alternative to synthetic superdisintigrant as it is cost-effectiveness, safe and non-toxic.

E035

Design, Development and Optimization of Anti-Cancer Drug Tablet Using Roller Compactor

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The objective of the research was to design and develop an immediate-release compressed tablet for an Anti-cancer drug employing varied concentrations of super-disintegrants, binder, as well as variable diluent concentrations, in order to achieve rapid action for myelogenous leukaemia and acute lymphoblastic leukaemia. This anti-cancer agent is a chemotherapeutic drug used to treat leukaemia in specific situations, which is used to treat adults with newly diagnosed Philadelphia chromosome–positive (Ph+) chronic myeloid leukemia (CML) in chronic phase (CP). Preliminary batches were formulated by direct compression technique using roller compactor, for screening of super-disintegrants, binder and diluents to be used for final formulation. Further batches were formulated using cross carmellose sodium as super-disintegrant, and Hydroxypropyl cellulose (HPC-H) & Klucel (HPC-HXF) as Binder to study the effect of different concentrations on drug release. The roller compaction technique was optimized using the factorial design on the critical process variables i.e. hydraulic pressure and fine granulator speed. The optimized formulation was selected based on pharmaceutical parameters and in-vitro release profile compared with the reference-listed product. The dissolution results showed a gradient increase in the drug release with the increase in the concentration of the super-disintegrants. It was concluded from the study that by increasing the concentration of super-disintegrant, by changing the type of binder and diluent, the desired release was achieved. Moreover, it was observed that hydraulic pressure and fine granulator speed play a significant role in improving micro-meritics properties of granules ready-for-compression, which yielded desired compressibility of tablet formulation.

E036

Drug-in-Adhesive Based Transdermal Patch of Atomoxetine Hydrochloride.

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Attention Deficit Hyperactivity Disorder (ADHD) is a neurodevelopmental disorder observed during childhood. Children with ADHD generally show difficulty in paying attention, impulsive behaviour and may be overactive. Drug, Atomoxetine Hydrochloride is widely used in the treatment of ADHD. In the market, tablets and capsules of Atomoxetine Hydrochloride are available. In the current research, an alternative approach, drug-in-adhesive based transdermal patch has been developed, which can improve the patient compliance for paediatric patients. The pressure sensitive adhesive was selected from a wide range of available marketed pressure sensitive adhesives. DURO-TAK 387-2054 was selected as pressure sensitive adhesive as it showed highest drug loading. In patch formulation, crystallization inhibitor was used along with pressure sensitive adhesive, to achieve highest drug loading. Various crystallization inhibitors were evaluated out of which PVP K30 was selected. Various penetration enhancers were evaluated out of which the best penetration enhancer selected was Transcutol HP. Transdermal patch was optimized using the face central composite design. Drug concentration, crystallization inhibitor concentration and penetration enhancer concentrations were the selected factors for optimization. Responses selected were percentage cumulative drug release after 12 hours and indicative 180° peel adhesion strength. The optimised formulation showed the assay of 98.67 ± 0.86 % and 180° peel adhesion strength of 202.37 ± 5.28 grams. The patch thickness was found to be 431 ± 15 µm. Percentage cumulative drug diffused after 12 hours was found to be 64.89 % ± 1.04 %. The formulation was found to be stable under accelerated stability conditions.

E037

Development of Immuno-nanoparticles for Multiple Myeloma for Parentral delivery.

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Polymeric immuno-nanoparticles are designed to incorporate targeting ligands by covalent coupling, which combine passive and active targeting in one platform. An immuno-polymeric nanoparticle system that results from the self-assembly of an amphiphilic copolymer. Folate conjugation to the nanoparticle surface, these immuno-nanoparticles exhibit specific binding with receptor-overexpressing cancer cells. Multiple myeloma is a cancer that forms in a type of white blood cell called a plasma cell. In multiple myeloma, cancerous plasma cells accumulate in the bone marrow and crowd out healthy blood cells rather than produce helpful antibodies, the cancer cells produce abnormal proteins that can cause complications. Proteasome inhibitor that inhibits the chymotrypsin-like protease in the core of the proteasome. The fabrication of anticancer drug encapsulated nanocarriers using solvent emulsification method using Poly caprolactone as biodegradable polymer and further characterized in terms of particle size and PDI. The optimized composition of polymeric nanoparticle encapsulated with proteozome inhibitor would be further functionalized with folate conjugation using Dies elder reaction for targeting cancer cell. The result of characterization and evaluation parameters were discussed. In nutshell, developed immon based polymeric nanoparticles would provide platform for the delivery of anti cancer therapeutics at targeted site.

E038

Preparation, Statistical Optimization and In vitro characterization of Etravirine loaded solid lipid nanoparticles.

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Some studies repurposed small molecule antiviral medicines like Etravirine against the key viral proteins of SARS-CoV-2 and found that, with further validation studies, Etravirine could serve as a promising medication for the treatment of COVID-19. Etravirine is used to treat infection with the human immunodeficiency virus type 1 (HIV-1). The drug's low water solubility, 0.07 mg/ml, may result in the delayed onset of action. Herein an attempt has been made to formulate solid lipid nanoparticles of Etravirine in order to overcome its low aqueous solubility. To study the effect of lipid concentration, surfactant, stirring speed, stirring time, and cooling conditions against the particle size of the solid lipid nanoparticles of Etravirine, a custom design was inculcated to achieve different experimental runs utilising design JMP software version 13. ANOVA was used for the study, with a significant level of P 0.05. The optimization was achieved at a desirability of 0.5249. Hot homogenization technique was used for formulation. The poly dispersity index less than 1 indicated that the particle size distribution is uniform. The zeta potential of F1 to F9 formulations was shown to be in the range of -20.3 mV to -34.4 mV. On the basis of custom design Formulation F8 was determined to be Optimized Formulation and confirmed drug release of 96.46%. The experimental and predicted values of optimized formulation were found in close agreement with each other, indicating appropriateness of the optimization procedure in the successful development of Etravirine solid lipid nanoparticle formulation.

E039

Development of Protein nanoparticles containing EGFR for the treatment of lung carcinoma.

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Nanoparticles are emerging carrier mechanism providing high stability, high solubility, and high drug loading with the controlled release pattern for the drug delivery, Nanoparticles are providing larger surface area so we can achieve a good bioavailability. Protein nanoparticles have certain unique functionalities and application both in biomedical and material sciences, Hence they are recommended as ideal material for the preparation of nanoparticles have promising properties of both animal proteins and plant proteins like; biodegradability, amphiphilicity surface modification, low toxicity of end product. Cancer is one of the leading cause over the world in current senerio. Lung cancer is uncontrolled cell proliferation and absence of cell death of lung. Common treatment of cancer include chemotherapy and targeted therapy. Anticancer Drug is active against non small cell lung cancer with activating EGFR mutation by inhibiting the phosphorylation and tyrosine kinase activity of the intracellular ATP-binding domain. The preparation of Anticancer Drug nanocarriers for parentral delivery is done by solvent emulsification method by mixing the aqueous phase (Protein in water) and organic phase of drug in methanol. The optimized batch was evaluated for Particle size, encapsulation efficiency and potential. The developed protein therapeutics would be further surface functionalized using targeting probe for better targeting the cance cells and tumor site. The resulting system will provide platform delivery for targeting anti cancer drug as site specific delivery for minimizing risk at non cancerous cells.

E040

Design and Development of in-situ gelling sustained-release nevirapine suspension for treatment of HIV.

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Human immunodeficiency virus (HIV) is a virus that attacks the body's immune system. Nevirapine is used in the treatment and prevention of HIV/AIDS, specifically HIV-1. This study aims to develop and evaluate a novel pH-responsive in-situ gelling sustained-release nevirapine pediatric suspension (SRNPS) for treatment and prevention of mother-to-child transmission of HIV. SRNPS can reduce the number of doses administered with subsequent improvement of patient compliance. Nevirapine anhydrous (NA) is unstable in the suspension formulation which leads to the formation of clusters. So here, initially, nevirapine hemihydrate (NH) was synthesized using NA. Both NA and NH forms were later evaluated for DSC, FTIR and pXRD. Furthermore, for the preparation of SRNPS NH form was selected. The developed novel SRNPS was compared with marketed immediate-release nevirapine suspension (Viramune®). Further, both suspensions were evaluated for *in-vitro* drug release studies and *in-vivo* pharmacokinetic studies using a rat model. SRNPS has shown good in-situ gelling behavior and results have shown sustained drug release for 8 hours. The pharmacokinetic studies in rats also demonstrate an increase in the Cmax, Tmax and AUC for SRNPS compared to Viramune®. The observed Cmax for Viramune® and SRNPS is 0.548 ± 0.16 ng/mL and 0.670 ± 0.22 ng/mL respectively, observed Tmax is 3 ± 0.2 hours and 6 ± 0.5 hours respectively, while, AUC0-∞ for Viramune® and SRNPS is 26.61 ± 4.26 µg/ml*h and 59.23 ± 5.87 µg/ml*h respectively. The study thus supports the claim that development of SRNPS would minimize the dosing frequency along with sustained action.

E041

Development of micelles loaded mouth dissolving film

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Mouth dissolving film is the most advanced oral solid dosage form due to its flexibility and comfort in use. Mouth dissolving films are solid oral dosage form that disintegrate and dissolve within a minute when placed in mouth without taking water or chewing. This dosage form allows the medication to bypass the first pass metabolism so bioavailability of medication may be improved. Mouth dissolving film has potential to improve onset of action lower and the dosing and also eliminate the fear of chocking. Fast dissolving Film is prepared using hydrophilic surfactant that rapidly dissolves on the tongue or buccal cavity, delivering the drug to the systemic circulation via dissolution when contact with liquid. Water-soluble surfactant are used as film formers for fast dissolving films. The water-soluble surfactants achieve rapid disintegration, good mouth feel and mechanical properties to the films. TPGS is used as a surfactant for encapsulation of model drug to prepare micelles by Direct dissolution /solvent evaporation method. After that thin film would formed using electrospinning technique. The optimised batch is evaluated for entrapment efficiency, folding endurance, thickness, tensile strength , surface pH etc.

E042

Formulation and Evaluation of Topical Dosage Forms of Bio-Active Phytoconstituents for Acceleration of Wound Healing Process.

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Wound healing is biological event of the body involving consecutive biochemical processes that are mainly involved in restoration of the cellular integrity of the organ. Introduction of an innovative technology is an urgent need for foster treatment of acute and chronic types of injuries. Nanotechnology is a foremost growing discipline of research deliberating many issues including wound healing. Although, there are many nano-formulations for encapsulating natural bioactives and of all this, nanoparticles (NPs) is one such alternative option providing sustained delivery at the wound site. Natural bioactive agents possess least side effects and have gained much attention in curing of wound and lawsone is one such example used in the wound management. Poor aqueous solubility and low skin absorption are major limitations hindering the therapeutic efficiency of the bioactive. So, overcoming its negative aspects and enacapsulation into NPs can elevate its pharmacological effect providing sustained release, solubility and stability. Polymers are most adopted materials for encasing the active compounds, thus forming a bio-degradable and bio-compatible drug delivery system. In light with this information, nanoparticles of the model compound were designed by selecting three distinct concentrations of lawsone (0.5 %, 1 %, and 1.5 %). For incorporating lawsone, Eudragit RS 100/Pluronic F-127 based NPs were designed. The selected concentrations were evaluated and it was found that NPs with lawsone concentration 1 % showed smallest particles size of 76.30 nm with % entrapment efficiency of 87.13274 ± 10.86562 along with desired results of FTIR and XRD studies. Developed formulation showed spherical shaped NPs showing highest 129.28 % cumulative drug release within 24 h study.

E043

Nanotechnology in Cancer diagnosis: Current perspectives.

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Nanotechnology is widely the area of science and technology. It gives the study of phenomena of the dimensions in the nanometre scale is utilized to design, production, characterization, structures, devices, and application of materials. However, Cancer is 2nd most common disease, causing death and poor quality of life globally. Early diagnosis holds a key to the improvement of the technology revolution in cancer detection and its treatment. Nanotechnology has been expanded to help the treatment of cancer therapy at a very tiny level. The cell of particulate of small sizes of nanoparticles helps them locate and kill the cancer cells precisely. In addition, nanoparticle systems have been shown to play a role in cancer drug resistance. For cancer diagnosis, nanomaterials have been applied such as quantum dots, gold nanoparticles as well biomarkers screening which is used at the molecular level. Numerous studies have been carried out to explore the tumor targeting of the design nanoparticle-based drug delivery systems in cancer therapy. Given that, several studies have examined different forms of nanomaterials such as polymers, antibodies, and liposomes with the conclusion that a combination of these nanomaterials in cancer drug design can achieve a balance between reducing the toxicity and increasing efficacy of drugs. Despite that, different medicines have been found to treat cancer therapy which is targeting cancer cells with different forms of nanomaterials. Furthermore, nanotechnology has been enhanced chemotherapy and reduced the adverse effects of drugs to target cancer cells. In this review, the roles of nanoparticles for drug delivery in radiotherapy, immunotherapy and describe the targeting as well the function on reversing drug mechanism.

E044

Process optimization of ecological probe sonication technique for production of drug loaded niosomes

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Niosome are non-ionic surfactant vesicles obtained by hydrating mixture of cholesterol and non-ionic surfactants. It can be used as carriers of amphiphilic and lipophilic drug. In niosomes drug delivery system, the medication is encapsulated in a vesicle. Niosomes are biodegradable, biocompatible non-immunogenic and exhibit flexibility in their structural characterization. Niosomes are prepared by different methods likes thin film hydration, reverse phase evaporation, ether injection and probe sonication methods etc. Probe sonication technique an eco-friendly green technique with no addition of organic solvents. Besides, it is a simple and low cost technique. In this method, only aqueous phase of drug is mixed with surfactant, cholesterol and other surface additives, and subjected to ultra-sonication with a probe. Niosomes produced by probe sonication technique are smaller with higher monodispersity having faster drug release rates as compared to niosomes produced by traditional technique. The probe sonication process is optimised by controlling various process parameters like sonication speed, amplitude and sonication time to formulate the niosomes of desired characteristic.

E045

Self micro Emulsifying Drug Delivery System: Novel Approach For Treatment Of Ocular Uveitis

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Uveitis is inflammation of uveal tract, which majorly affects the middle layer of the eyewall; and the prednisolone is widely used drug for the treatment of Uveitis. Currently, simple preparations are available in the market includes solutions, suspensions, gel, cream, etc.; however, several demerits associated with such conventional formulations are lacrimal drainage, poor residence time, and lesser absorption resulting in to poor bioavailability of drug at the site of action. Micro or nanoscale formulations like nano-particles, nano-emulsions, nano-suspensions, and micro-emulsion developed by several research scientists with the aim of better therapeutic effect by improving bioavailablity and prolonging the residence time of drug, to counter the above listed demerits. Among all approaches explored, the novel approach is self micro emulsifying drug delivery system (SMEDDS), which comprises of oil, surfactant and co-surfactant mixture as non-aqueous formulations. After applying to the ocular region, the preparation forms spontaneous emulsion after coming in contact with tear fluid secreted, forming very small globules in the micron size. Major advantage of SMEDS comprise of incorporation of poorly water soluble drug, reduced changes of drug elimination due to lacrimal drainage, high drug loading capacity, better physical stability as monophasic liquid, etc. This review comprises of study on various formulation components, formulation approaches, challenges to develop formulations, and evaluation parameters for SMEDDS as novel approach for treatment of ocular uveitis. This review would be beneficial for young formulation scientists to get overall understanding and thorough knowledge on ocular SMEDD formulation and characterization.

E046

Implication of Solution Phase Behavior on the Co-administered Drugs: The Case of Rifampicin, Saquinavir and Darunavir

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The study was designed to investigate the impact of drug rich phase of Rifampicin generated on Saquinavir and Darunavir as an effect of pH shift on the maximum attainable supersaturation. Rifampicin – Saquinavir and Rifampicin –Darunavir systems were studies to understand the impact of Rifampicin on these anti-retroviral drugs. Significant lowering of concentration was observed for the anti-retroviral when studied with Rifampicin by pH shift method using HCl - USP phosphate buffer 6.8 and HCl - Fasted state Simulated Intestinal fluid pH: 7.0. The drugs precipitated in amorphous form on pH shift was characterized using DSC and PXRD. However, FTIR data showed no intermolecular interaction. Ex-vivo studies were carried out for pure Rifampicin, Saquinavir, Darunavir, Rifampicin – Saquinavir combination and Rifampicin – Darunavir. Significant lowering of flux was observed for Darunavir when studied in combination with Rifampicin. However, no significant decrease of concentration was observed for Saquinavir when studied in combination with Rifampicin. The free drug concentration achieved in the bulk of the drug solution was found dependent upon the mole fraction of the respective drug component within the drug-rich phase. The relative mole fraction of each drug component within the combination drug-rich phase is determined by pH-dependent solubility and molecular weight of the individual drug component in the system.

E047

Recent Trends and Challenges in Development of Medicated Shampoo

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Currently, hair care plays a very important role in self-perception. Shampooing is the most common form of hair treatment. Shampoos are primarily been products aimed at cleansing the hair of accumulated sebum, scalp debris, and residues of hair-grooming preparations. The added functions of a shampoo include lubrication, conditioning, body building, prevention of static charge builds up and medication etc. Conventional shampoos are used for cleaning. However, various medicated shampoos are used for resolving issues related to -- dandruff, Seborrhoea and lice as well as scalp. Dandruff chronic, non-inflammatory condition of the scalp that is characterized by excessive scaling of scalp tissue and it caused by a fungus called Malassezia restricta and Malassezia globose. It occurs exclusively on skin in areas with high levels of sebum. For development of medicated shampoo various actives such as anti- fungal agents, keratolytic agents, anti - proliferative agents, herbal ingredients etc are used against dandruff. Along with the active ingredients primary surfactant for lathering and cleansing, Co-surfactant for lathering, Conditioning agent, pH adjuster, Viscosity booster, Preservation, Fragrance, Solvent (Deionized water) etc. used for formulation point of view. There is minor issue of stabilization of medicated shampoo. Thus, stability of formulation by adding thixotropic agent that leads to better stability and exhibited ideal thixotropic rheological behaviour. The current review highlights the recent challenges in development of medicated shampoo for treatment of dandruff.

E048

Electrospun Nanofibers as an Effective Alternative for Ocular Drug Delivery System

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Nowadays, ocular dosage forms are immensely evolved as a topical dosage form due to their rapid local action, less systemic side effects and easy self administration. Conventional dosage forms like; eye drops, ointment, gel, suspension and emulsion have certain limitations due to the unique anatomy and physiology of eye. This review discusses the electrospun nanofiber as a potential option for ocular inserts. Nanofibrous ocular inserts have some distinguish features such as high surface area to volume ratio, high porosity, achievement of sustain drug release with good mechanical strength and as it is a solid formulation it has excellent stability, which overcomes the limitations of conventional dosage forms. Electrospinning is widely preferred method for the generation of nanofiber film, due to its simplicity, high production rate and ability to control the diameter and morphology of nanofibers. This review summarizes how electrospun ocular nanofibers act as an effective alternative to conventional dosage forms.

E049

Nano-emulsion loaded with Amphotericin B: A New Approach for the Treatment of Leishmaniasis.

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Leishmaniasis is a neglected infectious disease caused by protozoan parasites of the leishmania genus that affects millions of people worldwide. The current treatment for cutaneous leishmaniasis (CL) has a long list of negative side effects. Topical therapy is beneficial since the medications target the infection site and reduces the risk of systemic side effects. Micro and Nanotechnology are key procedures in this regard, as they may be effective for modifying the release profile of CL medicines and therefore enhancing their bioavailability. Amphotericin B is a macrolide antibiotic and has a broad spectrum of action. Literature evidence indicated that droplet size, morphology, drug content, stability, in-vitro release profile, and ex vivo skin permeability were also to define NEs. NEs containing AmB presented droplet size lower than 60 nm with a polydispersity index lower than 0.5. AmB-NEs had a minimal skin permeation and a gradual and regulated AmB kinetic release. AmB-NEs led to significant reduction in parasite burden in the liver and spleen and did not result any sign of acute toxicity and higher anti-leishmanial effect against L. amazonesis promastigotes. This review summarizes recent advances of Amphotericin B containing Nano-emulsion as topical carrier to improve the therapeutic performance of Leishmaniasis.

E050

Investigating the influence of physicochemical interactions of co-administered anti-malarial and anti-retroviral medications

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Human Immunodeficiency Virus (HIV) patients are prone to be affected with infectious diseases like malaria, tuberculosis (TB), cancers, etc., due to immunosuppression. Combined, malaria and HIV causes more than 2 million deaths each year. Given the considerable geographical overlap between malaria and HIV/AIDS, a substantial number of co-infections occur. Especially in sub-Saharan Africa and Southeast Asia regions sharing the highest global burden. Recommended first line treatment from World Health Organization (WHO) for HIV and malaria are "Artemether (ART), Lumefantrine (LUM), Efavirenz (EFZ) and Nevirapine (NVP)". Recent clinical data demonstrated decrease in bioavailability of either or all drugs given in combination for treating comorbidity of malaria and HIV. If we look into the physicochemical aspects of these drugs have similar physicochemical properties with high Logp values, weakly basic in nature and their pKa values range between 2-8. Such physicochemical properties increase the likelihood of physicochemical interactions (Liquid-liquid phase separation, complex formation, and micellar solubilization) amongst them. However, there are no reports exploring the physicochemical interactions to address poor bioavailability of co-administered anti-malarial and anti-retroviral drugs. The effect of physicochemical interactions on combination drugs was studied by pH shift dissolution (with and without bio-relevant media) and *ex vivo* permeability studies where there is significant decrease in solution concentration of ART and LUM in the presence of EFZ and NVP. Solid state characterization and zeta-potential is implemented for all the residues collected after the dissolution studies to understand the mechanism of physicochemical interactions. The above characterization studies support the presence of amorphous micelles in the dissolution media which led to decrease in the solution concentration of these drugs when compared to the pure drug concentration.

E051

Hydrogel Drug Delivery System for Effective Wound Healing.

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Skin is a multifunctional organ having basic purpose of protecting the internal tissue from the external environment. Maintenance of ideal mechanical properties of the skin captures significant attention. Wound is condition in which the normal function of skin is disturbed. Nowadays, the healing of wound is challenging process as there are unavailability of precise treatment which helps to treat the wound as well as grow natural skin. Hydrogel Drug Delivery system has received significant attention as it exposes properties such as extremely high-water content which absorb the exudate at the site of wound during healing process. This system provides moisture, transparency, fluid balance, water evaporation control, mimics the structure and function of Extra Cellular Matrix (ECM) by promoting cell adhesion, cell proliferation, and cell migration at the site of wound. The hydrogel drug delivery system is designed in such a way that polymer (natural as well as synthetic) and drugs (Combination of Allopathic and herbal) produces the synergistic effect at the site of wound which results into the reduction time of rate of wound healing process. In this review, there will be a discussion on combination of some natural and synthetic polymers as well as drug which fulfil the requirements of wound healing process

E052

Micelles loaded hydrogel for ocular uveitis using QBD approach

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Uveitis is a complex multifactorial autoimmune disease.The four anatomical types of uveitis include anterior uveitis, intermediate uveitis, posterior uveitis and panuveitis. This disease is mainly common in male with mean age group of 35 to 45 years. According to survey, in US Uveitis is identified as a cause for 10% of total blindness. Polymeric Micelles system is prepared by using direct dissolution method (DDS) and loaded in hydrogel solution for better retention of drug at site of action and for better permeation in cornea. For the preparation and optimization of Micelles Central composite design (CCD) is used. As per QBD design result Particle Size analysis by using DLS Zetasizer shows for batches 1&2 shows 46.92nm with PDI 0.292 and 13.61nm with PDI 0.210 which is acceptable for ocular delivery and same for %Entrapment Efficiency for batches 1and 2 is 39.23% and 68.16% respectively.

E053

Formulation Development and Evaluation of Floating Tablets Of Zolmitriptan

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Zolmitriptan is the antimigraine agent widely used for the treatment of the migraine. Literature survey reveals that the half life of the drug is 2.5 – 3 hours which indicate the frequent dosing to achieve proper pharmacological action of the drug. GRDDS is a common approach to decrease the dosing frequency and increase patient compliance, and delivery of drug through such an approach of floating tablet formulation will meet the requirement. This system showed significant impact on the drug release through floating and swelling properties. The floating tablets were prepared by using direct compression technique using hydrophilic polymers and gas generating system.

In the preliminary study the drug shows UV absorption maxima at 222 nm and 224 nm in 0.1 N HCl and Ethanol respectively. FT-IR study shows that there is no significant interaction between polymers and drug. In the preliminary trials, the effect of various polymers i.e. HPMC K4M, HPMC K15M, HPMC K100M and PVP K30 was studied on floating properties. HPMC K100M and PVP K30 were found to be suitable for floating buoyancy. Physical parameters like hardness, weight variation, thickness and friability were within pharmacopoeial limit. % drug release of the formulations (F1 – F9) was studied up to 6 hours and it was found from 52 to 91 %.

The present study was carried out to develop the floating drug delivery of Zolmitriptan using HPMC K100M and PVP K30 polymers. *In-vitro* dissolution studies showed good percent drug release, which is in accordance with robinson-errikson equation. Good buoyancy for more than 6 hrs, followed by the diffusion transport. Thus, results of the current study clearly indicate, a promising potential of the zolmitriptan floating tablet as an alternative to the conventional dosage form. However, further clinical studies are needed to assess the utility of this system.

E054

Nanosuspension Loaded Electrospinning Nanofibers for Sublingual Drug Delivery: Novel Approach

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The concept of sublingual film dosage form has become popular as new delivery system. The sublingual portion is rich in capillaries, which allows drugs to go directly into the blood without the influence of intestine, gastric acid and first pass effect. This system will provide maximum therapeutic efficacy, increased bioavailability and maximum stability by reducing the frequency of dosage. This study was formulation and evaluation of Mucoadhesive sublingual film containing Nanoparticles of poorly water soluble drug to get quick disintegration for rapid release and onset of action. Formulations were prepared by varying the concentration of polymer and plasticizer. Electrospinning fibers were formulated and explored as potentially sublingual membrane. The addition of synthetic polymers like polyethylene glycol (PEG), Poly Vinyl Alcohol (PVA), polyvinylpyrrolidone (PVP) to the formulation shows improved flexibility and reduced fluffiness of the fiber mat. The fibers take the form of uniform cylinders with smooth surfaces, and contain drugs in the amorphous form. Nanosuspension was evaluated for parameters like Particle size, PDI and Zeta potential. Films were evaluated for parameters like drug content, tensile strength, in-vitro drug release, folding endurance, surface pH, taste, thickness, disintegration time, ex vivo Mucoadhesion time, ex vivo permeation study and drug excipients compatibility study. Overall the developed fast dissolving Electrospinning polymeric film is a promising delivery carrier for the sublingual delivery.

E055

Screening of co-formers for the fabrication of co-amorphous systems: An *In silico* approach

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Ceritinib is a chemotherapeutic molecule that is administered as a capsule, taken orally with the standard starting dose of 750mg once daily with food. Although Ceritinib is used to treat NSCLC, it has some drawbacks like low solubility and oral bioavailability due to P-gp inhibition and first-pass metabolism. Ceritinib is a substrate for P-gp efflux transporter, these P-gp efflux transporters are present in the gut, intestine, and liver. They reduce the Ceritinib permeability by effluxing it out from the cell/enterocytes, which affects the amount of drug available for therapeutic action. This phenomenon leads to the administration of Ceritinib in high dose to make it available for the desired therapeutic action. It further leads to common adverse effects such as diarrhea, vomiting, weight loss, and loss of appetite due to exposure to a high amount of Ceritinib to the gastrointestinal tract.

Above mentioned issues can be addressed by developing co-amorphous systems of Ceritinib using a suitable co-former to convert the crystalline Ceritinib to its amorphous form with improved solubility. Two insilico methods were selected based on the thorough literature search to optimize the co-formers for the preparation of co-amorphous systems, which includes free energy calculations and induced fit Docking. Both the methods were built with the help of Schrödinger software. Binding energy and dock score were calculated for the optimized molecules. Thirty molecules individually and in combination with the Ceritinib were screened by using both the methods.

E056

Electrospun Nano scaffolds for Wound Healing

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Healing of Wound represents an extremely complex physiological response of a living system to physical, chemical, mechanical or thermal injury. Due to the limitations of Conventional wound dressings, impressive efforts are required in the development and evaluation of new and effective platforms for wound healing. Scaffold structure is a new carrier for cell and drug delivery that enhances wound curative through differentiation of endothelial and epithelial cells and production of angiogenic growth factors in cutaneous wounds. Electrospinning scaffolds provide several advantages, including proper adaptability for wound bed microstructure and architecture, facile application, patient compliance and enhanced therapeutic effects. Natural or man-made, composite or hybrid biomaterials represent appropriate candidates for accelerated wound healing, by providing proper air and water vapor permeability, suitable structure for macro- and microcirculation, support for cellular migration and proliferation, protection against microbial invasion and external contamination. In any case it is being the most promising choice for wound care applications, polymeric biomaterials (either from natural or synthetic sources) may exhibit intrinsic wound healing properties. Electrospun scaffold based biomaterials proved great potential for wound healing applications. Currently, scaffolds have application in various fields of tissue engineering in repair of organs and its management. This review discussed the recent advances and developments of electrospun nano scaffolds for wound healing and could be established as a promising move for wound healing in near future.

E058

Novel Pharmaceutical Composites for Tissue Regenration In Non Healing Diabetic Foot Ulcers

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Diabetic Foot Ulcers**;** An unmet therapeutic challenge, Statistics says 74.19 Million cases of Diabetes (2021) of which, 15-25% contribute to Diabetic Foot Ulcers of which 10-15% are infective and 5-24% goes towards amputation. Currently available absorbable collagen wound dressings; utilizes the tactics of Lyophilization in Indian Market. However, Comparative market search states the leading gap over the Indian products for wound healing composites and need to be concerned to prioritize research in regenerative tissue scaffolds and its manufacturing techniques. Biodegradable multiparticulate structure containing anti-infective agent loaded proteinous base acting as body's native Extracellular Matrix which will act as rejuvenating structure in tissue regeneration using Electrospinning Technology. This methodology constitute fabrication of robust nanofibrous system in terms of Biocompatibility, Biodegradability, Sustained Release of drug thus reducing dosing frequency, ease of application, less drainage of medicament and removal from the wound area if any complications seen. Application of QbD approach for optimization and further evaluation of so formulated composites for thickness, tensile strength, morphological characterization by the means of SEM analysis, in- vitro release study for the sustained release of the drug from the composite and the pre-clinical study using diabetic rat model on the rats. Emergence of Electrospinning Technology in the field of wound care can lead to economic as well as the therapeutic benefits as this area requires continuous debridement and dressing procedures. Also, the technology has the scale up feasibility for the production at large scale.

E059

Development and Characterization of the formulation containing Alectinib Hydrochloride for solubility and dissolution enhancement

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Oral route is considered the most desirable route of drug administration. However, the majority of new chemical entities (NCEs) are reported as poorly water-soluble and exhibit poor solubility thus, poor oral bioavailability. The present study aimed to improve the solubility & dissolution of a poorly water-soluble drug, Alectinib Hydrochloride (ALB) (aqueous solubility 0.0221 mg/mL), using a solid dispersion technique. Soluplus (SOL) and Gelucire 44/14 (GEL) were selected as polymer and surfactant respectively due to their potential to improve the solubility of ALB. The ratio of ALB, SOL, and GEL was optimized using the Design of Experiments (DOE). The optimized formulation showed a significant improvement in solubility (550-fold) which translated into dissolution improvement in media spanning physiological pH range and bio-relevant media. Further, the optimized solid dispersion was also characterized using different spectroscopic techniques namely, Differential scanning calorimetry (DSC), Fourier Transform Infrared Spectroscopy (FTIR), Powder X-ray diffraction (p-XRD) for examination of any chemical compatibility and change in crystallinity. FTIR showed that there was no chemical interaction among ALB, SOL, and GEL. Improvement in solubility and dissolution may be attributed to two pathways: amorphization, as evidenced by DSC & p-XRD, and further encapsulation of ALB in SOL/GEL micelles. An 11-fold increase in dissolution in bio-relevant media [Fasted state Simulated Gastric fluid (FaSSGF)] indicates potential to show improvement in bioavailability. These results indicate that the optimized formulation has the potential to improve solubility and dissolution of ALB in physiological pH and in bio-relevant media (FaSSGF) opening a promising way in pharmaceutical application.

E060

Development Of Cationic Polymeric Nanoparticle for Occular Drug Delivery

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Conjunctivitis is contagious and can readily spread within a family, childcare center, or eldercare facility Children with conjunctivitis may be required to stay home from School or daycare to prevent contagious spread or until they receive treatment for the disease. It affecting 3-6 million people annually in the United States. Acute conjunctivitis has been estimated to have a bacterial cause in >70% of cases in children and ~50% of cases in adults.1 in 8 children develops Acute conjunctivitis every year. Polymeric NPs as drug carriers include their potential use for controlled release, the ability to protect drug and other molecules with biological activity against the environment, improve their bioavailability and can improve precorneal residence time and ocular penetration, also reducing side effects as well as reducing frequent dosing. As a result application of QBD approach for optimization and further evaluation of so formulated composites for particle size Analysis, entrapment efficiency, isotonicity, morphological characterization by the means of TEM analysis, In- vitro release study for the sustained release of the drug and in- vivo irritation study in rabbit.

E061

Nanoformulations for the Treatment of Atopic Dermatitis

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Atopic dermatitis (AD) is a chronic, highly pruritic and relapsing inflammatory skin disease which often emerges during childhood. The pathophysiology of AD has not been completely elucidated, however one of the main events which appear to give rise to AD is the dysfunction of the natural skin barrier. Additionally, immune dysregulation, environmental and infectious agents also appear to be involved. This skin disorder significantly impacts an individual's quality of life by causing both physical discomfort and emotional distress. Treatment of AD focuses on restoring the skin barrier by hydrating and repairing the skin, limiting itching and reducing inflammation. It includes an anti-inflammatory treatment with first line topical corticosteroids and/or calcineurin inhibitors (TCIs), as well as patient education and skin care practices. Recent advancements for the treatment of AD uses nanotechnology for its potential in enhancing the delivery of drugs dermally. Nanoparticles are used for the delivery of classical drugs in which they reduce adverse effects, increase skin permeability and bioavailability. Different types of nanoparticles such as cubosomes, transferosomes, nanoemulsions and nanosponges are used. Cubosomes are nanoparticles of lipid matrix that can incorporate both water soluble and oil soluble drugs. They show an increase in skin permeation for dermal applications. Transferosomes have high flexibility and deformability, which allow for superior penetration capability of drugs. Nanoemulsions result in enhanced drug absorption due to their positive charge, which is attracted to the negatively charged corneocytes in the stratum corneum. Nanosponges allow for a sustained release, have better retention, reduce side effects and dosing frequency. The present review focuses on the progress of nanoformulations for the treatment of AD and its future opportunities.

E062

Ultrasonically Fabricated Borage Oil Nanoemulsion Containing Docetaxel for Improved Cancer Therapy: Development, Optimization, In Silico and In Vitro Investigation

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Cancer has been known to be complex diseases, posing a huge health related challenge throughout the world including the population of both the developed and developing countries. Although, conventional therapies are available but failed to control the spread of this disease completely. Among the various target based novel therapies, Nanotechnology has emerged as the main contender which makes it possible to load drug and directly target it to cancerous cells. In our current investigation we have formulated nanoemulsion using Borage Oil (known to contain Gamma linolenic Acid) for the delivery of Docetaxel, a well known anticancer agent to have a better anticancer response. Optimization was done using statistical design to get the final formulation. Physicochemical characterization technique like DLS (Dynamic Light scattering), (Transmission and Scanning electron microscopy) TEM&SEM, DSC, FTIR, XRD (X-ray Diffraction Analysis) were employed to confirm the size, spherical shape, drug dispersion and drug excipients interaction. The average particle size and Polydispersity index (PDI) were found to be 180.2± 4.5 nm and 0.178±0.01 respectively, which were within the range to be used for *i.v* administration and passive targeting of cancerous cell exploiting its leaky vasculature. *In vitro* drug release studies displayed a sustained pattern of release from the formulation. *In vitro* cell viability studies showed remarkable cell killing potential of the Nanoformulation against MCF-7 breast cancer cells. *In silico* molecular docking studies were undertaken to confirm the β-tubulin binding potential of Gamma Linolenic Acid similar to Docetaxel. The overall effect, being a considerable improvement in anticancer efficacy with our developed formulation.

E063

A Comprehensive Review on Nano Formulations Loaded Microneedle for Transdermal Drug Delivery

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Drug delivery through the transdermal route is highly advantageous due to bypassing the first-pass metabolism and providing a sustained release of the drug. However, some factors like molecular weight, nature of drug and thickness of stratum corneum (SC) plays a major role in limiting drug permeation through the skin. Nano formulation as an excellent drug delivery system can overcome this limitation and increase the permeation of the drug. Nano formulations are formulated in various types like vesicular, particles, nanoemulsion, etc. for transdermal drug delivery. The nanosize leads to enhanced drug permeability, stability, retention, and targeting, making nano formulations suitable for transdermal drug delivery. Nano formulation loaded microneedles (MNs) is a novel approach for the site specific drug delivery. Microneedles can penetrate through the SC layer of the skin into the viable epidermis, avoiding contact with nerve fibres and blood vessels that reside primarily in the dermal layer. MNs works by disruption of the stratum corneum and thereby creating a micro-size pore in the skin. Nano formulation easily penetrate by this pore and release the drug in the systemic circulation. MNs are fabricated using materials like silicon, metals, glass, ceramic and polymer using various techniques. One of the techniques is 3D printing for the manufacturing of MNs. It offers customization, cost-efficiency, a rapid turnaround time between design iterations, and enhanced accessibility. This review discusses different modes of characterization and the manufacturing technologies associated with MNs. It also discusses their potential impact on drug delivery, vaccine delivery, disease diagnostics, and cosmetics applications.

E064

Quality by Design driven fabrication of targeted Nano formulation of natural Peptidyl-prolyl isomerase-B inhibitors against Bacterial biofilm

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Nosocomial infections, also known as hospital-acquired infections, are newly acquired infections that are contracted within a hospital environment. Transmission usually occurs via healthcare workers, patients, hospital equipment, or interventional procedures. Disease relapse occurs due to incomplete pathogen clearance and reactivation of the antibiotic tolerant bacilli. Staphylococcus aureus, E. coli and Pseudomonas aeruginosa, like other bacterial pathogens, create an ecosystem of biofilm formed by several proteins, including the cyclophilins. We show that cyclophilin peptidyl-prolyl isomerase (PpiB), an essential gene, is involved in biofilm formation and tolerance to antimicrobial drugs. We predicted interaction between enzyme and drug by in-silico docking studies. So, by using a design expert, a nanoformulation (Bilosome) was formulated integrated with response surface methodology. Such efforts successfully achieved to prognosticate and control levels of formulation variables viz, bile (15mg), cholesterol (25mg) and span 60 (87mg) required to design the novel carriers (size:171.5 nm, PDI: 0.178, EE:60% and DL:12.4 %) of Rutin and ciprofloxacin with good stability (DSC and FTIR) and improvement in the overall performance as evidenced by ex-vivo skin permeation study, confocal laser scanning microscopy and histological study, Bilosome exhibits significant enhancement in terms of pharmacokinetic parameters viz, AUC (1135.43 v/s 945.42 ng.h/mL), Cmax (219.35 v/s 181.2 ng/mL). Rutin and Ciprofloxacin showed bacteriostatic effects and disrupted biofilm formation. Dosage of the antimicrobial drug decreased 2-fold. Targeting bacterial biofilms could be a generic strategy for intervention against bacterial pathogens.

E065

Study on Impact of Brexit for Drug Product Registration in European Region

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Brexit is the term coined in March 2017, when the United Kingdom (UK) notified the European Union (EU) of its intention to leave the alliance; and in January 2020 the UK formally exited the EU. This big decision of the UK has not only affected the political scenario but also affected the ongoing functionality of various fields, and the pharma field considered as one of the most regulated industries has been affected a lot. The transition period began from February to December 2020, whereby many regulatory approval processes were at different stages were affected a lot like a centralized and decentralized pathway. The UK withdrew from EU institutions, notably the European Medicines Agency (EMA) during this time; while EU pharmaceutical law remained in force in the UK, which had generated a lot of turbulence. Except for Northern Ireland, which is governed by the Protocol on Ireland / Northern Ireland; EU pharmaceutical law has been outlawed in the UK since January 2021. The Protocol is a part of the EU-UK separation agreement, which outlined the conditions of the UK's exit from the EU. The aim of the present investigation studies the impact of Brexit on drug product registration in the UK as well as, other alliance countries as an EU. Two different scenarios demonstrated in the present study to as dossier submission process for UK-NI vs UK-GB. The present regulatory research will clarify queries regarding regulatory compliance submission formats and processes for drug product approval of the desired country for marketing.

E066

Levothyroxine Sodium – Thyroid Hormone Replacement Therapy for Hypothyroidism: A Review of Patent Literature

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Levothyroxine sodium is a thyroid hormone replacement therapy for hypothyroidism. Levothyroxine sodium is approved to treat hypothyroidism to suppress thyroid hormone release from cancerous thyroid nodules, and to prevent the growth of goiters. In addition, it is also used to treat conditions such as myoedema, cretinism, and obesity. This assessment highlights the overview of the recent patents of Levothyroxine sodium. This review includes patents grouped in sections like product patents, process patents, composition-related patents along with the treatment methodology. The objective of this article is to impel pseudoscientists with all existing patents in a solitary place. Data were searched from different internet-based data sets. In which, paid data sets include SciFinder®. Free data sets include Patentscope® (WIPO), Worldwide Espacenet® (EPO), Google Patents, and InPASS (Indian patent database). Extensive exploration has been carried out on various processes for the preparation of Levothyroxine sodium and the composition thereof., many excipients have been tried to stabilize the Levothyroxine sodium composition which included potassium iodide, anhydrous magnesium sulphate, anhydrous potassium carbonate, and more. Besides, commercially drinkable drops, Lyophilized powder, and an inhaler device suitable for the administration of a stable dry powder blend of levothyroxine sodium-related compositions were also reported. It was important to note that those formulations that are converted to lyophilized form were having more stability. This sort of dynamic exploration will clear the path for many generic players, which lead to the reduction of the expense of the composition and accordingly enhance global health care at less expensive cost.

E067

Update on Hydroxypropyl β-cyclodextrin (HPβCD) as a stabilizer for protein and peptide-based Anti-VEGF formulations

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Proteins are relatively large molecules which complex structures. Peptide chains in peptide and protein are linear and & adapt a variety of specific fold 3D patterns and conformations. Physical degradation, chemical degradation, food protein interference leads to poor stability of protein which is a great challenge in the delivery of proteins. This review tries to focus on the stabilization of protein formulation by using Hydroxypropyl β-cyclodextrin (HPβCD). HPβCD is cyclic oligosaccharides obtained from starch by enzymatic cyclization using cyclodextrin glycosyltransferases. HPβCD inhibits protein aggregation by shielding hydrophobic interactions and by displacing proteins from the air-water interface. A comparative study between the control formulation of 25mg/ml anti-VEGF in 50 mM phosphate buffer pH 6.2 and Formulation with HPβCD was performed by Roquette. This study supports the claim that HPßCD acts as a formulation stabilizer by reducing the formation of protein aggregation during agitation and thermal stresses and it will extend the shelf life and improve the stability of Protein formulation.

E068

Microneedle Technology: An Insight into Recent Advancements and Future Trends in Drug Delivery

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Microneedle is a small sized needle-like structure that has the ability to pierce the skin associate degree exceedingly in a non-invasive and painless way. Over the last decade, microneedle (MN) elicited microporation multifunctional approaches to reinforce the delivery of drugs through the skin. MN technology enclosed micron-sized needles to form microchannels into the stratum corneum of skin, the foremost vital protecting layer. Delivery of medicine and vaccines through the percutaneous route is an alternate route for hypodermic and oral. It overcomes the problems regarding gastrointestinal aboard drug deterioration. It's affordable, noninvasive, painless, simple, and self-administered techniques that offer prolonged unleash of drugs to enhance patient compliance. The MN delivery centered on biopharmaceuticals like proteins or peptides. The novel ideas have drawn interest in using these techniques in tandem with different enhancement approaches. MN techniques can play an important role in promoting clinical applications and innovative analysis for scientists and researchers operating among the pharmaceutical field.

E069

Development of lipidic nanovesicles containing anti-cancer drug using extrusion technique by changing One factor at a time (OFAT)

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Hydrophobic anti-cancer drugs require lipidic nanocarriers and among different lipid-based nano-system lipid nanovesicles are a promising approach. Cancer therapy requires nanoparticles to be in the size range of 50-200nm for passive targeting and for effective uptake by cells. In the present study lipid nanovesicles containing the anti-cancer drug were prepared using thin-film hydration and extrusion technique. For the preparation of crude vesicles by thin-film hydration OFAT was applied to screen various excipient factors like lipid ratio, drug to lipid ratio and process factors like RPM of rotary flask, temperature of process and vacuum pressure were varied. The lipid vesicles prepared by thin film were analysed for particle size, PDI, zeta potential and entrapment efficiency. By changing one factor at a time factors were selected on the basis of least particle size, PDI and high entrapment efficiency. The crude lipid vesicles were subjected to extrusion through polycarbonate filters through high pressure and above phase transition temperature. The prepared nanovesicles had size of around 120nm as confirmed with DLS and TEM, PDI less than 0.4 and zeta potential more than -20mV. The entrapment efficiency of the anti-cancer agent in the prepared nano-vesicles was found to be around 80%. Thus, OFAT is a suitable technique to screen preliminary factors for the preparation of crude vesicles and for further size reduction using extrusion technique.

E070

Formulation, Development and Validation of RP-HPLC Method For Estimation of Lumefantrine In Nanosupension

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The present study was intended to formulate lyophilized nanosuspension of Lumefantrine to resolve its solubility issues for the improvement of oral bioavailability. Lumefantrine nanosuspension developed by the anti-solvent precipitation and ultrasonication technique.Optimized Lumefantrine nanosuspension was lyophilized and analyzed using DSC, XRPD and FT-IR, which indicated complex formation between Lumefantrine, soya lecithin and PVPK30. This complex converts crystalline drug in amorphous form, which was responsible for increased solubility of drug, which was confirmed by in vitro release characteristics of Lumefantrine from nanosuspension. Lyophilized nanosuspension showed about 8-folds increase in drug release, which indicated a better way to offer higher release of Lumefantrine in controlling malaria. The RP-HPLC method was developed by using Poroshell 120 EC- C18 column (150 × 4.6 mm, 4µ, Agilent) with water/acetonitrile (0.1%TFA) as the mobile phases in a gradient elution mode. Detection was performed using PDA detector at wavelength 240 nm. The method showed to be linear over a range of 10-50 µg/mL. The mean recovery was observed 99.4% for Lumefatrine. The % RSD was found to be less than 2% for retention time and area response revealing the precision of the developed method. A simple, specific, precise and rapid HPLC method was developed and validated according to the ICH guideline for estimation of Lumefantrine in nanosuspension.

E071

Challenges and Novel Approaches for Transungual Drug Delivery

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Nail diseases are predominantly observed in under-developed and developing countries; however, drug delivery to nails is one of the most challenging tasks for formulator scientists. The nail has multiple layers of flattened keratinized cells, which fused to form a denser nail plate that acts as a barrier. Onychomycosis and Nail psoriasis are two major diseases observed across the globe, seeking the attention of clinicians and formulation scientists. Onychomycosis is a fungal infection in the nail region of the finger resulting in the thick and discolored nail, and sometimes separation of the nail plate from the nail bed. More than 3/4th of the patients suffering from skin psoriasis as an auto-immune disease develops in nail psoriasis on longer duration. Systemic delivery of a drug causes several undesirable adverse effects, whereas current topical treatments like nail lacquers are not able to penetrate into the deeper region of a nail. Several approaches explored for local penetration enhancement include mechanical approaches like Nail abrasion & Nail avulsion, chemical approaches like the use of Keratolytic enhancers & Keratinolytic enzymes; as well as, physical approaches like Iontophoresis, Etching, laser, Hydration, and occlusion. Moreover, formulation scientists have explored liposomal films, transferosomes, liposome/ethosomes, microemulsion gel, nanoemulsion gel, nanovesicles containing penetration enhancers, use of lipid diffusion enhancers, etc. The aim of this review is to enlighten the young and budding formulation scientists and clinicians to get an insight into various approaches for nail diseases and characterizations; to explore new avenues in the area of transungual drug delivery.

E072

Characterization of Drug-Carrier miscibility in Amorphous Solid Dispersions

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The present study is focused on examining the drug-carrier miscibility and stability in Amorphous Solid Dispersions (ASD) of a poorly water-soluble Glibenclamide (GLB). PEG-1500 and Acconon C-50 were selected as water-soluble carriers. *In-silico* molecular dynamics simulation tool, Hanson solubility parameter, Flory Huggins theory, and Gibb's free energy concept were used to predict the miscibility of GLB with selected carriers. The effervescence concept was introduced to enhance the solubility further (ESD). SDs were prepared by microwave, solvent evaporation, lyophilization, and Hot melt extruder (HME) methods. The *In-silico* and theoretical approach suggested that the GLB would show good miscibility with the selected carriers. The FTIR, 1HNMR, confirmed the formation of intermolecular hydrogen bonding. The amorphous nature of the prepared SDs was approved by the DSC, PXRD, microscopic techniques. The solubility, dissolution, and *exvivo* flux study proved that all ESDs had shown improved solubility than ASDs and the pure drug. The ESDs might offer improved bioavailability confirmed by the *exvivo* intestinal absorption study.

E073

Multifunctional Nano Sponge as A Carrier for The Treatment of Oral Cancer

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As per NIH 10.5 adults per 1,00,000 develops cancer. Oral cancer is the sixth most common type of cancer in India. 84-97% cases in India are of oral squamous cell carcinoma dominates all the oral cancer cases. The common cause includes smoking, betel-quid chewing, excessive alcohol consumption, and sustained viral infections that include the human papillomavirus are some of the risk aspects for the incidence of oral cancer. The traditional chemotherapeutic treatment involves various drawbacks such as poor aqueous solubility, limited bioavailability, high frequency dosing, poor physiochemical stability, belongs to BCS Class IV and adverse effects like nausea, vomiting, hair loss etc. In recent years, the focus on the nanomedicine as a delivery system for anticancer agents has been considered due to improvement in therapeutic index of many compounds. As tumor exhibits increased vasculature permeability, leakiness and decreased lymphatic function so if the drug is delivered in nano sponge (NS) form, then the delivery is done in small packets (100-500nm) which leads to enhanced permeation, retention and increase in the aqueous permeability of the anticancer drugs thereby increase in bioavailability. NS are highly porous hyperbranched cyclodextrin based polymers that forms stable colloidal nanosuspension upon dispersion in water, resembling sponges microscopically. They are non-toxic, thermally stable and can incorporate hydrophilic as well as lipophilic drugs. However, they are under clinical trials, efficacy is yet to be proven and manufacturing still requires detailed study. The current review highlights nano sponge as a carrier for the treatment of oral cancer with its challenges.

E074

Influence of Formulation Parameters on Dissolution Rate Enhancement of Eclipta alba Using Liquisolid Technique

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Herbal medicine are currently being adopted as alternative to orthodox medicines for the management of diseases. Many formulation of Eclipta alba are available. Eclipta alba is proven as an anti-inflammatory and antioxidant agent. The limitation of Eclipta alba has low solubility and poor bioavailability. The solubility and bioavailability are affect the efficacy there is a need to develop the novel formulation containing Eclipta alba with high solubility and bioavailability. To overcome this limitation and all challenges the novel liquisolid techniques explore as a novel tool to enhance the dissolution rate and solubility. Formulation development is carried out using different ratio of non-volatile solvents, carrier and coating materials and in order to make a palatable formulation other excipients like sweetening agent, flavouring agent and preservatives are added. Pre-formulation parameters like, Φ value, Bulk density, Tap density, Angle of repose, Carr's index, Hausner's ratio and liquid load factor are evaluated. And post-formulation parameters like Solubility study and dissolution profile study are performed. Pre-formulation analysis showed that the flow property of powder is excellent, having the angle of repose is 28°. The Carr's compressibility index and Hausner's ratio were found to be 10 and 1.1 respectively. The selection of carrier and coating material on the basis of the preformulation parameters and it gives a fine free flowing powder. The formulation was 100% released in 35 min while the pure extract was 100% released in after 70 min based on the in-vitro dissolution study.

E075

Current status of novel vaginal dosage forms for the treatment of trichomoniasis

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Currently, the research on mucosal drug delivery is considered promising for those drugs which have poor bioavailability after oral administration. Although being less frequent as compared to oral route, drug administration through vaginal mucosa is considered to be more prominent as it surpasses the first pass metabolism, having low enzymatic activity and is highly permeable to many of the drugs with easy insertion. The vaginal drug administration can be used for both local as well as systemic effect, such as for hormone replacement therapy, treatment and prevention of genital diseases and also in vaginal infections. Trichomoniasis is one of the non-viral, sexually transmitted vaginal infection. Earlier for the treatment if trichomoniasis betadine flush was used after that vaginal tablet of metronidazole and also combination therapy has been used for the same. Creams and gels, pessaries, ointments, capsules are some of the conventional dosage forms that have been developed till now for vaginal drug administration. However, it requires novel dosage forms such as foams, films, vaginal rings, implants can also be formulated for better results. For effective and prolonged vaginal administration, various agents such as mucoadhesive polymers, permeation enhancers and solubility-enhancing agents can also be used in the formulation. These novel dosage forms were developed to provide controlled release, reduce dose frequency, better compatibility and improved bioavailability. The current review highlights the status of these novel dosage forms for the treatment of trichomoniasis.

E076

Self-emulsifying drug delivery system: An approach to deliver lipophilic drugs

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Self-emulsifying Drug Delivery System (SEDDS) can be considered as the best option to formulate a BCS class II drug. Various oils, surfactants and co-surfactants are tested for solubility of the drug. The selected oil, surfactant and co-surfactant are analysed for emulsification ability by constructing pseudo-ternary phase diagrams. The self nano-emulsifying pre-concentrate are prepared and evaluated for droplet size, self nano-emulsification time, in-vitro drug release study. The selected excipients are optimized using a mixture designs as the relative ratio of the excipient are important and not the absolute amount. The developed liquid formulation can be filled into a soft gelatin capsules or can be converted to solid dosage form so as to increase stability of the same. The SEDDS is proved to be a fruitful approach for dissolution enhancement of drugs with log P greater than 4 where dissolution is a rate limiting factor in bioavailability. Hence it was concluded that SEDDS can be exploited for bioavailability enhancement of the poorly water-soluble drugs and the marketed products like Sandimmune® and Neoral® are the evidence for the same

E077

Thermal and in silico techniques for screening of appropriate Coformer in the manufacturing of Pharmaceutical cocrystal

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Pharmaceutical cocrystallization is a process through which two molecules are combined in a homogenous phase in a specific stoichiometric ratio. The cocrystallization process gained attention from pharmaceutical manufacturing industries in the virtue of enhancement of solubility and bioavailability of BCS-II and BCS – IV drugs. The selection of proper coformer in preparation of cocrystal is time-consuming and in vain of money. The present study aims to define and validate the appropriate method for the selection of coformer. Our special emphasis is on the design and validates the cost-effective method for screening of coformer. Efavirenz an antiviral BCS- II drug and a set of seven coformer were screened through the thermal and *in silico* technique. The predicted screening results of the thermal technique exhibit the formation of three cocrystals of efavirenz whereas the *in silico* technique explores the possibility of the formation of H- bond between the coformer and API. The thermal method of screening was performed by utilization of differential scanning calorimetry (DSC) and *in silico* techniques involving the application of CCDC GOLD software.

E078

Statin Nasal Spray for Covid 19 Infection

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The COVID-19 has become a serious threat to global health. Unfortunately, no particular drug has been validated for the treatment of COVID-19 other than symptomatic treatment. In such a situation, repurposing an existing drug in better formulation would be most beneficial. Patients with COVID-19 have an increased risk of cytokine storm and cardiovascular complications. SARSCoV2 enters the human body mostly through the nose and mouth, where it infects the mucosae on its way to the pulmonary tissues. As a result, the oral and nasal mucosae serve as the primary routes and reservoirs for viral particle aerosolization into the external environment, and results infection transmission. So, by administering statins through nasal route via nasal spray will directly allow the drug to show its fastest onset of action with less Side-effect and less daily dosage than oral. Statins are known for their antilipidemic property. Statins have been shown to have antimicrobial, antiviral, antifungal, anti-inflammatory, immunomodulatory, and antioxidant properties So, using Statins (ACE inhibitor) in nasal spray for treatment will inhibit the corona virus to enter through the ACE2 receptor and downregulates cytokine storm. Statins may plan in protecting innate immune responses to viral respiratory infections (including to SARS-CoV) through inhibiting the MYD88 pathway. In addition to that, its Anti-inflammatory, anti-thrombotic effect, will improve endothelial function in the covid-19 patients. It will also prevent cardiovascular complication in covid patient.

E079

Solid Dispersion: A Solubility Enhancement Strategy

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Solid dispersion has become a well-established solubilization method for weakly water-soluble medications. The drug-polymer interaction is the defining factor in the design and performance of a solid dispersion since it is essentially a two-component drug-polymer system. The creation of solid dispersions as a feasible way for increasing the bioavailability of poorly water-soluble pharmaceuticals overcame the constraints of previous efforts including salt production, cosolvent solubilization, and particle size reduction. Solid Dispersion is prepared by various methods and it is more cost-effective and efficient as compared to conventional dosage forms. When preparing solid dispersions, a few elements must be considered, such as carrier selection and physicochemical characterization methods. In this, we especially emphasize on Spray drying method for changing the Crystalline form of the drug into its amorphous form. The amorphous form of any drug has greater solubility and bioavailability as compared to the crystalline form because they have no crystal structure in amorphous. It is not necessary for medications in solid dispersion to be micronized. A small amount of the drug may molecularly disperse in the matrix, resulting in a solid dispersion. The carrier dissolves when the solid dispersion is exposed to watery solutions, and the medication is released as fine colloidal particles. Poorly water-soluble medicines have a higher dissolving rate and bioavailability as a result of the increased surface area. So, solid dispersion is a method that is used to enhance the solubility of BCS class II and IV drugs. And spray drying is the best, most efficient technique which we can use to prepare solid dispersions.

E080

Approaches for Targeted Drug Delivery in Treatment of Colon Cancer

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Colon Cancer is the third most common diagnosed cancer with second most mortality rate worldwide. Surgery and Radiotherapy are the first approach for colon cancer treatment, chemotherapy is included at the higher stage of colon cancer. Chemotherapeutic agents are delivered through traditional dosage forms. This conventional chemotherapy shows high toxicity, side effects and less specificity towards site of action. Advancement in targeted drug delivery systems can reduce the toxicity and side effects, this approach helps chemotherapeutic agent to accumulate at disease site and improve the drug efficacy. In this review different targeted approaches are discussed like Conventional approach, Integrated approach, Receptor based approach and Targeted nano drug delivery approach. Targeted nano drug delivery is a novel approach with more advantages. This system protects chemotherapeutic agent from degradation and release of drug in upper GI Tract region. By Active and Passive targeting, nano formulation exhibit site specific release of drug and lead to increase in cytotoxicity. Drug loading capacity is high in nanoparticles so it reduces the dosing frequency and dose of treatment. This work provides discussion of current therapy, conventional approach, as well as investigated Nano formulation approaches for treatment of Colon Cancer.

E081

Development and Optimization of Oral Paediatric Suspension For Adjunctive Treatment of Epilepsy

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The objectives of the present investigation were to formulate the flocculated suspension of drug X (BCS Class – II category) in the structured vehicle as a pediatric oral formulation, with the desired product characteristics like robustness, stability, as well as, pharmaceutically and therapeutically equivalent to the reference listed product. Drug X a non-competitive AMPA glutamate receptor antagonist is indicated as adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in children patients with epilepsy. The preliminary batches were formulated by varying the type and concentration of the suspending agent/wetting agent (i.e. Avicel, poloxamer), anti-foaming agent (simethicone), sweetener(neosorb), preservatives, buffers, etc.with an aim to screen the excipients. Formulations characterized for stability (i.e. sedimentation behavior, viscosity, particle size distribution, etc.) and drug release to match the innovator product as a quality target product profile (QTPP). The quality-by-design approaches were employed for systematic optimization of critical process parameters (CPP) to obtain a product with critical quality attributes (CQAs). The experimental studies revealed that the poloxamer 188 as a surface-active agent and the method of homogenization played an important role to obtain desired product characteristics. An increase in the concentration of the avicel was able to reduce the sedimentation rate; whereas homogenization time had helped to reduce the particle size, uniform mixing and reproducible drug release rates. The Final optimized formulation was also characterized for the accelerated and long-term stability study, and the results were found satisfactory; and were comparable to that of innovator reference standards.

E082

Solid-Lipid Nanoparticles as Drug Delivery Carriers for The Treatment Of Breast Cancer

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Breast cancer (BC) is the most prevalent and deadliest cancer in women around the world. Surgery, followed by chemotherapy or radiotherapy, is currently the gold standard for breast cancer treatment. Chemotherapy and radiotherapy have frequently failed to increase the survival rate in BC due to side effects and increased toxicity levels in normal tissues and organs which has also disrupted day to day life of patients. Nanoparticles (NPs) are considered promising candidates for targeting and site-specific delivery. They possess bioavailability while reducing the associated risks. Among various nanoparticles, Solid lipid nanoparticles (SLN) are the most proven nanocarriers in the treatment of breast cancer. Low toxicity, high drug bioavailability, adaptability in incorporating hydrophilic and lipophilic medicines, and large-scale production feasibility are all advantages of SLNs. Furthermore, SLNs are capable of overcoming physiological barriers that prevent medication delivery to tumours, as well as escaping multidrug resistance mechanisms that are common in cancer cells. SLN enhances the targeted drug delivery by using passive targeting which benefits from the tumour microenvironment and active targeting that include modifying the surface of SLNs and co-delivery mechanisms. SLNs-mediated DDS as alternatives to traditional BC treatment techniques in this paper. It highlights the importance of SLNs-mediated DDS and serves as a roadmap for finding the best methodology for future targeted drug delivery for effective BC therapy.

E083

Natural Product-based Nano-Pharmacotherapeutics for Management of Chronic Wounds

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Wound healing process involves an intricate series of well-orchestrated cellular and biochemical phenomena to reinstate skin and subcutaneous tissue integrity. Numerous phytoconstituents and plant extracts are promising agents for wound healing owing to the ease of access, presence of diverse active components, and their limited side effects. Currently, several efforts have been made for developing novel wound dressings to meet the required conditions for the treatment of chronic wounds. Numerous studies have been performed to evaluate the wound healing potential of natural products with antioxidant, anti-inflammatory, pro-collagen synthesis, and anti-bacterial properties. Development of nanotechnology-based products can significantly improve the wound healing potential of natural products. Several pharmacological targets are included in the wound healing effects of natural based nanostructures such as suppression of inflammatory cytokines production, enhancement of antioxidative enzymes and reduction of oxidative factors, promotion of neovascularization and angiogenic pathways via increasing the expression of fibroblast growth factor, platelet derived growth factor, and vascular endothelial growth factor. Furthermore, nanostructure of plant extracts and phytochemicals will provide advantage of increased bioavailability, provide sustained release to the wound site, as well as enhance the permeability. Overall, several studies have represented that various natural compound when used in nano-formulations, have demonstrated more efficiency in management of wounds and thereby can be an excellent therapeutic approach for chronic wounds.

E084

Formulation and optimization of Dispersible Tablet for the treatment of Pulmonary Arterial Hypertension

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Formulation of drugs into patient acceptable form is the most basic requirement in this emerging era. In order to get the desired effect the drug should be delivered to its site of action at such rate and concentration to achieve the maximum therapeutic effect and minimum adverse effect. The major aim of the present research was to formulate a Quadrisect dispersible tablet with optimum hardness. Dispersible tablets allow ease in administration to patients who are unable to swallow. Drug X was the first in a new class of drugs: endothelin-receptor antagonists (ERAs). Drug x has shown a reduction in mortality of some forms of Pulmonary arterial hypertension. Hardness is a critical process parameter which directly affects the disintegration time (DT) and splitability. Initial trials were taken with Croscarmellose sodium, due to which there was high DT. The concentration of Croscarmellose sodium was increased from 2% to 4% which comparatively reduced the DT, yet satisfactory results were not obtained. So to overcome this issue first Microcrystalline cellulose (MCC 102) was replaced by Dicalcium phosphate but the problem was decrease in flowability. Finally, Ceolus – UF 702 was used instead of Dicalcium Phosphate. With this excipient, not only better flow but DT was also reduced significantly.

E085

Development and Characterization of Telmisartan Immediate Release Tablets.

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Hypertension is a chronic illness characterised by chronically high arterial blood pressure. It is not a disease in and of itself, but it is a significant risk factor for cardiovascular death and morbidity. Telmisartan is a drug that belongs to the class of AT_1 receptor antagonists, which act on the renin-angiotensin system and lead to the eventual decrease in blood pressure. It is an FDA approved, first line drug in the treatment of hypertension. As the drug is a BCS class 2 substance, it is practically insoluble in water and shows soluble behaviour only in a highly basic media. Therefore, here we've developed a method to prepare immediate release tablets of the drug using wet granulation method, and match all the parameters according to the reference tablets. First of all, the reference tablets were evaluated and the critical processing parameters were identified. The prepared tablets were evaluated for appearance, weight variation, friability, disintegration time and dissolution. Optimization of the formula as well as the processing parameters was also done such that it favoured better dissolution, reduced disintegration time and reduction of processing cost. Stability batches were prepared and stability data is being generated according to the ICH guidelines.

E086

Surface functionalized Mesoporous Silica Nanoparticles in Drug Delivery: Future Perspectives

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Novel drug delivery carriers have been proven by the researchers to be a breakthrough point in the delivery of drugs in the recent times. Various nanotechnology have paved the path for the delivery of BCS Class II, IV drugs. Mesoporous silica nanoparticles (MSN) have proven to be a versatile nano-delivery method due to its honeycomb- like structure and large surface area, high drug loading capacity and adsorption of drug molecules into the carrier matrix. The silanol groups present on the surface of the particle aids in its targeted delivery to various receptors. Functionalization plays an important role in modifying the physico-chemical properties of MSNs which can also help in improving the drug loading capacity, solubility and binding to the receptor site. pH, temperature, etc sensitive delivery can be attained by doing so. Over the last decade, there has been a positive increase in the rate of research on MSNs as drug vehicles for various therapies indicating its potential benefit in the long run. The drug incorporated in MSNs can be delivered through almost all routes. In the present review, the manufacturing process with surface functionalization of MSNs and their applicability in various drug delivery system have been discussed at length.

E087

Regulatory requirements and life cycle management of parenteral products in ASEAN countries

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There are different countries in the world and each and every country has own regulations and requirements. So main thing is to understand the process of specific region and how it is different from another when it comes to regulations. ASEAN region includes the 10 different countries like Singapore, Cambodia etc. parenteral products has more efficacy and high bioavailability then the other forms like tablet, capsules. Proper regulations are required for registration. Pharmaceutical market of ASEAN countries are rapidly growing also their regulations changes very rapidly so life cycle management protocols are required to maintain parenteral products in these countries. The regulatory environment is similar among all countries. But still requirements and process of registration is varying among countries of ASEAN region. The goal of this study is to get knowledge about registration and regulations across ASEAN nations. Singapore and Malaysia are the only ASEAN nations with well-established pharmaceutical rules that are more stringent on product quality and safety. Small companies are having good opportunities in the ASEAN market.

E088

Novel Technique for Taste Masking of Bitter Drug Levocetirizine Dihydrchloride

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The orally disintegrating tablet is an attractive and novel dosage form in which the drug disintegrates or dissolves in the buccal cavity. Designing these dosage forms has been limited by the unpleasant taste of the drug substance. Levocetirizine Dihydrochloride, an antihistaminic drug, is white, crystalline, water-soluble powder used for the relief of symptoms associated with allergic rhinitis in adults and children 6 years and above. The taste of levocetirizine dihydrochloride is generally bitter. The objective of the study was to develop & evaluate the taste masked Levocetirizine Dihydrochloride orally disintegrating tablets. The study design involved direct compression method to formulate orally disintegrating tablets using coated Levocetirizine dihydrochloride using a pH-independent water insoluble polymeric dispersion of Ethylcellulose "Surelease E-7019040" in combination with pH-independent water-soluble polymeric dispersion of Hypromellose "Opadry YS-1-19025-A" as a pore former in different ratios to mask bitter taste of the drug. To determine effective masking of bitterness of the drug, in vitro and in vivo evaluation were performed. Uncoated and coated drug substances and prepared tablets were evaluated for physico-chemical properties such as flow, compression, Fourier Transform Infrared absorption spectra, Powder X-ray Diffraction, Scanning Electron Microscopy, and in-vitro dissolution, disintegration properties. Result of the study indicated no change in polymeric form of drug post taste masking application however significant retardation in drug release at initial time point was achieved to avoid bitter sensation possibly during its transit through esophageal tract followed by complete drug release in stomach. The study concludes, easy to use and simple technique to mask taste of unpleasant drug followed designing palatable pharmaceutical dosage form with desired formulation properties.

E089

Advances in iron based products for the management of malnutrition

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Deficiency or imbalance in person's intake of nutrient is called malnutrition. 45 % child death worldwide is associated with the malnutrition. Among that the one third of child death is linked to the deficiency of the micronutrient especially zinc , iron and vitamin A. Among the many symptoms of malnutrition , one of the symptom is tiredness all day. This is due to the deficiency of iron. Daily iron supplement is recommended by WHO for iron deficiency anaemia. Though Iron treatment given orally is very cheap, safe and effective, a recent study covering thousands of patients treated with oral iron supplement reported intolerance of the iron therapy. They have reported substantial gastrointestinal side effects in 70 % patient. These will lead to decrease in the adherence of the treatment. There are many formulations available for the management of the malnutrition like tablets, capsules, syrups, cookies. As per our knowledge these conventional dosage form are available in market but cost effective as well as patient friendly formulation containing iron is not available. Also stability and consumer variability related issues still need to be resolved. This provokes need for novel dosage forms like sprinkle granules, jelly, mouth dissolving film, jam etc…The present review focuses on these innovative formulations containing the iron to improve the bioavailability with better patient compliance. Further, review also discusses manufacturing and characterization with future opportunities.

E090

Non-Oral Approaches in the treatment of Parkinson's disease

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Parkinson's disease is the neurodegradative disorder. In Parkinson's disease there is a loss of the neuronal cell because of so many different pathologic factors, environmental factors and genetic factors. These leads to the neuronal loss in the brain that leads to the Parkinson's disease which is characterized by the different symptoms like tremor, rigidity, postural instability, bradykinesia. These symptoms are controlled by the different kinds of the drugs like dopamine agonist, anti-cholinergic drugs, glutamate antagonist and most basic drugs which is levodopa and carbidopa. The symptoms of Parkinson's disease is only controlled and it cannot be cured permanently. There are mainly oral treatments and non-oral treatments. Oral treatments mainly contain tablet and capsules and they are the starting therapy of the Parkinson's disease. Over the period of time this oral therapy becomes ineffective and patient starts experiencing on and off phenomenon also the dysfunction of the gut also been observed so to overcome this kind of problem associated with the oral therapy and levodopa-based therapy alternative treatment like non-oral and non-levodopa-based treatments should be used. These non-oral treatments include the dosage forms based on their route of administrations like transdermal patch, intranasal powder, parenteral injection, intrajejunal infusion and rectal suppositories and many more dosage forms are available which is discussed in this review.

E091

Recent Advances in Nasal Drug Delivery

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Conventionally the nasal route has been used for the delivery of drugs in the treatment of local diseases; however, the last three decade has recognized the importance of the nasal cavity as a potential route for drug delivery, particularly of small molecular weight polar drugs, peptides and proteins. The inability to administer these drugs by routes other than parenteral injection motivated scientists to explore other possibilities such as pulmonary and nasal administration. Advancement in pharmaceutical biotechnology resulted in possibilities for large scale productions of biopharmaceuticals especially proteins and peptides which further motivated the development of nasal formulations. The development of nasal formulation is supported by the recognition of the advantages the nose presents for drug delivery purposes. These include a large surface area available for drug deposition and absorption, highly vascularised nasal epithelium, avoidance of hepatic first pass metabolic, direct access to CNS via olfactory pathway, low enzymatic activity of the nasal epithelium etc. These days, reformulation of existing drugs as nasal products is trending because of the possibilities for the pharmaceutical companies to extend the life cycle of their products. The present review will cover the latest developments in the field during last few years.

E092

Recent Advances and The Emerging Role of Electrospun nanofiber In Cancer Therapy

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Cancer is a malignancy engendering enormous global mortality, steering extensive research for early diagnosis and efficacious prognosis leading to the emergence of cancer sensing technologies for multitudinous biomarkers. Despite great efforts and advancement in the treatment of cancer, tumor recurrence and metastasis remain significant challenges and demand novel therapeutic strategies. So far, many anticancer drugs have been used to treat cancer patients. However, the direct use of anticancer drugs has adverse side effects for patients and several limitations to treat process. Nanotechnology empowered localized cancer chemotherapy has indicated a promising performance for targeting and controlled release of anticancer agents over some time to eliminate local-regional recurrence of cancers and also to improve tissue regeneration during/after treatment. Electrospun nanofiber-based implantable drug-delivery systems are also being established as one of the most effective approaches for localized cancer treatment, improves on-site delivery of anticancer agents, and reduces systemic toxicities and side effects to normal cells. nanofibers prepared by electrospinning method have unique properties such as high surface area, high porosity, suitable mechanical properties, nontoxicity, biocompatibility, biodegradability, bio-renewable, low immunogenicity, better clinical functionality, analog to extracellular model, and easy production on large scale. This article focuses on the recent progress of Electrospun nanofibers in cancer research. The presentation discusses brief introduction of the emerging potential of Electrospun nanofibers in cancer research. Next, several recent advances on the important features of Electrospun nanofibers critical for cancer research are discussed including the incorporation of drugs.

E093

Current Updates on Nano formulation for Gout Therapy-Opportunities & Challenges

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Gout is an increasingly common rheumatic disease. Global studies have found an increase in mean serum urate in both genders during the past four decades. Uric acid is the final product of the metabolism of endogenous and exogenous purine in patients. Gout is a Chronic disease associated with the Intense joint pain, Discomfort, Swelling, Redness and hence NSAIDS are prescribed, NSAIDs are frequently used for treatment of acute and chronic pain conditions. However, their use is associated with serious dose-dependent gastrointestinal (GI), cardiovascular, renal, and hepatic adverse effects, which pose a serious clinical concern for both patients and physicians. These novel nano-based systems can either be therapeutic agents themselves, or else act as vehicles to carry different active pharmaceutical agents into specific parts of the body. Nanotechnology offers multiple benefits in treating chronic human diseases by site-specific, and target-oriented delivery of precise medicines. Owing to their small size and excellent biocompatibility, nanosized polymer therapeutic agents can circulate in the bloodstream for long periods of time, allowing them to reach the target site Nano formulation provides a wide range of engineered nanomaterials, such as polymeric nanoparticles (NPs), lipid-based NPs, liposomes, silica NPs, metallic NPs, etc. Nano formulation-based drug delivery systems exhibit multiple advantages such as the ability to pass through different physiological barriers within the body and specifically deliver drugs to the required sites without affecting healthy cells and tissues. This review will discuss about novel approaches which will hopefully lead to improved management of hyperuricemia and gout, and also to improvements in patient-centred outcomes, even for those who have previously failed to respond to treatment.

E094

Formulation and Evaluation of Three Dimensional (3D) Mesoporous Silica Nanoparticles for Solubility Enhancement of Poor Aqueous Soluble Drug Luliconazole

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Luliconazole is potent BCS class II drug but its dermal action is limited by poor aqueous solubility, lipophilicity, permeability, less retention in skin issues while conventional formulations in market exhibits many drawbacks like burst release of medicament which leads to erythema, burning sensation, itching, pruritis rash and less retention in skin layer and low stability of product. Other traditional solubility enhancement techniques suffer from many drawbacks like they just dump the drug at site of action where it may recrystalize again, presence of high concentration of surfactant, physical and chemical instability with drug, unable to encapsulate all categories of drugs, aggregation and precipitation etc.

The Aim of the proposed work is to develop MSNs and characterize MSNs by modified stober's method then characterised by using particle size analysis, zeta potential, DSC, FT-IR, BET analysis and finally their solubility in water and phosphate buffer 7.4 for 24 hrs were checked. Particle size were found to be in range of 300-400 nm after drug loading and zeta potential were in range of - 28 ± 2.38 mV to - 43 ± 0.96 mV. After drug loading, the specific surface area was considerably decreased from 915.35 m2/g for MCM48 to 416.48 m2/g for drug loaded MSN, showing that drug has been successfully inserted into the MSN mesopores. DSC and FT-IR results concluded that there was no significant interaction between drug and MSN. The BJH–KJS method showed reduction in the pore size and mesopore volume from 0.62 cc/g for blank MCM48 to 0.41 cc/g for drug loaded MCM48. Solubility study showed significant 8 folds higher solubility of drug in water after functionalization than in free drug. These results indicate promising features of MSN as a carrier to deliver low solubility drug with improved bioavailability via the topical route and enhance the solubility and antifungal action of luliconazole and overcome the shortcomings encountered by other delivery system.

E095

Development and Characterization of Nano - Drug Delivery System for the Treatment of Tuberculosis

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Despite potentially curative pharmacotherapies being available for over 50 years, tuberculosis (TB) remains the leading cause of preventable deaths and endemic in developing countries. As per World Health Organization (WHO), India ranks first for global burden of TB, with an account of 26%. Bio-distribution properties of anti-tubercular drugs (ATDs) are challenging since they are responsible for requirement of daily administration. The oral delivery of anti-tubercular drugs remains challenging, despite being the most compliant route of administration. The main aim of current investigation demonstrates development of drug loaded solid lipid nanoparticles (SLNs) comprising of first line anti-TB agent. Both formulation variables (concentration of drug, concentration of surfactant, concentration of emulsifier) and process variables (stirring speed, homogenization cycles, homogenization pressure) were screened for the development of SLNs. Further, the developed drug loaded SLNs were characterized for particle size, polydispersity index (PDI), zeta potential (ZP), % entrapment efficiency, % drug loading, etc. The results of the study revealed that the concentration of drug, concentration of emulsifier, and homogenization cycle mainly affects the particle size, %EE and %DL.

E096

Novel Luliconazole Spanlastic Nanocarriers: Development and Characterisation

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The aim of the current study was to enhance the dermal delivery of luliconazole, an antifungal drug through spanlastic vesicles. A 2^3 regular factorial design was employed, using the Design Expert® software. The independent variables chosen were Span: Edge activator ratio, type of Edge activator and sonication intensity and their effect on the dependent variables i.e. particle size and entrapment efficiency were determined. Spanlastics were formulated by ethanol injection method using Tween 80 as an edge activator. Spanlastics were found to possess size in the nano range with entrapment efficiencies between 77- 88% with optimum zeta potential and polydispersibility index indicating a stable formulation. Differential scanning calorimetry, X-ray diffraction and Fourier transform infrared studies revealed complete encapsulation of the drug within the elastic carriers. Spanlastics were further incorporated into a gel base and were evaluated for homogeneity, viscosity, spreadability, *in-vitro* release and skin irritation studies. The flux values obtained for luliconazole entrapped in the vesicular spanlastics (0.2292 mg/cm2.h) was also found to be higher than that of the marketed (0.1302 mg/cm2.h) and conventional gel (0.1122 mg/cm2.h). Moreover, the optimized gel formulation also possessed a greater antimycotic activity against *Candida albicans*. The spanlastics loaded hydrogel formulation was found to have a greater zone of inhibition in comparison to the marketed formulation, thus proving to have optimum anti-fungal activity against *Candida albicans*. Collectively, the results revealed that, spanlastics could be a potential nanocarrier for well-controlled delivery and for targeting deeper skin layers thus providing new opportunities for dermal treatment.

E097

Multifunctional Surgical Sealant: A Surface Modified Fiber Reinforced Nanoporous Multifunctional Scaffold for Biomedical Applications

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The present study aims to develop surface-modified multifunctional cotton fibers reinforced nanoporous scaffold for different biomedical applications. The scaffold is composed of randomly arranged cotton fibers as dispersed phase (Dp) and nano thickness film-forming tissue regenerative composition as continuous phase (Cp), which was composed of a mixture of chitosan (0.5%) and PVA (0.5%). The scaffold was developed by the cryodesiccation method (48 h). The composition can surface coat the dispersed phase and interconnect the fibers, resulting in the formation of the nanoporous scaffold. Further, the surface was modified by attaching ultra-fast dissolving film (UFDF) to the surface of the scaffold. FESEM was used to study the morphology of the developed scaffold, and uniformity of the drug distribution was studied by FTIR imaging. The pharmacodynamic activity of the developed product was studied in the excision wound model (12 mm wound size) on rats. The scaffold's hemostatic ability was studied using the liver injury model and the rabbit super facial ear artery injury model. The results obtained from various in vitro studies showed, pore size <5 nm, film thickness ranges from 400 to 1000 nm. The scaffold was hygroscopic; no hemolysis was observed in the presence of the scaffold. The developed scaffold intensified the wound healing process and resulted in quick wound healing in 10 days from the wound induction. The histopathology of skin samples showed thick epidermis, granulation tissue, angiogenesis, fibroblast proliferation, and collagen disposition in the treated group. We conclude that the developed scaffold can intensify hemostasis and tissue regeneration and be used as a wound dressing material for open wounds or foot ulcers.

TRACK-F

PHARMACEUTICAL CHEMISTRY

F001

Design of Some Benzimidazole Derivatives for Antifungal activity: An *Insilico* Study

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More than 1.5 million people are killed due to fungal infections and over a billion people get affected. Nevertheless, they remain a neglected concern for public health officials, although the majority of deaths from fungal diseases can be prevented. When compared to treatment options available for bacterial infections, the therapeutic options for fungal infections are limited. Currently, only three drug classes are used in clinical practice for fungal infections. Also, in the last 30 years only one new category of drug has been invented. Benzimidazole is a class of heterocyclic aromatic organic compound which possess pharmacological activities including antifungal, antitumor etc. The study's objective was to perform the *in-silico* drug design and molecular docking of some benzimidazole derivatives for antifungal activity and compare the derivatives with the standard drug Ketoconazole. Comparison of derivatives docking scores with Ketoconazole showed that the derivatives exhibited a greater binding strength to the chosen proteins.

	5ESG		5ESM		5ESI	
Structure	CDE	CDIE	CDE	CDIE	CDE	CDIE
2-(chloromethyl)-5-methyl-benzimidazole	19.5458	22.8988	17.1007	20.4637	14.0416	17.5002
5-bromo-2-chloromethyl benzimidazole	18.4672	22.3552	20.3209	23.992	20.0818	23.9603
2-(chloromethyl)-4,5-dimethyl benzimidazole	18.9818	23.3467	20.7660	24.9263	21.4308	25.5113
2-(chloromethyl)-4-methyl benzimidazole	17.3000	21.6862	17.5272	20.9952	17.4488	20.7679
4-bromo-2-chloromethyl benzimidazole	17.6675	22.6273	18.1239	22.3651	19.5579	23.8939
2-(chloromethyl)-4-fluoro-benzimidazole	11.4323	16.2301	11.5253	16.1806	16.0872	20.8733
2-(chloromethyl)-4-cyano-benzimidazole	17.5794	21.4091	18.6310	22.8956	17.3514	21.8616
2-(chloromethyl)-4-nitro-benzimidazole	14.9868	22.8106	8.8416	16.7218	15.5148	22.9859
Ketoconazole	30.1681	54.7465	31.2463	56.7017	32.7041	57.9578

CDE- CDocker Energy

CDIE- CDocker Interaction Energy

F002

Design & identification of novel 2- benzoxazolinone derivatives as potential candidates for the management of Type-II diabetes through molecular docking studies

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Diabetes mellitus is observed to be a serious metabolic issue for ages and the current treatment for the disease is associated with some serious side effects, and henceforth there is a need to find new potent therapeutic agents with high potency and fewer side effects. In this report, we present a novel class of benzoxazolinone derivatives involved with inhibitory activity against membrane bound ATP-sensitive potassium channels. 2-benzoxazolinones (BOA) is a molecule of interest due to its origin from nature & diverse pharmacological importance. This research is based on identification of 2- benzoxazolinone derivatives by studying the SAR via varying electron donor, electron withdrawing and other possible substitution that could potentially emerge as a successful clinical candidates for the treatment of type-2 diabetes. The structures were designed &analyzed by molecular docking software; Auto dock vina. The designed molecules were also analyzed by molecular modeling software, in order to resemble the highest binding affinity molecule with selected protein (5yw7) ATP-sensitive potassium channel bound with Glibenclamide as a drug target. The research methodology included downloading A Pdb for insulin protein(5yw7) from protein data bank Thereafter a protein-ligand docking with Auto dock-Vina by using following steps: 1.Ligand and Protein Set up 2. Mapping of the binding site 3. Docking & 4. Analysis.. we synthesized Five derivatives based on their binding scores i.e. 1b, 1d, 1g, 1h & 1J (-6.8, -7.1, -6.7, -7.4, -7.2). After the docking studies all the best scored molecules were further investigated for In silico Toxicity and ADME predictions which revealed the non-carcinogenicity, good absorption as well as solubility characteristics through substrate binding sites & drug-likeness of the selected compounds. The selected compounds showed better-calculated lipophilicity (iLogP) was found to be 0.76 to 1.88.

F003

Antimicrobial study of dimethoxyphenyl substituted pyrazolo [3,4b]quinolin-5-one

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In this work, we synthesised twelve dimethoxyphenyl substituted pyrazolo[3,4-b]quinolin-5-one 4(a-f) and 5(a-f) via one-pot synthesis. One-pot synthesis of dimethoxyaldehydes 1(a-c), 1,3-cyclic diones 2(a-b) and 5-Amino-3-methyl-1-phenylpyrazole 3 produced 4(a-f). While 5(a-f) were produced via areal oxidation of 4(a-f). Structures of 4(a-f) and 5(a-f) were confirmed by 1H-NMR, 13C-NMR and HRMS analysis. Then they were evaluated by antimicrobial activity. Antimicrobial activity was carried by broth microdilution method against two gram-positive bacteria: S.Aureus, S.Pyogenus; two gram-negative bacteria: E.Coli, P.Aeruginosa and three fungal strains: C.Albicans A.Niger A.Clavatus.1 Ampicillin, Chloramphenicol and Ciprofloxacin were used as standard drug for antibacterial activity whereas Nystatin and Greseofulvin were used as standard drug for antifungal activity. Results of the antimicrobial study displayed that all compounds have good antibacterial activity. 5a and 5b displayed the highest antibacterial activity with MIC value of 12.5 μg·mL−1 against gram-positive bacteria S.aureus and S.pyogenus, respectively. In addition, all compounds were tested against M. tuberculosis H37Rv in L. J. Medium (L-J agar method).1 For this antitubercular activity, Isoniazid & Rifampicin were used as standard drugs. This antitubercular activity of 4(a-f) and 5(a-f) displayed that compound 5c have the highest antitubercular activity with MIC value of 12.5 μg·mL−1 against H37RV tubercular cell line. Furthermore, 5a, 5b and 5c, were evaluated for drug-like properties by Lipinski's,2 Ghose's,3 and Veber's4 rules. Required physicochemical properties were calculated using a property calculator available at an online drug discovery platform:https://mcule.com. Results show that 5a, 5b and 5c comply with drug-likeness properties.

F004

Design, synthesis, ADMET, Molecular dynamics, and biological evaluation of some PPAR-γ Partial Agonist as Insulin Sensitizers

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Diabetes, a metabolic disease that affects around 463 million people worldwide, is anticipated to rise to 700 million by 2045. Weight gain and hepatotoxicity are the most common side effects of oral hypoglycemic agents (e.g., thiazolidinedione). This research aims to develop a series of new PPAR-γ partial agonists with improved insulin-sensitizing properties with fewer adverse effects. Newly designed compounds were synthesized using a suitable synthetic route (2-actyl furan used as starting material), and their structures were confirmed using different spectral analyses (IR, 1H NMR , 13C NMR, Mass spectroscopy and Elemental analysis). The compounds were subsequently tested for their insulin-sensitizing property and toxicity. Molecular modelling tools (Maestro integrated with Schrodinger Suite) were used to investigate their specific selectivity towards the PPAR-γ receptor (PDB: 5Y2O). The insulin-sensitizing properties of all the synthesized compounds ranged from moderate to excellent. Furthermore, compared to the standard drug pioglitazone, one synthetic molecule, TZ5, displayed remarkable antidiabetic action by lowering blood glucose levels. It was promising to note that all the tested compounds have displayed no significant liver toxicity due to the partial activation of the PPAR-γ receptor. Compound TZ5 demonstrates hydrogen bond interaction with SER342 amino acid in molecular docking studies (Docking score -7.98), which is an important property for PPAR-γ partial agonism and maintains the same interaction throughout the 100ns molecular dynamics simulation study (Desmond in Maestro integrated with Schrodinger Suite). According to histopathological investigations of the organs and regular bodyweight monitoring, compound TZ5 is found to be less toxic. Further, the structure-activity relationship study reveals that the modified head and tail portion of the compounds significantly improves antidiabetic effectiveness. In conclusion, synthesized compound TZ5 can be developed further as a safer insulin-sensitizing agent with fewer adverse effects.

F006

Design and Molecular modeling study of Novel Imidazole and Pyrimidine based Schiff Bases to find potential hits against fungal Biofilm

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We designed series of Imidazole and Pyrimidine Schiff bases on the basis of Bioisosteric replacement principle when validation for druglikeness using FAFdrug4 online tool for ADMET prediction suggests that most of them have excellent pharmacokinetics properties, Low toxicity and most of them following the Lipinski rule of five. The inhibition potential of the designed hits when predicted using AutoDock Vina and then compared with standard drug Fluconazole suggesting that designed top hits has similar potential that as of standard drug. The top docked hits MIMD9, MIMD13, MIMD5, MIMD4, MIMD10 of Imidazole series and MPYM3, MPYM7, MPYM6, MPYM4, MPYM8 from Pyrimidine series against fungal drug target secreted aspartic proteinases (Sap5) signifying they have free energy of binding in between -6.50 to -4.50 kcal/mol and they forming intense network of conventional hydrogen, carbon hydrogen, van deer waals and π interactions as that of standard. The current work will be excellent attempt to employ freely available platforms of computer aided drug design and discovery for the quest of Novel Schiff bases (SBs) that has very high selectivity, No drug or multidrug resistance that is ultimate goal of current drug design and discovery process.

F008

AKT's Role and Significance in Cancer Treatment

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According to the research, cancer is caused by a combination of factors. Cancer is caused by a variety of circumstances. It could be due to environmental influences, hereditary reasons, or the individual's constitution. Cancer is currently the world's greatest hazard to human health. The diagnosis of the condition and tailored treatment with minimal side effects are the key challenges. Because of the high prevalence, significant efforts are being made to improve strategies for diagnosing the disease, preventing metastasis, and treating it. The present anticancer medication development and research is mostly focused on targeted medicines that are used to stop cancer from progressing, growing, or spreading. Protein kinase B, also known as AKT, is a therapeutic target in cancer treatment. Akt-1 is engaged in cellular survival pathways, whereas Akt-2 is involved in insulin signaling. Akt-3 is a protein that is found in the brain. Many medications targeting the PI3K/AKT pathway are being tested in clinical trials for solid and haematological malignancies, either alone or in combination. The focus of the development of AKT inhibitors as a potential anticancer chemotherapy or in combination with radiation, or other targeted therapy.

F009

Molecular modelling investigation of inhibitors of PIM-1 kinase triazolo-pyridazines as anticancer agents: 3D-QSAR, molecular docking and dynamics simulation studies

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PIM kinases are the members of the class of kinase family serine/ threonine kinases which plays a crucial role in the cancer development. As there is no drug in the market against PIM-1 kinase has transpired as a budding and captivating target for discovery of new anticancer agents targeting PIM-1 kinase. The current research pondered on development of new PIM-1 kinase inhibitors by the application of ligand based drug discovery approach and structure-based drug discover approach involving 3D QSAR (Vlife MDS), molecular docking (Glide suite of Schrodinger package) and dynamics simulation (GROMACS). In this study, association allying the structural properties and biological activity was undertaken using 3D-QSAR analysis. The 3D-QSAR model was generated with help of 35 compounds from which the best model manifested an appreciating cross validation coefficient (q2) of 0.8866 and conventional correlation coefficient (r2) of 0.9298 respectively. Moreover, value of predicted correlation coefficient (r2 pred) was obtained as 0.7878 respectively. The molecular docking analysis demonstrated that the analogs under analysis occupied the active site of PIM-1 kinase receptor (PDB ID: 4A7C). Interactions with Lys67 in the catalytic region, Asp186 in the DFG motif and Glu171 were noticed with numerous compounds (T24, docking score: -7.196 and ki value: 10 nM). The molecular docking of the compounds was compared with the standard molecule ETP46546. Furthermore, the molecular dynamics simulation study stated the ligand portrayed the strong conformational stability within the active site of PIM-1 kinase protein forming maximum two hydrogen bonds until 50 ns respectively. Overall outcomes of the study revealed that applications of the ligand based drug discovery approach and structure-based drug discover strategy conceivably applied to the discovery of new PIM-1 kinase inhibitors as anticancer agents.

F010

Discovery of Selective, Nontoxic CDK2 Inhibitor with the Aid of Ligand Based and Structure Based Drug Design Approach

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In the present research work, initially potent CDK2 inhibitors were selected for the pharmacophore based scaffold hopping. Further, pharmacophore was generated and virtual screening was carried out through the ZINC database which provided 18,021 molecules. For the efficient screening, structure based approach was adopted. In this approach, five hits obtained through the virtual screening were taken for the molecular docking and dynamics study. Through this study, one of the hit molecule showed appropriate and similar binding interactions as that of the standard co-crystallized ligand of the CDK2. Further, this hit molecule was modified to mitigate the toxicity effects of the designed CDK2 inhibitor through the in-silico ADMET study. This designed CDK2 inhibitor was taken for the molecular docking assisted simulation study where all the required parts for the CDK2 inhibition were identified. Additionally, this crucial parts of the designed molecule required for the CDK2 inhibition were identified with the aid of Lee Richard contour map analysis. In future, this novel CDK2 inhibitor could be explored for the synthesis and biological evaluation.

F011

PI3K/Akt/mTOR A Novel, Prominent Oncological Pathway For The Treatment Of Triple Negative Breast Cancer: A Review

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Triple-negative breast cancer (TNBC) represents roughly 10-20% of all breast cancer cases. Despite the fact that there have been progresses in the treatment of hormone receptor-positive and human epidermal growth factor receptor 2-positive breast cancer, designated treatments for TNBC stay inaccessible. A brief overview of the biological actions of small molecule compounds that target breast cancer had been attempted. TNBC has a lot of PI3K/AkT/mTOR pathway mutations. TNBC suppression by targeted medicines is predicted by these abnormalities, according to preclinical studies. In a newly published phase 2 clinical trials. An AkT inhibitor (ipatasertib) coupled with paclitaxel in the first-line scenario improved outcomes in a subset of patients with metastatic TNBC. In addition, novel drugs with different specificities and potencies are being developed to target various PI3K/AkT/mTOR components and cognate molecules (e.g., mitogen-activated protein kinase). These drugs have a wide range of toxicity profiles and early efficacy signals, which must be addressed before novel drugs are advanced to later stages of clinical trials. The improvement of medications focusing on the PI3K/AkT/mTOR pathway for the therapy of TNBC is an advancing field that should consider the efficacy and toxicity of novel therapies, as well as their interactions with other cancer pathways.

F012

Insights into the structural features of anticancer 1,6-naphthyridines and pyridopyrimidines as FGFR inhibitors: 3D-QSAR, Molecular Docking and Dynamics studies

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Fibroblast growth factor receptor (FGFR) plays a vital role in tissue regeneration, angiogenesis and embryogenesis. 3D QSAR and molecular modelling methods are widely used for designing novel compounds for determination of inhibitory activity against the biological target. In the present study, 3D QSAR (CoMFA and CoMSIA) analysis was performed on 1,6-naphthyridines and pyridopyrimidines as potential FGFR inhibitors as anticancer agents1. The best CoMFA and CoMSIA models were generated from test and training set derivatives with leave-one-out correlation coefficients (q2) 0.591 and 0.667, cross-validated correlation coefficients (r2cv) 0.584 and 0.652, conventional coefficients (r2ncv) 0.978 and 0.975 respectively. Both the models were validated by a test set of 12 compounds providing acceptable predictive correlation coefficient (r2pred) 0.61 and 0.68 for both models. The generated CoMFA and CoMSIA contour maps were used to design novel 1,6-naphthyridine analogs. Molecular docking (Glide suite of Schrodinger package) studies indicated that the compound 75 (docking score: -8.99, ki: 8.397) and 29 occupied the active site of the FGFR-4 kinase (PDB: 4UXQ) interacting with Glu520 in catalytic region, Asp630 in the DFG motif and Met524 in the hinge region. The molecular docking of the most active compound 75 was compared with the standard marketed drug Ponatinib (docking score: -7.88). The molecular dynamics simulation analysis (Desmond suite) revealed that the inhibitor 75 displayed binding stability in the active site of the FGFR-4 by making two hydrogen bond and one π-cation interactions2. Collectively the outcome of the study suggested that the applications of ligand based and structure based approaches can be applied for the discovery of new FGFR-4 inhibitors as anticancer agents.

F013

Computational Exploration, Synthesis and Screening of Glun1-1a/NMDA Antagonists: Potential Ligands to Treat Epilepsy

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GluN1-1a/NMDA receptor has known as potential target for the treatment of epilepsy. Herein, we have employed multiple pharmacoinformatic methods to identify selective GluN1-1a/NMDA antagonists using Schrödinger software (1). A potent set of quinoxalines were used for generation of 3D-QSAR model and validated by chemometric protocols such as cross validation, decoy set and Y-randomization test. The validated 3D-QSAR model was used to screen virtual hits from ZINC database by pharmacophore mapping and docking process (PDB: 1PBQ, 2). PubChem and SciFinder search tools were employed to arrive atpotential leads as GluN1-1a/NMDA antagonists (3). We have synthesized sixteen different 2-((7-chloro-4-oxoquinazolin-3(4H)-yl)amino)-N-substitutedphenylacetamides and evaluated for antiseizure activity. A single step one-pot method for synthesizing substituted quinazolinone in presence of p-toluene sulfonic acid was carried out. N-alkylation reaction between quinazolinone and 2-chloro-N-(substituted phenyl) acetamides afforded targeted compounds. Synthesized compounds were characterized by different spectral methods. Compound 3d emerge as archetype with excellent action in mice against electroshock, chemically induced and pharmaco-resistant 6Hz preclinical seizure models with no symptoms of neurotoxicity and hepatotoxicity (ED50 = 21.7 mg/kg, MES; ED50 = 29.2 mg/kg, scPTZ; ED50 = 33.9 mg/kg, 6Hz; TD50 = 325.9 mg/kg; docking score = -8.47). Phenytoin, carbamazepine and ethosuximide are used as standards. Active compound 3d have shown good binding affinity at crucial amino acids of NMDAR and fit adequately in cavity of receptor. Promising antiseizure activity, through computational studies and no toxicity symptoms make us to anticipate emergence of these compounds as valid leads for further chemical optimization as potential ligands to treat intractable epilepsy.

F014

Heterocyclic Scaffold As Promising Telomerase Inhibitors For The Development Of Chemotherapeutic Agent: A Review

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Telomeres as well as telomerase nowadays are the focused targets in treating cancer. Telomerase is a ribonucleoprotein (RNP) responsible for maintenance of chromosomal integrity by stabilising telomere length. This enzyme is being considered as one of the most common factors in almost all cancer cells, that is mainly responsible for regulating the telomere length. Inhibition of telomerase by different heterocyclic scaffold provides a path that leads to a new target for development of cancer therapy. The aim of the review to enlighten the fundamental research on telomeres as telomerase inhibitors with heterocyclic derivatives.

In this literature survey, we sum up late revelations related to the pharmacology of the telomerase inhibitory pathway of different NNRIs and heterocyclic molecules for sum-up evidence of the anticancer agents inhibiting telomerase. The review summarized the inhibitors of the telomerase enzyme and RNA component, heterocyclic derivatives that target and inhibits the transcription and post-transcriptional levels. The detailed discussion regarding the telomerase biology will provide multiple information towards rational anti-cancer drug design. The basic focus of the review is to explore various anti-telomerase therapies and telomerase inhibiting molecules for the treatment of cancer. The purpose of this work is to discuss the challenges behind the development of novel telomerase inhibitors and to identify various perspectives for designing anti-telomerase compounds.

F015

Design of PLK Inhibitors as Potential Cytotoxic Agents

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Polo like Kinase (PLK) is a serine/threonine protein kinase and plays a key role in cell cycle progression and proliferation in cancer cells. It plays a role in anticancer drug resistance and has emerged as an attractive target in anticancer drug discovery. PLK inhibitors are reported to induce apoptosis in a variety of tumor cell lines. Hence there is a need for design and development of PLK inhibitors as potential anticancer agents. In this study, we have used ligands bound to PLK protein which showed nanomolar inhibition of the protein (PDB ID: 2RKU, 2YAC, 3COK, 3FC2 and 3KB7) as a reference to search hits from the Zinc 15 database. PLK protein (PDB ID:2RKU) was prepared for docking using Autodock. 336 potential hit molecules retrieved from Zinc15 database by applying appropriate filters were prepared and docked with the prepared protein by using pyrx 0.8. Autodock vina was used to find the binding poses of the selected molecules into the active site of PLK. Molecules with good binding affinity and favorable interaction with the active site of PLK were identified. These would be subsequently taken up for identification of potential lead compounds that can be synthesized in the laboratory as cytotoxic agents via the PLK inhibition pathway.

F016

In-silico studies- new hits as potential AK inhibitors in cancer

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Aurora kinases (AURK) are serine/threonine protein kinases that play a critical role during cell proliferation. Three types isoforms of AURKs are reported in mammals- AURKA, AURKB, AURKC, and these share a similar C-terminal catalytic domain with differences in their sub-cellular location, substrate specificity, and function. Recent research reports indicate an elevated expression of these kinases in several cancer types highlighting their role as oncogenes in tumorigenesis. Inhibition of AURKs is an attractive strategy to design potent inhibitors modulating this target. The last few years have witnessed immense research in the development of AURK inhibitors with relatively few FDA approvals. In the present work, filters have been applied in ZINC databases, and 400 compounds were selected and virtually screened against the target using Autodock vina in PyRx 0.8 in an effort to identify potential hit molecules. Protein 6C2T: Aurora ligand complex was chosen from the protein data bank (PDB) for conducting molecular docking studies depending on their resolution. Of the 400 compounds, some of these displayed good interaction with the target AK protein. Based on binding score and binding interaction results with AK protein 6C2T, identified hits were further subjected to evaluate their ADME (pharmacokinetic) and drug-likeliness. These screened potential hits can be tested further for biological evaluation as potential aurora kinase inhibitors.

F017

Guanidine-Based β Amyloid Precursor Protein Cleavage Enzyme 1 (BACE-1) Inhibitors for the Alzheimer's Disease (AD): A Review 2006-2021

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Alzheimer's disease (AD) is an irreversible, progressive neurological disorder characterized by amyloid plaques, neurofibrillary tangles, neuronal damage, memory loss, etc. Various factors, such as age, lifestyle, family history, environmental factors, and gene mutation, cause AD. BACE-1 cleaves APP into sAPPβ and C99, a rate-limiting step, and C99 is further cleaved by □-secretase to generate neurotoxic amyloid β plaque. Currently available drugs are ineffective for inhibition of AD progression and provide only symptomatic relief since these drugs do not have target specificity. Thus, BACE-1 becomes an interesting target to prevent or reverse AD progression. The Discovery and development of selective BACE-1 inhibitors have a great potential for the treatment and maintenance of AD. In this review, we have compiled literature pertaining to guanidine-based novel BACE-1 inhibitors for the treatment and maintenance of AD. In the literature review, we found that the guanidine scaffold accomplished the structural features for BACE-1 inhibitors (need HBD atom and hydrophobic group to interact with catalytic aspartic acid residues and large hydrophobic pockets including S1, S2', S3) to bind with BACE-1 enzyme to target AD. We have also discussed the role of BACE-1 substrates, and their crystal structure, BACE-1 inhibitors in the clinical trial, and essential points to overcome challenges associated with the selective development of BACE-1 inhibitors. This paper provides valuable information for the design and discovery of selective new BACE-1 inhibitors over other aspartyl protease enzymes.

F018

Design, Synthesis, Anti-inflammatory Activity and Docking Studies of Pyrimidine Derivatives

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Systemic inflammation, is triggered by microbial infection the result of release of the pro-inflammatory cytokines from immune-related cells and the chronic activation of the innate immune system and often leads to impaired function of the lungs, kidneys or other vital organs and leads to death. Despite recent advances in the approaches to cure condition of inflammation, there are still problems in managing patients with this condition. A novel series of pyrimidine derivatives were designed, synthesized and characterized via different techniques like H1 NMR, C13 NMR and mass spectrometry. Docking and scoring were used for design inflammatory inhibitors and show their binding affinity with active site key residues of receptor. The different new pyrimidine derivatives were synthesized via Petasis reaction. Physical parameters such as Rf values, LogP values, Mpts were also determined and purification of compounds was performed using Column chromatography. All the synthesized compounds were evaluated for their drug like properties using Lipinski's rule of five and also the pharmacokinetics studies were performed. The elucidated synthesized target compounds can be subjected to the biological evaluation as anti-inflammatory candidates because such scaffold have been reported as therapeutically important anti-inflammatory and antitumor agents.

F019

A Review on Discovery of Novel Heterocyclic Agents as PfDHODH Inhibitors and Antimalarial Agents

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The world continuously suffering from a devasting burden of Malaria with significant mortality and morbidity. The appearance of ACT failure in the Greater Mekong Subregion, increase trouble that plasmodium falciparum resistance to all available antimalarial drugs. Plasmodium falciparum dihydroorotate dehydrogenase (PfDHODH) found in inner mitochondrial membrane, catalyzes flavin mononucleotide (FMN) dependent oxidation of dihydroorotate (DHO) to orotate, is a very new and promising target that shown considerable potential in arresting parasite growth at blood and liver schizont stage by inhibiting fourth step of de-novo pyrimidine biosynthesis. This review focuses on new advancements and implications of PfDHODH inhibitors. High throughput screening discovered many heterocyclic scaffolds (such as Triazolopyrimidine, Pyrrole, Isoxazolopyrimidine, Thiazole, Dihydrothiophene, N-alkyl-5- (1H-benzimidazole-1-yl)-thiophene-2-carboxamides) that were used to build selective PfDHODH inhibitors, which covered 10-14 years of literature. Lead optimization of a pyrrole and Triazolopyrimidine series has identified an analogue with good plasma exposure and bioavailability. A hydrophobic resign (aromatic & planner arrangement) and a polar resign were recognized as key features for SAR analysis by the docking result. Phe188 forms π- π interaction, and Phe227 forms edge-to-edge π interaction. His185 and Arg265 play essential roles in polar contacts and amino acid residues involved for van der waals interaction (Gly181, Cys184, His185 Leu189). These findings suggest that PfDHODH is a well-validated target for the development of novel antimalarial drugs. This review provides all the efforts for the development of variety of specific inhibitors classes against PfDHODH and modern and future therapeutic perspective for this target.

F020

A novel 4"-alkyl ether derivative of green tea polyphenol EGCG as potent and selective EGFR inhibitor

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The Epidermal Growth Factor Receptor (EGFR), a transmembrane protein involved in the regulation of signaling pathways, is frequently overexpressed in epithelial tumors. First-second-and third generation EGFR tyrosine kinase inhibitors (TKIs) such as Gefitinib, Erlotinib, Afatinib, Cetuximab and Osimertinib, are clinically approved to treat advanced cancer patients. However, despite significant advances in the development of small-molecule synthetic drugs to treat cancers, resistance to chemotherapy and off-target toxicity often limits their clinical applications. On the contrary, several natural products and their derivatives have been found to exhibit anticancer properties with excellent selectivity. In this study we report the rational design and discovery of 4"-C14 EGCG, a lipophilic derivative of (–)-epigallocatechin-3-gallate (EGCG), which is a major green tea polyphenol as a potent and selective EGFR inhibitor. A series of 4"-alkyl EGCG derivatives have been synthesized and tested for their antiproliferative activities against high (A431), moderate (HeLa), low (MCF-7) EGFR-expressing cancer cell lines and the action mechanism behind the inhibition of EGFR autophosphorylation was explored through western blot analysis, immunocytochemistry and computational approaches, providing valuable clues for the research of antitumor agents based on EGFR inhibitors. Our findings demonstrate that 4"-C14 EGCG can act as a promising potent and selective EGFR inhibitor with improved stability.

F021

Modulating Wnt Signaling Pathway: Will it be a future therapeutic strategy for the treatment of Type II Diabetes Mellitus?

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Diabetes is a chronic, metabolic disorder characterized by elevated blood glucose levels which leads over time to serious other complications such as retinopathy, kidney disease, neuropathy and cardiovascular diseases. Over 90% diabetes patients are having T2DM. Despite of the many antidiabetic drugs available in the market, treatment goals to achieve normal HbA1c value over a long period of time is still challenging. Recent study of genome-wide association (GWA) revealed new targets for T2DM and Wnt signaling is one of them. The Wnt signaling pathway is an evolutionarily conserved complex pathway involved in embryogenesis, cell proliferation and differentiation, adult tissue homeostasis etc. Various in-vitro studies suggested that Wnt signaling is involved in production of the incretin hormone, glucagon-likepeptide-1 (GLP1), β-cell proliferation, glucose-induced insulin secretion and lipid metabolism. Various Wnt pathway effectors like transcription factor 7 -like-2 (TCF7L2), Wnt5b and co-receptors like LRP5/6 etc. are involved in the type-2 diabetes and other metabolic diseases. According to the studies, polymorphism in the TCF7L2 gene increases the risk of T2DM. This review describes the role of Wnt signaling pathway in the occurrence and development of T2DM based on compilation of various related research studies. It also discusses the possibilities to explore Wnt modulators; Wnt activators and Wnt inhibitors as new therapeutic strategy for the treatment of T2DM.

F023

A Review on Synthetic Account of 1,2,4-Oxadiazoles as Anti-infective Agent

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Most of the currently marketed drugs consists of heterocyclic scaffolds containing nitrogen and oxygen as heteroatoms in their structures. Several research groups have synthesized diversely substituted 1,2,4-oxadiazoles as anti-infective agents having anti-bacterial, anti-viral, anti-leishmanial, etc. For the first time, the present review article will provide the coverage of synthetic account of 1,2,4-oxadiazoles as anti-infective agents along with their potential for SAR, activity potential, promising target for mode of action. The efforts have been made to provide the chemical intuitions to the reader to design new chemical entity with potential of anti-infective activity. This review will mark the impact as the valuable, comprehensive and pioneered work along with the library of synthetic strategies for the organic and medicinal chemists for further refinement of 1,2,4-oxadiazole as anti-infective agents.

TRACK-G

PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE

G002

A comparative evaluation of LNB in Pharmaceutical Drug substances and Dosage forms using Green RP-HPTLC and Green NP-HPTLC methods

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LNB is highly potent anticancer drug administered orally in capsule formulation used in the treatment of thyroid cancer. Though, some RP-HPLC, UPLC methods have been reported for the estimation of LNB, but to the best of our knowledge, there hasn't been a green technique for LNB that incorporates the use of GAC. The majority of these methods were developed using ACN, which is not regarded as green solvent, or had a complicated mobile phase with low AGREE scores. Therefore, the current study looks at how GAC, was used in the development and validation of a HPTLC technique using LNB as a model drug. The LNB was evaluated in the drug substance and marketed capsules using validated green-reversed-phase high-performance thin-layer chromatography (RP-HPTLC) and normal-phase high-performance thin-layer chromatography (NP-HPTLC) techniques. The mobile phase for an RP-HPTLC-densitometry was a mixture of green ethanol and water (60:40). For a green NP-HPLTC-densitometry, a 50:50 mixture of ethanol and ethyl acetate was used. For both methods, detection was done at a wavelength of 243 nm. In compared to NP-HPTLC-densitometry, the RP-HPTLC approach exhibited great sensitivity for the analysis of LNB. As a result, RP-HPTLC-densitometry may be utilized to design and validate LNB in drug substances and pharmaceutical dosage forms. Both NP-HPTLC and RP-HPTLC methods were found to be linear in the range of 300–700 and 100–500 ng/band, respectively. The system suitability parameters for both of the methods were found to be acceptable for the analysis of LNB. The G-RP-HPTLC technique was found to be more rapid, accurate, precise, and greener for the determination of LNB compared to the G-NP-HPTLC technique. The greenness of both of the green methods was assessed using AGREE software which utilized 12 principles of green analytical chemistry. The eco-scales of G-RP-HPTLC and G-NP-HPTLC methods were predicted as 0.88 and 0.82, respectively. The both methods suggested excellent greenness. Based on these observations and validation studies, the G-RP-HPTLC methodology was considered as superior over the G-NP-HPTLC technique for pharmaceutical analysis. Accordingly, the G-RP-HPTLC technique could be utilized for the routine analysis of LNB in drug substance and commercial products.

G003

Development and Validation of Stability Indicating UV Spectrophotometric method for estimation of Levosulpiride in bulk and pharmaceutical dosage form

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The development and validation of new analytical method is critical in the discovery, development and manufacturing of pharmaceuticals. For the estimation of Levosulpiride in bulk and Marketed tablet dosage form the new, simple and precise economical UV Spectrophotometric method have been developed and validated. Levosulpiride is an antipsychotic drug. The λmax of Levosulpiride was found at wavelength of 292nm and the calibration curve were plotted over the concentration range of 4 -20 µg/ml with the correlation coefficient 0.9971. The validation was performed as per ICH Q2 (R1) guidelines for linearity, accuracy and precision by using UV spectroscopy. The recommended strategy has been proven to work. The linearity was found to be 0.0066 for concentration range of 4-20 µg/ml for levosulpiride. The calculated %RSD value for precision study was found to be 0.94 %. For the accuracy study the following results are observed for 12 ppm it gives 104.50 % recovery, for 15ppm it gives 119.16% recovery, for 18ppm it gives 110.10% recovery. So, the developed method is precise with %RSD less than 1, having good reproducibility and also having acceptable accuracy. The limit of detection (LOD) was found to be 0.02048 and the limit of quantitation was found to be 0.062. Thus, the proven method can comply with all acceptable criteria's so we can successfully apply it for determination of Levosulpiride in routine analysis.
Keywords: Levosulpiride, Methanol, Spectrophotometric, Validation

G004

Applications of Capillary Electrophoresis for Monitoring Environmental Pollutants

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Capillary electrophoresis is a versatile technique that has been applied to many fields including biomedical, clinical diagnosis, pharmaceutical drug analysis, food science, and environmental analysis. It is widely used for pollutant monitoring from the environment and analysis of chiral molecules. Various environmental pollutants are phenolic compounds, steroid drugs, aromatic amine compounds, hydrazines, nerve agents, nitroaromatic compounds, chemical warfare agents, inorganic and organic ions. To determine these compounds, various approaches of capillary electrophoresis are used like microemulsion electrokinetic chromatography, micellar electrokinetic chromatography, and microchip capillary electrophoresis with varying experimental conditions. The selection of proper analytical conditions is very essential for the analyst to separate very closely related compounds. In this review, an attempt has been made to compile all these experimental conditions which can be of great help to the scientific community.

G005

Indispensable role of β – Cyclodextrin in separation of enantiomers of pharmaceutical active ingredients

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Significant differences in the clinical performance between the two enantiomeric forms of many pharmaceutically active ingredients have come up with the need for enantiomeric separation of chiral drugs. In a recent time, chiral separation is more preferable by using the mobile phase additives over the conventional chiral stationary phase. As it is the most cheaper and rugged alternative along with availability of a broad range of chiral additives for selection. Macrocyclic antibiotics, chiral ion exchangers and β-Cyclodextrin (β-CD) are the most commonly used chiral mobile phase additives. Amongst them, this review highlights the indispensable role of β-CD for separation of enantiomers. β-CD is a cone shaped cyclodextrin composed of seven alpha-(1->4) linked D-glucopyranose units. β-CD is hydrophilic at the outer surface of the cavity while, hydrophobic within the cavity. So β-CD is soluble in water, and a variety of hydrophobic drugs can be encapsulated in its non-polar cavity. Due to its polar nature, it is widely used as a solubilizer in injectable drug products, for inclusion complex formation and for chiral separation. This review details about the methodology used for separation of enantiomers of pharmaceutical active ingredient using β-CD as a mobile phase additive and as a stationary phase. This review also highlights separation mechanism of β-CD in chromatography as well as in electrophoretic analysis in brief.

G006

Development and Validation of Analytical Method for Estimation of Aspirin and Dipyridamole in their fixed Combine Dosage Form

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Aspirin and dipyridamole sold under the brand name of Aggrenox is a medication used for the treatment of transient ischemic attack (TIA). A simple and precise stability indicating high performance liquid chromatography method was developed for aspirin and dipyridamole in their fixed combine dosage form. Chromatographic separation of aspirin and dipyridamole was obtained on Zorbax SB C8, (250 x 4.6mm, 5 µm column using gradient method with combination of mobile phase A-containing Buffer (pH 3.5 adjust with orthophosphoric acid): Acetonitrile (750:250), mobile phase-B containing Buffer (pH 3.5 adjust with orthophosphoric acid): Acetonitrile (250:750) and flow rate 1.5ml/min. Detection and quantification was done at wavelength 230 nm using UV detector. Linear relationship was observed in method for concentration range for aspirin 1.0-30.10 µg/ml and for dipyridamole 7.93-237.89 µg/ml with correlation coefficient of 0.99992 for both drugs. Different Stress Conditions were applied on the developed method such as Acid degradation, Base degradation, Peroxide degradation, Thermal degradation, Humidity degradation and degradation product has been found during the estimation of Aspirin and Dipyridamole. Developed method has not shown any interference during different stress conditions. The method for analysis of aspirin and dipyridamole was found to be accurate and precise with average recovery 98.0-102.0%. The proposed method was found to be suitable for the routine quantitative analysis for aspirin and dipyridamole in Extended-Release capsule.

G007

A Review on the Analytical Techniques for Different Poly-herbal Formulations and Bio-actives Used for Bone Tissue Regeneration

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In orthopaedics and dentistry, millions of bone transplant operations are conducted each year to correct bone defects. Synthetic alternatives that operate as active temporary templates for bone formation are needed to lessen the need for transplants and regenerate bone. Poly-herbal formulations and bio-actives derived from some herbs are the most alternative treatment for bone tissue regeneration. Due to the variability of herbal bio-actives, there is a need for standardization. Some of the poly-herbal formulations used for bone tissue regeneration are Abha Capsule, Lakshadi Guggul Vati, and Osheal Tablet. The present review includes detailed information regarding the analytical method development by using High Performance Thin Layer Chromatography (HPTLC) and High Performance Liquid Chromatography (HPLC) for standardization of Abha Capsule, Lakshadi Guggul Vati, and Osheal Tablet. The CAMAG TLC Scanner-3 was used to detect components of formulation using the HPTLC method at wavelengths of 254 and 366. In the HPLC procedure, the C18 column was mostly used. Also involves the method development using HPLC, HPTLC, and Nuclear Magnetic Resonance (NMR) spectroscopy for estimation of bio-actives like Soy Isoflavones, Allicin, Curcumin, and Vanillic acid. The spectra of bio actives were obtained using the CD3OD solvent in the NMR spectroscopy technique. In the HPLC procedure, a UV detector was used.

G008

Implementation of QbD Approach to Analytical Method Development and Validation for Sunroid: An Overview

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In today's fast paced and highly competitive industrial settings, fast and robust HPLC method development becomes increasingly important. Chromatographic method development can be a time consuming and subjective process. QbD is a systemic approach for drug development which begins with predefined objectives, and uses science and risk management approaches to gain product and process understanding and ultimately process control. A rapid reversed-phase HPLC method has been developed for the analysis of Sunroid. Software SAS JMP® has been used to optimize the column brand, column particle size, mobile phase ratio, injection volume and other HPLC conditions. The method uses isocratic elution from C18-thermo Hypersil Bds column, (250 mm × 4 mm, 5 µm particle size) and acetonitrile/water (45/55, v/v) as the organic mobile phase with UV detection at 245 nm. Using these conditions, the validation results confirmed that the method is precise, accurate and linear at concentrations ranging from 0.05 mg/ml to 0.15 mg/mL. The recoveries ranged from 99% to 102% at concentrations from 0.05 mg/ml to 0.15 mg/mL for total benzalkonium chloride. The validation also confirmed the robustness of the method as predicted by SAS JMP. As a result of these studies, the method performance can be understood and improved if necessary, and a control strategy can be defined to manage risk and ensure the method performs as desired when validated and deployed.

G009

Analytical method development and validation for impurity profiling of Sunpeptide and its characterization by LC-HRMS

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In the present scenario, peptide drugs replaced the smaller molecules for the effective treatment of various diseases. The quality of peptide therapeutic is of utmost importance. The impurity determination in peptide formulation is a challenging task. Various peptide therapeutics are available in market and the analytical methods are reported for the assay and impurity determination of these peptides. Sunpeptide is a therapeutic peptide developed and marketed by SUN Pharmaceuticals Industries Limited. Sunpeptide is a pleotropic peptide which is used for the treatment of various problems of reproductive system. Sunpeptide is considered as relatively safe as it gets easily metabolized. In the present research work, LC-HRMS compatible HPLC method was developed and validated for the impurity determination of Sunpeptide. The chromatographic separation was achieved on C_{18} column (250×4.0 mm, 3 µm) at 25^0C. The separation of analyte and impurities was carried out using ammonium acetate buffer as mobile phase A and 50:50 ratio of mobile phase A with acetonitrile as mobile phase B in gradient mode of separation. The flow rate was 0.7mL/min and the analytes were monitored at 220 nm using UV detector. The total run time was 70 minute. The retention time of Sunpeptide, impurity 1, 2 and 3 was found to be 42.21,59. 25, 60.66 and 54.67 respectively. In HRMS ion source used is electrospray ionization (ESI) with positive mode. Ion spray voltage 3.50kV, ion source temperature 256°C and aux gas heater temperature was 413 °C. The mass of the impurity mentioned was found to be 2012.8735, 2012.8726 and 1048.4475 for impurity 1,2 and 3 respectively and mass of Sunpeptide is 1006.4378. The method validation was performed as per ICH Q2 (R1) guideline and all the results of validation parameters were found to be within acceptance criteria.

G010

Development and Validation of Dissolution Method for Miglitol Tablets

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The objective of the present study was to develop and validate dissolution test for Miglitol in Mignar 25 tablet containing 25mg of Miglitol using absorption profile based on *in-vivo* data. Miglitol is Antidiabetic used to treat type II diabetes mellitus. It reversibly inhibit α glucoside hydrolase enzyme that is act by inhibiting ability of patient to breakdown complex carbohydrate into glucose. Result from testing sink condition and stability 37^{o}C shows stability in phosphate buffer of pH 6.The best *in-vitro* dissolution profile was obtained using Apparatus 2 (paddle) at 25 rpm, 900ml of dissolution medium phosphate buffer of pH 6. *In-vitro in-vivo* correlation was obtained (r^2=0.997). The fraction of dose absorbed was calculated using Wagner nelson Method. The in vitro dissolution samples were analyzed using a HPLC method and the validation was performed according to USP protocol. The method showed accuracy, precision, linearity and specificity within the acceptable range. Both the HPLC method and the in vitro dissolution method were validated and could be used to evaluate the release profile of Miglitol Tablet.

G011

A review on LC-MS/MS analysis of selected drugs in oral fluid

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Oral fluid (saliva) consists of gingival crevicular fluid mixed with secretions from the parotid gland (20–25%), the submandibular gland (70–75%), and other minor salivary glands to make oral fluid. Oral fluid estimation for drug testing is becoming more used in a variety of testing areas: pain management and medication monitoring, parole and probation, driving under the influence of drugs (DUID), therapeutic drug monitoring, and occupational drug testing. The sample collection itself is simple, quick, visible, and noninvasive, requiring no special equipment or medical personnel (compared to urine and blood). Because saliva has a slightly acidic pH compared to blood, substance that are more basic like: cocaine, amphetamines, oxycodone, morphine, methadone, and fentanyl. Conversely, acidic drugs and drugs which are strongly protein bound have lower concentrations in oral fluid than in blood: examples include benzodiazepines, barbiturates, and carisoprodol. Because of the low volume of specimen available for estimation and the drug concentrations present (generally much lower than those in urine), efficient extraction methods and sensitive confirmation procedures are necessary for routine estimation of drugs in oral fluid. So, solid-phase extraction methods are described for a variety of drugs with liquid chromatography—tandem mass spectrometry detection.

G012

Overview on Analytical techniques used for Metabonomics: Application to human health

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Organisms often respond in complex and unpredictable ways to stimuli that cause disease or injury. By measuring these changes caused in tissues, fluids, gives us an idea about the effects of diet, drugs, disease in our body. Metabolite profiling is applied to measure the conversion of an applied compound of interest to its Metabolites. Metabolites are endogenous compounds such as amino acids, lipids, sugars, organic acids, etc. which are routinely being formed in the anabolism or catabolism process. By using analytical techniques NMR- Nuclear Magnetic Resonance, MS- Mass Spectroscopy, GC/MS- Gas Chromatography/Mass Spectroscopy could be used to analyse, identify, and quantify the metabolite to identify the changes in body fluids. These techniques have shown brilliant outcomes in analysing the metabolite and diseases. Many new approaches have been made to analyse fluids such as COMET (Consortium for Metabonomic Toxicology), Density Superposition Classification of Unknowns (CLOUDS) which are also used to identify diseases. Continued development of these analytical techniques will result in more sensitive and accurate outcomes in integration of Metabonomic. Here application of Metabonomic are being discussed, furthermore the review comprehensively highlights the role of NMR and MS for analysing the Hydrogen and others present in fluids, which are used for Metabonomic study.

G013

DATA INTEGRITY REMEDIATION AND CGMP FACILITIES

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In the pharmaceutical industry, data integrity play an important role to maintain the quality of a final product because the poor practice can allow the substandard product to reach patients, so it's necessary to maintain data integrity, data traceability, and reliability. Violation of the integrity of data is termed as a breach of data integrity. China has received the highest number of letters for breach of data integrity in the year 2018. Some examples observed during FDA inspections are: alteration of raw, original data and records, repeat analysis of assay etc. The objective was to carry out the number of issues involved within data integrity in current GMP aspects, the root causes were addressed based on warning letters. Due to the rise in cGMP violations involving data integrity during regulatory inspections, there have been issuances of many warning letters, import alerts and consent decrees. To assure the data integrity many regulatory bodies such as USFDA, Health Canada, and EMEA recommended the use of ALCOA. There are certain ways to maintain data integrity such as always Validate Input Data, Implement Access Controls, Keep An Audit Trail, Always Backup Data, Adopting Security Best Practices, Educate Your Workforce. It can be concluded that it is important to enforce data integrity and develop strategies for the same.

G015

HPLC Method Development and Validation for Dissolution Study of Flucloxacillin Sodium Tablets

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Flucloxacillin sodium is a narrow spectrum antibiotic. It is widely used in the treatment of various infections. In literature, many methods have been reported for its estimation in various matrices, but no HPLC method has been reported for dissolution study of flucloxacillin sodium tablets. Hence, high performance liquid chromatographic method was developed and validated for dissolution of flucloxacillin sodium tablets. The isocratic HPLC method was developed on a reversed phase Inertsil ODS 3V C_{18} Column (150mm*4.6mm, 5µ). The mobile phase was selected as phosphate buffer (pH 5.0) and acetonitrile (60:40). The flow rate was 1 mL/min and injection volume was 20 µL. The column temperature was ambient (25 ^{0}C) and sample was kept at 10 ^{0}C.The column eluent was monitored at wavelength 225nm using a UV detector. By using the optimized experimental conditions, the retention time for flucloxacillin sodium was found to be 4.0 ± 0.2 minute. The linearity of the method was measured between 10-150 % of assay concentration. The correlation coefficient for linearity was found to be 0.999 with linearity equation Y = 2E-05X - 0.4912. The method showed good reproducibility (98 ± 1.97%) and recovery (99.6 – 101.5%) with percent relative standard deviation less than 2%. The sample solution was found to be stable, having a percent difference in peak area between initial concentration and concentration after 48 hr was less than 2%. The specificity showed no interference of placebo and diluent with the main peak of the drug. The proposed method is highly sensitive, precise and accurate and hence it can be applied for routine quality control of marketed formulations.

G016

Overview of Quantitative NMR Spectroscopy & It's Applications

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Quantitative NMR is a flexible analytical tool for quantification of content or purity of organic substances. The method is based on a direct comparison of NMR signal intensities of the compound of interest with reference signals. The reference signal can be derived from any internal reference compound with known structure and purity. In case of impurity analysis, the signals of the main compound often can be used as a reference. qNMR provides unique physicochemical view of the analyte based on nuclear magnetism and it yields qualitative and quantitative information simultaneously. qNMR usually of two types of Relative concentration determination, Absolute concentration determination. qNMR have six commandments SCSSRS- Selectivity, chemical inertness, solubility, stability, sufficient resolution, relaxation which make qNMR universal. qNMR is carried out through 3 basic steps: Sample preparation, NMR measurement, Processing/analysis/confirmation. Analysis is done by applying mathematical calculations. Here applications of qNMR are elaborated by paying special focus on Metabolomics and metabolite profiling for biomarker identification for disease diagnosis and juice adulteration, Natural products, Organic synthesis, Estimation of metal ions, furthermore the review emphasizes Internal standard method and external standard method of qNMR.

G017

Review on Forced Degradation Studies of Clopidogrel Bisulfate and Prasugrel Hydrochloride

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Clopidogrel and Prasugrel are antiplatelet medicines. They prevent platelets from sticking together and forming a dangerous blood clot. Stability studies are defined as the studies that are carried out to determine the quality of the API or the formulation under the influence of various artificially created conditions like acidic, alkaline, oxidative, thermal or photolytic. These studies were performed on clopidogrel and prasugrel. Acidic degradation was done by using 0.1-2N HCL, at temperature of 60°-80°C, for 30-180 mins. Alkaline degradation was done by using 0.1-2N NaOH, at temperature 60°-80°C, for time period of 30-180 mins. Oxidative degradation was done by using 3-30% H2O2, at a temperature of 60°C, for time period 30-60 mins. Thermal degradation was done by using 60°-100°C temperature, for 30-180 mins. Photolytic degradation was done by giving 1-5 days exposure in daylight. Various degradation impurities were generated during these studies. It was found that clopidogrel impurities A and B are degradation impurities that are listed in IP'2014. Impurity A is a result of alkaline degradation, while impurity B is due to acidic degradation In the case of Prasugrel, two of the four listed impurities i.e. A and B, are degradation impurities.

G018

Impurity Profiling of Sacubitril Valsartan Complex using LCMS Compatible Analytical Method

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Sacubitril and Valsartan (SAC/ VAL) complex is a novel acting drug combination that is highly popular in the treatment of heart failure. In the present ongoing work, mass spectrometer compatible method is developed and validated for the simultaneous estimation of SAC/ VAL in presence of their process related impurities and degradation products. The chromatographic separation was achieved on BDS Hypersil C8, (150 x 4.6) mm; 5 µm at 30° C. The peak was eluted using 0.5 % Trifluoracetic acid (TFA) in water as mobile phase A and 0.5 % TFA in acetonitrile as mobile phase B in a gradient mode. The flow rate was set as 1ml/minute and the analytes were monitored in the range of 200-400 nm using a Photo Diode Array (PDA) detector for 40 minutes run time. The method validation was performed as per ICH Q2 (R1) guidelines and all the validation parameters were found to be in acceptance criteria. The forced degradation study for SAC/VAL showed that the drug was susceptible to degrade under alkaline, photo as well as oxidative stress conditions. The unknown degradation products generated will be further identified using mass spectrometer.

G019

Development and validation of RP-HPLC method for Baclofen and its related substance in its tablet dosage form

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Baclofen is a muscle relaxant used as first option to treat spasticity and muscle spasms in patients with spinal cord injuries. A rapid, selective and sensitive RP-HPLC method was developed for determination of Baclofen and its related substance in tablet dosage form. The chromatographic separation of Baclofen was carried out by using C18 column (250 x 4.6 mm), 5µm with buffer as mobile phase A, and mixture of acetonitrile and methanol in the ratio of 50:50 % V/V using as mobile phase B. The flow rate was 0.8mL/min with gradient elution mode and wavelength for detection was 220 nm. Retention time for Baclofen peak was found 7.780 min and impurity peak was 15.340 min, Method selectivity was demonstrated by the forced degradation study. The developed method was specific, accurate as per ICH guidelines. The system suitability criteria were found to be within limits. The limit of detection was found to be 0.01% for impurity A and 0.01% for Baclofen and Limit of quantification was found to be 0.04% for impurity A and 0.03% for Baclofen. The linearity curve was found to be linear and the correlation coefficient for Baclofen obtained was 0.9997 and 0.9999 for impurity A. The average percentage of recovery found in the range of 97-101%.

G020

An Overview of Bioanalytical Techniques for Quantification of Biotherapeutics

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Biosimilars are developed after the patent expiration of biologics to enhance patients' access to innovative, cost- effective, targeted curative therapy and lifesaving quality medicines. Bioanalytical methods are crucial for the clinical similarity studies of proposed similar biological products. With the advent of technology in chromatography and LBA (ligand binding assay), multiple technology platforms and assay formats are now available which influence the performance of PK/PD (Pharmacokinetic/Pharmacodynamic) and ADA (Anti-drug Antibody) assays used in bioanalysis of complex biomolecules. Comparison of platforms and formats is essential to develop and validate a reliable, low cost, and regulatory-compliant assay. An overview on various aspects to consider and recent breakthroughs, as well as the evolving regulatory requirements for the Bioanalytical Method Validation, is presented for the development and performance evaluation of biotherapeutics quantification assay. To overcome the limitations of conventional LBA, hybrid LBA-LCMS (Liquid chromatography and mass spectrometry) methodology has progressed over the past decade. Bridging of assays is required by regulators before employing novel assay methods which impose an additional liability and risk on manufacturers. A consensus of the biopharmaceutical industry and regulatory agencies is required to establish the new harmonized guidelines, which embrace the use of advancing technology to confront the challenges of contemporary treatment modalities.

G021

The development and validation of a stability-indicating RP-HPLC technique for the simultaneous estimation of Vildagliptin and Metformin in bulk dose form

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Metformin is a diabetes medication (biguanide). It works by lowering glucose synthesis in the liver, delaying glucose retention in the intestines, and boosting insulin sensitivity in the body. Vildagliptin is a DPP-4 inhibitor that works by increasing the amount of insulin produced by the pancreas while decreasing the hormones that cause blood glucose levels to rise. As a result, both fasting and post-meal sugar levels are reduced. They work together to improve glucose management. Plethora of HPLC techniques that have been reported estimating Metformin with other drugs, but there are a very few HPLC methods reported for quantification of Vildagliptin and Metformin from their bulk dosage form. The stability indicated Reverse phase HPLC method is developed for simultaneous estimation of Vildagliptin and Metformin from their bulk dosage form. Validation is also performed for the developed method. Mobile phase consisting of Buffer(0.5 g Sodium chloride and 0.5 g 1-Heptane sulphonic acid sodium salt in 1000 ml of water, pH set to 4.5 with dilute Orthophosphoric acid solution), Methanol and Acetonitrile in the proportion of 750:150:100 and pumped at a flowrate of 1 mL/min, with Inertsil ODS 3V C18 column, in an Isocratic mode, gave good separation of the two drugs. Detection wavelength was 210 nm. Retention times were 4.904 and 13.330 minutes for Metformin HCl and Vildagliptin respectively.

G022

IMPORTANCE OF MULTI ATTRIBUTE METHOD (MAM) IN POST-TRANSLATIONAL MODIFICATIONS

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As of 2021, more than 370 biotherapeutic drug products have got an approval in various regulatory agencies in US and EU markets and is expanding rapidly. Process optimization by improving analytical techniques is the main recent requirement for better product characterization according to Qbd approach recommended by various regulatory agencies to develop new biologics. In recent times, Multi attribute method (MAM) has emerged to meet such demands using mass spectroscopy coupled to liquid chromatography. Unlike conventional chromatographic methods such as ion exchange chromatography (IEX) and hydrophilic interaction chromatography (HILIC) that depends on optical detection, peptide MAM is built on reversed-phase chromatography coupled with mass spectrometry (RPLC-MS). Utilizing the power of mass spectrometry and advanced informatics tools, MAM can monitor multiple PTMs such as oxidation, deamidation, succinimide modification, glycosylation, C- and N- terminal modifications, and isomerization with greater throughput, sensitivity, and dynamic range than these single attribute optical based detection assays. Traditional samples preparation or data processing caused a lot of variability due to various reasons. Hence this review focuses on a new automated analytical platform MAM, a working flow has been discussed and the aspects it which this technique can be explored. Also applicability of MAM to support cell line development, cell culture process development and downstream process development has been briefly covered.

G023

Deep Eutectic Solvents and It's Applications

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Large nonsymmetric ions with low lattice energy and thus low melting point are found in deep eutectic solvents (DESs). They are made by combining quaternary ammonium salt with a metal salt and a hydrogen bond donor to form a complex. Abbot et al. discovered in 2001 that a mixture of choline chloride and a metal salt may create a liquid at temperatures below 100°C. DESs have evolved as innovative and environmentally friendly solvents. DES precursors are natural deep eutectic solvents, which include amino acids, organic acids, or choline derivatives derived from natural sources (NADES). Intermolecular interactions such as Van der Waals and electrostatic forces created NADES and DES as a result of hydrogen bonding acceptor and donor molecules. DESs have a high thermal stability and are non-volatile. For chromatography, the use of DES as a mobile phase, mobile phase additives, stationary phase and solid phase modifiers was investigated. GC- gas chromatography with ECD- electron capture detector and FID- flame ionization detector, HPLC- high performance liquid chromatography, DLLME- dispersive liquid-liquid micro extraction, and LPME- liquid phase micro extraction were utilized. Both inorganic metallic components and organic molecules such as phenolic compounds, flavonoids, proteins, and aromatic amines from food samples can be extracted and separated using DESs.

G024

Development and Validation of Stability Indicating UV Spectrophotometric Method for Fluticasone Propionate in Bulk and Pharmaceutical Formulation

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The simple, precise and accurate method was developed and validated for the estimation of Fluticasone propionate in bulk and marketed formulation. The spectra of Fluticasone propionate in methanol showed maximum wavelength at 230 nm and calibration curve were plotted over concentrations ranging from 5-25 ug/ml of Fluticasone propionate with correlation coefficient 0.9996. The validation was performed as per ICH Q2 (R1) guidelines for linearity, accuracy, precision, and recovery using the UV spectroscopic method. The linearity lies between 5 to 25 µg/ml for fluticasone propionate (r^2=0.9996). The specificity and stability indicating capability of the method were proven through degradation studies, which also showed that there was no interference of the excipients. The accuracy was 98.69%. The limits of detection and quantitation were 0.209 and 0.55 ug/ml, respectively. Moreover, method validation demonstrated acceptable results for precision and robustness. The method had good reproducibility and recovery with % RSD less than 1. Thus, the proposed method can be successfully applied for determination of fluticasone propionate in routine analysis work.

Keywords: Fluticasone Propionate, Spectrophotometric, Methanol, Validation, Stability, Degradation

G025

MODERN TECHNIQUES FOR EXTRACTION OF HERBAL DRUGS

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Different standard methods of medicinal plant extraction includes conventional methods like maceration, infusion, percolation, digestion, decoction, hot continuous extraction, counter-current extraction , and modern methods like the microwave-assisted extraction, ultrasound extraction, supercritical fluid extraction, accelerated solvent extraction, and preparative HPLC. Supercritical fluid extraction is the technique of setting apart one component (the extractant) from another (the matrix) using supercritical fluids as the extracting solvent. It has many advantages like extraction of constituents at low temperature, which avoids damage from heat, low viscosity of supercritical fluid, and fast extraction. Microwave-assisted extraction is a technique based on heating an organic solvent. It has advantages like iincreasing the extract yield and selective heating of vegetal material. It is also regraded as a green technology because it reduces usage of organic solvent. Ultrasonic-assisted extraction, involves the use of ultrasound ranging from 20 kHz to 2000 kHz, which increases the permeability of cell walls and produces cavitation. It has advantages like shorter reaction/preparation time, usage of small amounts of material, useful for the isolation and purification of bioactive principles. In ASE system, the extraction process is carried out at temperatures exceeding the boiling point of solvent what implies that the pressure inside the extraction cell must be kept high to maintain the solvent in a liquid state. The extraordinary parameters of extraction are temperature, stress and static time which can be decided at some stage in the technique. This review presents advantages and principles of modern methods which are involved in extraction of herbal drugs.

G026

Review on in-depth understanding about drug-space radiation interaction and its evaluation model

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The major aim of a successful space mission is to maintain astronauts' health in a unique, isolated, and severe environment. As a result, pharmaceuticals that are often potent and have a long shelf life are crucial for the well-being of space explorers and the successful completion of a space mission. Few studies of medications in space imply that it is hard to ascertain pharmaceutical effectiveness or stability during spaceflight, which makes selecting an adequate formulary for exploration problematic. Using a ground-based simulated spaceflight environment, the proposed review will aid in the understanding of the stability, safety, and efficacy of selected medications. Different types of radiation, such as galactic cosmic rays, solar cosmic rays, and trapped radiation, abound in space and can permeate the spaceship despite the shielding material. In space or lower earth orbit, ionizing and non-ionizing radiation such as gamma rays, heavy ions, protons, and thermal or fast neutrons interact with matter and influence its physico-chemical properties. Such radiations can alter the stability of the pharmaceuticals during long duration space missions, so it is essential to evaluate the interaction of such radiation on different matters. This article examines the possible interactions between medications and radiation, as well as the mechanisms involved and it also demonstrates how environmental factors such as moisture may affect stability.

G027

QbD based development and validation of Green HPTLC method for the estimation of IRB drug substance and Marketed Tablet formulation

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The Green chemistry and Quality by Design concepts were combined to achieve the dual goals of environmental friendliness and robustness in a single process. IRB is the potent antihypertensive drug and different HPLC, HPTLC methods have been reported for the assay of IRB but no green chemistry method was reported with the application of both concepts like GAC and QbD. QbD based HPTLC method have been developed and validated for the estimation of IRB drug substance & drug products. The HPTLC analysis of IRB was performed using Silica Gel-60-F254. The QbD technique was used to optimize the technique using the Central composite design. The mobile phase composition, chamber saturation time and band width were selected as critical variables and area and retention factor were selected as response variables for the designing and optimization of method. The green solvents like Ethanol: Ethyl acetate (50:50 v/v) was selected as the mobile phase and 220nm as λmax and the Rf = 0.52. The proposed HPTLC method was found to be linear in the range of 2µl-10 µl with R2 = 0.9994. HPTLC technique was validated for linearity, precision, accuracy, robustness, LOD and LOQ. ICH guidelines were followed for the validation, and the results shows that they can be used for regular analysis in quality control laboratories with compatible results. The Analytical Greenness (AGREE) scores of HPTLC densitometry was found to be 0.83 suggesting an excellent greenness profile.

G028

Method development and qualification of host cell protein impurities in SunmAb by ELISA

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Monoclonal antibodies (mAbs) are one of the fastest growing class of biotherapeutic agent in today's biopharmaceutical market. A single mAb is used in the treatment and diagnosis of multiple indications which includes cancer, inflammatory and autoimmune disorders. SunmAb is a monoclonal antibody expressed in the E.coli bacteria (host cell). However along the expression of mAb, the host cell also generates proteins known as Host Cell Protein (HCP) and they are considered as process related impurities and are present in low levels (ng/ml or ppm). Identification and quantification of HCP is important because they reduce the formulations shelf life, efficiency, stability and further leads the proteolytic immune response i.e. Cytokine storm. According to the ICH Q6b guideline the concentration of HCP in any mAb formulation should be less than 100 ppm. The presence of HCP is quantified by different analytical techniques like ELISA, SDS-PAGE, Western blotting and odyssey Infrared image systems. ELISA is a primitive method to analyse the HCP content in biopharmaceuticals. The method developed to quantify the HCP content in SunmAb includes the use of 25mM Tris buffer (pH-8.6) as solubilizing agent. To quantify the HCP content the concentration of SunmAb used is 0.5mg/ml. Method quantification was performed according to the ICH Q2R2 guidelines, and applies for the stability of the formulation.

G029

Protein Aggregation Analysis by Size Exclusion Chromatography Coupled to Multi Angle Light Scattering Detector

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Objective of the study was to develop and verify an analytic method using size exclusion chromatography with detections of refractive index and multi-angle laser light scattering (SEC-RI-MALS) to accurately measure and compare the molecular weight, molecular radius and polydispersity ratio of selected mAb innovator product and its biosimilar formulations. The refractive indices (dn/dc) values were determined for each of the formulations using an Optilab rEX detector prior to SEC-RI-MALS analysis. The molecular weights of formulations were determined by SEC-RI-MALS on a TSKgel G3000SWxl column using phosphate buffer as the mobile phase at a flow rate of 0.5 ml/min. The molecular weight and radius change of the antibody formulations' following heat treatment and physical agitation was also investigated by the developed method. The monomer peak shows elution at 14 -18 min while an additional low molecular weight peak was also observed in the control samples at 12- 14 min. The heat treated samples at 55°C, show no prominent change for 1 week. However, at day 14 prominent changes like generation of shoulder peak at 14-15 min and low molecular weight peak at 18-21 min were observed. The agitation samples, showed no prominent change at day 1. However, at day 3 and 5 elution of high molecular weight peak at 12-14 min was observed. In conclusion the developed SEC-RI-MALS method showed good reproducibility and inter-precision, and thus can be applied for characterizing the physical properties of the selected mAb innovator product and its biosimilar formulations at various storage conditions.

G031

A REVIEW ON THE REGULATORY OUTLOOK FOR PEPTIDE THERAPEUTICS.

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FDA has defined peptides as alpha-amino acid polymers which are composed of 40 or fewer amino acids. FDA has given guidance on five approved peptide drug products of rDNA origin: Glucagon, Liraglutide, Nesiritide, Teriparatide, and Teduglutide. Before the issuance of final guidance, the peptides were regulated by the Federal Food, Drug, and Cosmetic Act (FD&C Act) as a new drug application (NDA) under section 505(b) of the FD&C Act. After 23rd March 2020, peptides drug products of rDNA origin were regulated as biologics under the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The marketing application for these drug products is submitted via Biological license application (BLA) under section 351 of the PHS Act. Later on with the advancement of technology, the FDA believed to establish similarities between synthetic peptides and peptides of rDNA origin. As of 20th May 2021, any application for a synthetic peptide drug product that refers to a previously approved peptide drug product of recombinant deoxyribonucleic acid (rDNA) origin (peptide of rDNA origin) is to be submitted as an abbreviated new drug application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) rather than as a new drug application (NDA) under section 505(b) of the FD&C Act. An ANDA for a generic version of a reference-listed peptide must show the drug is essentially the same as the reference-listed drug concerning the active ingredient and impurities. In terms of the active ingredient, the proposed generic peptide must show the sameness of the active ingredient concerning the primary sequence and physicochemical properties, secondary structure, oligomer and aggregation states, and biological activity/function in *in-vitro* or animal studies. This review highlights the approach of FDA for regulating peptide marketing application in the USA with some case studies. This review will benefit the fellow researchers of academia and industry to understand the marketing application process for the peptide therapeutic of their interest.

G032

Development of LFIA based Sandwich-ELISA method for detection of Aflatoxin B1

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Aflatoxin is most toxic carcinogenic secondary metabolites produced by moulds of Aspergillus species. Common heath issues related to aflatoxcigencity are cancer, immunosuppression, inflammation, growth impairments and hepatic necrosis. Aflatoxin causes loss of total harvest because small amount of its contamination can spread among the produce and thus rendering produce unfit for human consumption. Highly sensitive detection of aflatoxin B1 (AFB1) is of great significance because of its high toxicity and carcinogenesis. Regulatory guidelines of the U.S. Food and Drug Administration (FDA) specifically prevent the sale of commodities if contamination by aflatoxins exceeds 20 ppb total aflatoxins for interstate commerce of food and Animal Feed. Chemically, aflatoxins are stable and may withstand food processing. Aflatoxins can be ingested directly or indirectly with infected food. Due to simplicity, flexibility, rapidity, specificity, and sensitivity lateral flow assays (LFAs) are an excellent choice for aflatoxin testing. This study developed a fast and sensitive gold nanoparticle (AuNP) immunochromatographic strip for detecting aflatoxin B1 (AFB1). It's a Sandwich ELISA-based approach that uses LFIA strips to conduct a reaction between antigen and gold nanoparticle conjugated antibody, yielding a rapid response. UV Visible spectrophotometry, Zeta Sizer, and Infrared spectroscopy are used to analyse gold nanoparticles and conjugates. Immunochromatographic strips are used to test contaminated food samples, and the results are compared to the HPLC method to determine the LFIA method's dependability.

G033

A Review on PEGylated Filgrastim Characterization

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Pegfilgrastim is a covalent conjugate recombinant of methionyl G-CSF (Filgrastim) with monomethoxy polyethylene glycol. The preparation and characterization of new mono PEGylated derivative of recombinant form of filgrastim synthesized by enzymatic site specific 20 KDa PEG conjugated to glutamine 135 residue by microbial transglutaminase catalyzed reaction. Covalent attachment of polyethylene glycol to therapeutic proteins is an crucial tool for enhancing stability, pharmacokinetic and pharmacodynamic profile. The stability was assessed as a function of pH, protein, fusion, buffer type, tonicity modifiers, repeated freeze thaw cycle, real-time analysis, and stress studies. Examples of PEGylated products include Adagen, Cimzia, Asparlas, Neulasta. Analysis methods such as reverse phase HPLC, HPLC size exclusion, Mass spectrometry, Circular dichroism, Fluorescence spectroscopy, Amino acid sequencing analysis, Peptide mapping and RP-HPLC analysis / MSI can be hired. The NH_2 terminal sequencing and peptide mapping did not show any differences when comparing the main PEGylated structure with the non PEGylated filgrastim . The higher order protein structure was maintained by circular dichroism and fluorescence spectroscopy. Challenges include the separation of PEGylated proteins into reaction products, limited concentration capacity, side product production and loss of function. Determination of the purity of the PEGylated form was determined by a number of analysis in which the PEGylated form was stable for more than two years when stored at 4 to 8 ° C. 5% sorbitol and 0.004% polysorbate 20 usually stabilize for two years when stored at 2 to 8 ° C.

G034

Review on Analytical Method Development and Validation of Teriflunomide by RP-HPLC

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Teriflunomide (Aubagio, marketed by Sanofi) is an Immunosuppressive Agent. Immunosuppressive agents or Antirejection medications are drugs that inhibit or prevent activity of the immune system. They are used in immunosuppressive therapy for prevent the rejection of transplanted organs and tissues and to treat the autoimmune diseases. Teriflunomide was investigated as a medication for multiple sclerosis (MS). The drug was approved by the FDA on September 13, 2012 and in the European Union on August 26, 2013.Various method used for the development of teriflunomide drug are UPLC,HPTLC,UV-LC,MALDI-MSI,RP-HPLC,LC-MS/MS.There is not much report available for RP-HPLC method development, force degradation and validation of analytical method for determination of the teriflunomide drug. Various columns are used in this method such as Agilent, Eclipse XDB C18 column (4.6mm*150mm, 5µm).The tests must show that its specificity, linearity, precision, sensitivity, accuracy and limit of quantification and qualification are adequate for the analysis. System suitability parameters such as RSD of Area, Resolution,, Tailing Factor, Theoretical Plates (N) related to system suitably test have been analysed. Method precision has a relative standard deviation (RSD) below 1% for repeatability and intermediate precision, which comply with the acceptance criteria proposed (RSD) not more 2.0%.Accuracy is measured the overall percent recoveries of Teriflunomide in pure and drug–matrix solutions were 100.0 and 98.02, respectively. Robustness refer to how sensitive the method is to uncontrolled small changes in parameters such as sample, temperature, pH of solution, reagent concentration, and flow rate. The method for the estimation of teriflunomide is specific, rapid, linear, accurate, precise, and suitable for intended use. Result obtained from the force degradation, indicates that in hydrogen peroxide used for quality control analysis of Teriflunomide in active pharmaceutical preparations.

G035

Development and Validation of HPLC Method for Estimation of Diroximel Fumarate

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Diroximel fumarate is used for the treatment of relapsing forms of multiple sclerosis (MS). Diroximel fumarate was approved for medical use in the United States in October 2019 and in the European Union in November 2021. A rapid, selective and sensitive High-performance liquid chromatography method was developed diroximel fumarate. The column was Nucleosil C18 column (250 x 4.6mm, 5µm). The mobile phase was a mixture of water (Adjusted 85% OPA, PH 3.5) and ACN in the ratio of (70:30 v/v.) The flow rate was maintained at 1.0 mL/min. Detector wavelength was monitored at 210 nm, and the injection volume was 20µL and run time was kept 20 min. The developed method was validated in terms of linearity, range, and specificity, robustness, LOD and LOQ as per ICHQ2R (1). The developed method can be used to monitor the quality control of the drug and it can be applied to stability study.

G036

Applications of Photoacoustic Spectroscopy

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Photoacoustic spectroscopy is an unconventional form of spectroscopy which uses light and sound fusion for the analysis of an analyte. It is also called optoacoustic spectroscopy as it is part of the Optothermal techniques family. Photoacoustic spectroscopy is the measurement of absorbed electromagnetic irradiations on matter by means of acoustic detection. It can sense molecular concentrations below the parts per billion (ppb) level and there is no pretreatment required before the analysis of the sample. It is used in analysis of various solid, liquid and gas samples. Its applications are multiple gas detection such as environmental and atmospheric monitoring of harmful gas such as CO_2. It is used in detection of solid samples like dangerous drugs having microgram quantities such as morphine. It is also used as depth resolved characterization of internal biological tissue and internal organs of animals and humans by non-invasive method called photoacoustic imaging. Recent advances are seen in characterization of microbial biofilms. It is used as a promising method to provide critical guidance of multiple surgeries and procedures such as in the liver. It has been used in characterization of food stuff. The infrared photoacoustic spectroscopy is used in soil analysis and plays a significant role in non-invasive glucose monitoring for diabetic patients. In this review, the applications of the photoacoustic spectroscopy are presented in a compiled form. It is a versatile and unique technique than any other conventional spectroscopy.

G037

Review on Various Analytical Methods for the Estimation of Poly (ADP-ribose) polymerase1 (PARP1) Inhibitors: API, Pharmaceutical Dosage Forms, and Biological Samples

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Poly (ADP-ribose) polymerase 1 (PARP1) inhibitors are the group of pharmacological inhibitors which are currently in use for the treatment of various BRCA mutated breast and ovarian as monotherapy as well as in combination with other cytotoxic agents. Clinical trials are also going on for the treatment of peritoneal, pancreatic and prostate cancers. Currently there are five PARP1 inhibitors approved by USFDA; Olaparib, Rucaparib, Veliparib, Talazoparib and Niraparib. In present review, we have compiled various analytical and bio analytical methods for the quantitative estimation of different PARP1 inhibitors in API, Pharmaceutical dosage forms such as tablets and injections and biological samples such as blood samples and human plasma. Various reported analytical methods ranges from chromatographic techniques like HPLC, LC-MS, LC-MS/MS etc. to UV-Visible spectroscopy. The purpose of review is to gain a better understanding of these methodologies used in quantitative estimation of PARP1 inhibitors alone as well as in combination. It will also discuss about the comparison of various techniques which may help to identify the best method for respective drug estimation in its sample type.

G038

Overview on new trends in HPLC and an insight on Nano HPLC

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HPLC is the most widely used technique for separation in all research lab and pharmaceutical industries. Recent advancements in HPLC technique helps to improve in better separation and minimum wastage. The first evolution of HPLC is UPLC which refers to Ultra Performance Liquid Chromatography, it reduces the particles size and reagents in micro meter. UPLC is widely used in bio-equivalence studies and also in analysis of various natural products and herbal medicines. Nano HPLC is the modality of chromatographic technique that minimizes consumption of reagents, samples in nano litre, flow rates in Nano milli litre per minute; therefore, resulting into less generation of waste and also enhances for highly specific separation. Generally, Nano HPLC utilizes very small internal diameter due to which the sample is more concentrated and results are highly specific and accurate. A recent development in Nano HPLC is the introduction of the chip based structures. This system aims at incorporating connections, columns and spray needle in one device to make installation and operation of nano HPLC system easier. Nano HPLC is widely used in various different fields such as in separation of sulfonamides, peptides. It is also used for extraction of fluoroquinolones and xanthene derivatives from human serum samples. Recently, nano HPLC is widely used in discovery of Glycomics. In a nutshell, nano HPLC is a latest innovation in HPLC technique in which detection is achieved at nano grams.

G039

A review on forced degradation strategies to establish the stability of therapeutic peptide formulations

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Peptides are small polymers made up of 40 or fewer amino acids and are increasingly important class of drugs due to their greater safety, selectivity, effectiveness and specificity. Hence, they are challenging to mould in a stable formulation due to their susceptibility to proteolytic degradations. With the knowledge of the degradation behaviour of such peptide drugs, researchers and pharmaceutical manufactures can find out the remedy to design the safe, effective and stable peptide formulation. From the scientific standpoint, forced degradation studies are an indispensable tool to forecast the stability of any molecule during its development phase. Currently, about 100 peptide drug products are marketed worldwide and are regulated as small molecules. Being structurally diverse, degradation of peptide drug products are different from the small molecules. Based on the published scientific literatures, our current review provides a practical summary on strategies adopted to perform the stress stability testing for different peptide therapeutics including a selection of stress conditions, degradation products formed and an analytical methodology used for identification and characterization of degradation products. This will help fellow researchers and pharmaceutical manufactures to build up the protocol to perform forced degradation studies for novel peptide therapeutics. Additionally, it will accelerate the generic peptide drug products development based on the fact presented here in the form of case studies. We have also discussed in detail proposed degradation mechanisms reported with the role of amino acids. Based on degradation mechanisms, this review presents in brief the way of controlling the degradation from synthesis to formulation development of peptide drug products.

TRACK-H

MODERN HEALTHCARE CHALLENGES AND OPPORTUNITIES

H001

Significance of Laboratory Findings in Novel SARS-CoV-2 Disease Prognosis: A Review

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The pandemic of the Coronavirus diseases 2019 has created social, medical and scientific complexities. To be able to guarantee prompt treatment, it is crucial and important to identify appropriate laboratory biomarkers that are capable of differentiating patients based on the severity. The precise analysis of all the parameters that help in the analysis of the early progression of the disease may help identify the new laboratory biomarkers. An analysis of recently published studies helps to highlight the role of systemic vacuities and cytokine-mediated coagulation disorders in patients with serious COVID-19 complications as the key factors of multi-organ failure. This review aims to report on the current state of knowledge of recognized biomarkers for COVID-19 infection, with a focus on those, who are potentially predictive of organ harm in individuals with severe complications and death. The following biomarkers have been identified: hematological (lymphocyte count, neutrophil count, basophile count, monocyte count, eosinophil count and WBC count), inflammatory (procalcitonin (PCT), C-reactive protein (CRP)), immunological (interleukin (IL)-6 and biochemical (D-dimer, creatinine, aminotransferase (AT), aspartate aminotransferase(AST)), platelet counts, alkaline phosphate(ALP), and red blood cell distribution width (RDW) are specifically related to disseminated intravascular coagulation (DIC), coagulation cascades and acute respiratory distress syndrome (ARDS).

H006

Combination Nanotherapies for TNBC Based on RNAi

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TNBC is the most aggressive and virulent breast cancer subtype with the highest mortality rate of all breast carcinomas. Triple-negative originates this type of cancer has negative action of estrogen receptor, progesterone receptor, and HER2 receptor, ascribed to mutations in BRCA1 gene. The advanced treatment of TNBC is based on immune nanotherapies by working on immune checkpoint receptors, combinations of nanotherapies, and many other ways, treatment using nanotechnology and the triple hit approach. Relapsed and metastatic TNBCs usually progress more rapidly, showing strong resistance to chemotherapy and radiotherapy, alternative treatments have failed to improve the prognosis of these patients due to a lack of combinatorial targeted drugs. Current RNA-based therapeutics represent a novel tool in oncology with their ability to alter intrinsic cancer pathways that contribute to poor patient prognosis exist as two major areas of investigation RNA nanotherapeutics and RNA-interference (RNAi) that can be further classified as small interfering RNA (siRNA) or microRNA (miRNA). The role of small interfering RNA (siRNA) in silencing the genes/proteins that are aberrantly overexpressed in carcinoma cells has shown considerable potential as part of the TNBC therapeutic regimen. The therapeutic efficiency of anti-cancer drugs can be significantly improved by additive or synergistic effects induced by combining siRNA with such therapeutic agents that can overcome the multidrug resistance phenomenon by simultaneously silencing genes and enhancing chemotherapeutic activity utilizing RNA-derived nanoparticles to deliver chemotherapeutics to target cells.

Keywords: TNBC – Triple-negative breast cancer; RNA interference; microRNA; small interfering RNA; combinations nanotherapies; RNA derived nanoparticles; Nanomedicine

H008

Artificial Intelligence-based Content Uniformity Detection: The Changing Paradigm of Pharmaceutical world

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The Issue of Powder Blending especially with Potent API or low-load drug formulation is a major concern in Pharmaceutical Industry due to insufficient or improper blending which ultimately promotes the production hold, more time consumption & Increases cost to a significant level. Regulatory authorities often find the failure in content uniformity of many marketed formulations of reputed pharmaceutical companies. So the motive of research work is to establish a quick IPQC test to determine the endpoint of the Powder-blending process every time in just a few moments using Artificial Intelligence. The Ideal candidate selected as potent drug was glipizide. The reference formulation of the glipizide tablet was optimized to make Mixed and Not-mixed formulations using order and geometric mixing method in a double cone blender. A novel sampling technique using adhesive tape based slide sampling was developed. Then sample slides was carried out to capture microscopic images (1500+ Images) of both Mixed and Not-mixed formulations for using it in training and validation of Deep Learning (AI) based predictive model developed through python script in TensorFlow®. All the Batches prepared, passed through the UV analysis to cross-check the prediction of the Model. Also model had the inbuilt accuracy & loss analysis, which achieved 94% overall accuracy & 6% overall loss. So by using artificial intelligence and deep learning we can establish low cost, accurate and a time saving quick-check test detecting endpoint of powder blending during manufacturing.

H009

Development of More efficient and cost effective Virucidal Coated Face Masks to reduce spread of COVID-19 infection.

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Introduction: In the absence of effective treatment of COVID-19, the prime focus is on prevention. Hence Facial mask is most effective mass preventive measure. Considering, the COVID-19 crisis, recently we thought on the limitations of the currently available masks to develop better solutions. We have planned to develop more efficient masks to tackle spread of viral infection. Therefore, herewith we are proposing development of multilayer masks coated with virucidal agents to act on viruses to destroy the viruses before entering the host.

Methods**:** We developed various coating solutions containing pharmaceutical grade excipients like binder, anti-smell (odour trapping) agents along with virucidal and antimicrobial agents. The coating formulations were coated on the woven cotton layer. Virucidal agents which have been used are of proven virucidal efficacy and established human safety. Three different types of masks in which at least one layer is layer coated with virucidal agents:

1)Reusable mask covered with replaceable filter, the filters of Masks were developed using 3D printing;

2)Mask similar to N-95 with virucidal layer;

3) surgical mask with virucidal layer.

Masks are characterized for various parameters like activity against SARS-COV2 virus, bactericidal activity, bacterial filtration efficiency, breathing resistance, splash resistance, coating efficiency.

Results: The coating formulation shown virucidal activity >90% against SARS-COV-2 virus and also shown bactericidal activity. Theses masks has shown bacterial filtration efficiency of >95%, splash resistance and breathability as per the Indian standards.

Conclusion: Thus, the virucidal masks developed enhancing the effectiveness of mask beyond just Bacterial filtration efficiency (BFE), considering specific need for COVID19.

H010

Preclinical evaluation of phloretin on cisplatin induced nephrotoxicity in peri-menopausal mouse model

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Introduction : Cisplatin is an effective anti-cancer therapy, however causes remarkable toxicity to the kidney. From literature it is evident that women are more prone to Cisplatin induced nephrotoxicity, and the women >45 yrs of age (specifically women of 45-55 peri-menopausal age) are more prone to cisplatin induced nephrotoxicity. Phloretin is responsible for the inhibition of inflammatory mediators and oxidative stress by scavenging reactive oxygen species (ROS) and known for its nephroprotective effect. The objective of the present study is to determine the nephroprotective effect of phloretin on cisplatin induced nephrotoxicity in primenopausal mouse model.

Method: Mice were overiectomised unilaterally to mimic clinical perimenopausal condition. Cisplatin was administered in the perimenopausal and normal mice for 5 days in Swiss albino mice. Test drugs phloretin 20, 60 mg/kg was given to perimenopausal mice receiving cisplatin via oral gavage needle.

Result : In the Cispaltin induced nephrotoxicity study in perimenopausal mouse model, Cisplatin significantly increased level of serum creatinine, BUN, ALP and decreased the level of albumin. Cisplatin treated mice shown enhanced level of oxidative stress parameters. Cisplatin treated animals shows the histological damaged to the kidney. Phloretin shows the significant protective effect in kidney function parameters (CRE, BUN and albumin in serum), oxidative stress parameters and microscopic tissue injury in histopathology studies.

Conclusion: The observed results of the current research work clearly exhibited the clinical potential of phloretin as co treatment with cisplatin for cancer treatment in perimenopausal women to reduce susceptibility of these population to cisplatin induced nephrotoxicity.

H011

Artificial Intelligence for Alzheimer's disease Diagnosis: A Boost in Accurate Prediction Approach

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Alzheimer's disease (AD) is a widely recognized as a type of dementia. According to Alzheimer's Disease International (ADI) the prevalence of AD gauges more than 50 million people worldwide, a figure expected to rise up to 152 million by 2050. Alzheimer's disease management is complex due to many unrevealing pathologies such as amyloid plaque and neurofibrillary tangles, but still it's unclear. Despite ample research effort, we still do not have a cure capable of modifying or curing the disease. The recent studies uses machine learning for image processing and statistical learning of PET-scans, FDG-PET scans and MRI scans. The current growth of data sharing initiatives collecting lifestyles, clinical and biological data from AD patients can be applied for interpretation of disease more effective ways. Artificial Intelligence (AI) have modernised many industries and can renovate the care in Alzheimer's disease. AI technology plays a vital role in interpretation of pathological mechanism of AD by analysing complex data. In this review focus on the recent finding of AI for AD research and challenging of its application. This will help to enhance clinical understanding of AD diagnosis and improve clinician's decision making ability in AD finding.

H012

Current Approaches and Emerging Novel Therapies for Idiopathic Pulmonary Fibrosis

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The review compromises of brief and systematic information about introduction, therapeutic strategies in the current landscape as well as throws light on the emerging future potentials for the treatment of idiopathic pulmonary fibrosis (IPF). It initiates with the introduction and elaborates IPF as continuous, inevitable and lethal age related respiratory disease which, can be portrayed as condensed and rigid tissues of lungs and leads into declination in its normal functioning. The disease has affected a wide range of population and is diagnosed through the usual interstitial pneumonia (UIP) pattern on high resolution computed tomography (HRTC) or lung biopsy. The pathophysiology of IPF has not been completely understood and hence, the current strategies are still behind the time in the aspect of improved condition of IPF patients with increased survival rates. Further, it establishes information about therapeutic approaches for IPF. The pharmacotherapy involves Pirfenidone and Nintedanib which are the most promising API used in the therapy of IPF. The review wraps up about the mechanism involved behind aging which is a major risk factor for IPF with their respective emerging novel therapies. The ageing disruption such as, telomere attrition, senescence, epigenetic drift, stem cell exhaustion, loss of proteostasis and mitochondrial dysfunction are promising targets for the treatment of IPF.

H013

Assessment of Gaps Between Standard Diabetes Treatment Protocols Available In India And National List Of Essential Medicines And Who Essential Medicines- A Comparative Review Study.

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Introduction: Diabetes mellitus is a syndrome of multiple aetiologies characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat, and protein metabolism resulting from defects in insulin secretion, insulin action, or both. The current study mainly focuses on the comparison of various standard diabetes treatment protocols available in India with the National List of Essential Medicines and World Health Organisation Essential Medicines List.

Methodology: Through analysis of all standard diabetes treatment protocols available in India and comparison with National list of essential medicines, World Health Organisation Essential Medicines List, and Indian Public Health Standards for diabetes drugs.

Results: All the guidelines have Metformin as the drug of choice and the dosage varies from 250 to 2000mg/day. NPCDCS guidelines are based on the BMI of a patient. IPHS has a set of drugs for diabetes treatment, these drugs are present at all levels of healthcare delivery systems (i.e.,10,20,30). Glucagon is not included in IPHS standards.

Key Words: Diabetes Mellitus, Standard treatment protocols, Essential Medicines, Gap assessment.

H014

Regulatory Framework For Artificial Intelligence And Machine Learning Driven Software As A Medical Device (SaMD)

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Artificial intelligence (AI) and machine learning (ML) technologies have the potential to transform medical devices which helps in diagnosing, managing and treating a wide variety of medical conditions. Medical device manufacturers are using these technologies to innovate their products to better assist health care providers and improve patient care. The application of AI/ML in SaMD is it can support remote monitoring for in-patient and out-patient use cases for data collection and management for clinical efficiency and productivity. These would involve sensor data acquisition, connectivity, cloud integration, and user application development. AI/ ML technologies can be used in SaMDs for supporting diagnostic (imaging as well as non-imaging) and prescriptive use cases, often using aggregated multi-modal data, in order to analyze data image data streams from diverse modalities like MRIs, X-ray scans, and CT scans to detect and diagnose physiological conditions, abnormalities, non-image data streams like audio and biochemical test data and heterogeneous medical history data to aid decisions for an individual, group, or large population.FDA's Centre for Devices and Radiological Health (CDRH) is considering a total product lifecycle-based regulatory framework (TPLC) for AI/ML enabled devices to allow for modifications to be made from real world performance along with ensuring the safety and effectiveness of the medical device. This approach would apply to those AI/ML based medical devices that require premarket submission and not those that are exempt from requiring premarket review (i.e. Class I exempt and Class II exempt). To fully adopt a TPLC approach in the regulation of AI/ML-based SaMD, manufacturers can work to assure the safety and effectiveness of their software products by implementing appropriate mechanisms that support transparency and real-world performance monitoring. In addition, summary of the marketed AI/ML enabled medical devices is also being discussed.

H015

Experimental Acute and Chronic Pancreatitis Models: History, Current Status and Success

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Pancreas is a complex organ of gastro-intestinal tract consisting many different types of cell populations. It has two main functions: endocrine and exocrine. There are many pancreatic diseases which are of major concern among which the highest observed are acute pancreatitis, chronic pancreatitis and pancreatic cancer. Pancreatitis is major inflammatory disease of pancreas. Main causes of this disease are gallstones, alcohol abuse and pancreatic hyperstimulation. It is an inflammatory which is characterized by symptoms like abdominal pain, rapid pulse, nausea, abdominal pain radiating towards back. The number of cases of pancreatitis globally observed in 2019 was around 250000-300000 cases. There is about 65% rise in cases of pancreatitis has been observed since 2009 till 2019. There is no such particular treatment available for pancreatitis as the underlying cause of pancreatitis is not specific and mechanism of it is also not understood well. There are different induction models used to understand the disease pathophysiology and to study medication effect in animals. Here we are going to look into different induction models of acute pancreatitis in rodents. There are major 2 types of induction models for pancreatitis acute models and chronic models. Acute and chronic models are used to induce acute pancreatitis and chronic pancreatitis respectively. Basic types of induction models for pancreatitis includes: Chemical induced models, Stress induced models, Genetic models and surgery induced models.

H016

Therapeutic advances in Dravet and Lennox-Gastaut Syndrome the devastating forms of Epilepsy: A targeted literature review

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Dravet Syndrome and Lennox Gastaut Syndrome are severe disorders of epileptic encephalopathy. This disorder occurs in childhood age and lasts for lifelong they consist of mixed types of seizures such as generalized, febrile, atypical seizures, etc. The dravet syndrome occurs by Mutations in voltage-gated sodium channels are associated with epilepsy syndromes with a wide range of severity. Complete loss of function in theNav1.1 channel encoded by the SCN1A gene is associated with severe myoclonic epilepsy in infancy (SMEI). Lennox Gastaut is associated with slow spike waves in the waking electroencephalogram (EEG) and also caused due to Congenital brain Malformations. Various treatments are available such as keto diet, vagal nerve stimulation. Various drugs such as clobazam, valproate, topiramate, stiripentol are used for Dravet syndrome. Valproic acid, rufinamide, felbamate, topiramate are used for Lennox Gastaut syndrome**.**

H017

A Comprehensive Study on Traditional and Cutting-Edge Techniques for the Detection of the Vitamins and Minerals.

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Micronutrient deficiency is spreaded globally; it negatively impacts morbidity, mortality and quality of life. More than 20% of chronic diseases are due to micronutrient deficiency in body affecting either directly in patho-physiology or indirectly. Proper diagnosis is lacking because of two reasons, selection of standard biomarker and sensitivity and robustness of analytical techniques. There are various traditional analytical techniques available but it requires centralized laboratory facilities which are not readily accessible in terms of cost, time, and requirement of sophisticated instrument and expertise to perform the task. Ongoing advancements in nutritional identification techniques, discoveries are enabling the objective and accurate assessment of an individual's micronutrient status within minutes results are obtained. In this paper, we have summarized background on nutritional biomarkers used till now for diagnosis of vitamins. Further it focuses on the analytical techniques available with the emerging technologies that exploit them at the point-of-need enabling an increasing its sensitivity and scalability globally. Its features that allows reducing costs, workload and improving the turnaround time, reproducible results, etc. All these features leading us towards the point of care technology which encompasses concepts like biosensors, microfludic chip, Lateral Flow Immunoassays, 3d printing, miniaturized devices, artificial intelligence and smart phone have become one of the most popular tools for point of care test to obtain results in a timely manner. It has application in various fields like clinical, food safety, pharmaceutical, veterinary, environmental and self testing etc.

H018

An Overview and Comprehensive Study of Current Emerging Trends in the Diagnosis and Treatment of Autism Spectrum Disorder

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Neurodevelopmental disorders are leading causes of disabilities in children, affecting 1 in 59 children alone in USA from a very early age. Autism Spectrum Disorder (ASD) is one such type of neurodevelopmental disease which affects young children and mostly lasts till they reach adulthood or even after that as well. Moreover this disorder causes impairment in three core domains namely (1) social communication, (2) behavioral patterns (3) language development and usage, which are the basic tools and necessities utilized by children to cope up with the ever changing surrounding environment, Loss of co-ordination in these three primal functions not only makes them susceptible to varying range of physical and mental manifestation of disease like depression and irritability but it also makes them a victim of discrimination in personal and professional lives, especially in developing countries and communities where the awareness for the same is significantly less. In addition, the heterogeneity and involvement of strong genetic components in the ASD makes it even more complicated to be diagnosed and because it affects young children, safe pharmacological intervention to manage this disorder is much tricky rather than complicated. 80 plus years have been passed since this disease was first officially mentioned and still the quest is ongoing at all time high pace to develop sterling diagnostic tools and treatment options. This review gives an comprehensive overview of Current Emerging Trends in the Diagnosis and Treatment of ASD.

H019

Network Pharmacology: A Novel Paradigm for Drug Repurposing and Synergism

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Network pharmacology is a rapidly expanding field that is routinely employed in the drug discovery process. It combines computational biology with systems biology and omic technology. Many medications used to treat cancer, heart disease, neurological disorders, and other chronic illnesses have the ability to act on multiple targets via different biochemical pathways. Therefore, it is vital to comprehend the diverse routes by which a drug can act in various disorders. Furthermore, it has been suggested that medications taken in combination can affect several targets and be more effective in managing complicated disorders than a single treatment that binds to a specific target. Network pharmacology has been greatly utilized for exploring new drugs. It is additionally used to investigate already existing drugs for re-purposing. Another application of network pharmacology is to unravel the mechanisms of drug formulations which have multiple drug components in it. It also tries to find new treatment leads and targets, as well as repurpose current drug molecules for alternative therapeutic diseases, by allowing an impartial exploration of prospective targets. In this review, we present the application of network pharmacology in identifying synergism between the drugs. With the help of examples from the literature, the review throws light on the different tools and databases that can be utilized in finding potential drug targets and proteins with an emphasis on construction and creation of networks using Cytoscape software. Network pharmacology analysis attempts to improve the safety and efficacy of existing drugs as well as offer up new therapeutic possibilities.

H020

Nuclear Medicine an Opportunity or Obstacle for the Healthcare System

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Every advantage has its own disadvantage as well. This topic empompasses the dynamic research in various fields of healthcare among which the nuclear medicine is outshining. Vast innovations in healthcare technology has uprooted a newer emerging system of medicine which involves the knowledge and action of radioactive substances like Iodine-131, Cobalt-60 etc. in diagnosis as well as treatment of numerous ailments. It is a branch of medicine in which radioactive material is administered into the patient's body and its concentration in particular site will give output results which are useful in detection via scintigrams which can be Positron emission tomography(PET) and Single photon emission computed tomography(SPECT) or radioactive tracers and as therapeutic agents. The key methodologies used in diagnosis are SPECT and PET unlike other radiological techniques which only detect the existence of disease, here the root cause of disease and its treatment approach is also recognized. It is a boundless system having its utilization in numerous disorders like cardiac, skeletal, oncology, endocrine, genitourinary, dentistry etc. It is an effective strategy which gives the advantage of targeted treatment and also allow the monitoring of its response, rapid onset of action, early detection, specificity etc. Despite of the advantages it includes some disadvantages like radiation risk, post disposal problems, relatively high cost, insufficient trained staff etc. It is an ever-growing field as it has proven to be a blessing in many areas of inoperable disorders but at the same time considering the associated risk is prerequisite. Winding-up with the pros and cons of nuclear medicine.

H021

Microplastics: A threat to the terrestrial and aquatic ecosystem

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Plastic pollution is a leading cause of concern globally. Microplastics [MPs] are derived leachable plastics. The size of these particles ranges from 5millimeter or less, hence they are called as MPs. These particles are of varying shape as well. Due to their size, these particles escape from the filtration units and get introduced into the aquatic and terrestrial ecosystem. The various types of MPs used in the industries include polyethylene, polystyrene, polypropylenes, polystyrenes, polyvinylchlorides, etc. The potential toxic effects associated with MPs like neuroendocrine toxicity, reproductive toxicity, carcinogenicity, cytotoxicity, etc have been identified. The entry of MPs in the foodchain and hazardous effects associated with them are posing a threat to human beings. One of the studies has also revealed the presence of MPs in packaged drinking water as well. Because of the plastic cycle, it reaches the location devoid of plastic pollution. In the present review we intend to focus on the entry of MPs in the food chain, its toxic effects on the aquatic and terrestrial ecosystem and an overview of the toxicities caused by these particles.

H022

Reducing Toxicity in Critically Ill Patients by using Therapeutic Drug Monitoring

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The healthcare system continues to face high death and morbidity rates associated with serious infections among the critcal illness. By the dose individualization, minimize the toxicity in critically ill patients. Today, patient and organism complexity are expanding the need for precision dosing through TDM services. TDM (therapeutic drug monitoring) is an effective approach for dose individualization. Traditionally, this therapeutic drug monitoring (TDM) of antibiotics, antifungal, antiviral and antimicrobial have primarily involved quantitative drug measurements in patient's plasma to minimize toxicity risks with agents of narrow therapeutic indices. There is significant variation among institutions in terms of TDM practise, including patient selection, sampling time, concentration monitoring, assay technique, PK/PD target selection and dosage optimization procedures. The goal of this research was to examine the available information on several drug TDM practises and illustrate how TDM might be used to reduce toxicity in critically ill patients with severe infections.

Keywords: Critically ill patients, reducing toxicity, Therapeutic Drug Monitoring, Pharmacokinetics, Pharmacodynamics

H023

Post Covid Opportunities In Pharmacy

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Coronavirus disease 2019 (COVID-19) is a highly contagious viral illness caused by severe acute respiratory syndrome SARS-CoV-2. It has had a devastating effect on the world's demographics resulting in more than 5.3 million deaths worldwide. It has emerged as the most consequential global health crisis since the era of the influenza pandemic of 1918. COVID-19 spreads when an infected person breathes out droplets and very small particles that contain the virus. These droplets and particles can be breathed in by other people or land on their eyes, noses, or mouth. In some circumstances, they may contaminate surfaces they touch. People who are closer than 6 feet from the infected person are most likely to get infected. The current pandemic has brought the entire world to its knees and the whole world has observed the adverse catastrophe of this Global Pandemic. As healthcare professionals, pharmacists can play key role during the pandemic, acting directly with the community, continuing to care for patients with chronic diseases, working in hospital pharmacies and providing pharmaceutical care to COVID-19 patients. Moreover, they may provide reliable information for preventing, detecting, treating and managing coronavirus infections. As a result, several challenges have emerged and innovative strategies are being adopted by pharmacists to overcome them. AI is being successfully used in the identification of disease clusters, monitoring of cases, prediction of the future outbreaks, mortality risk, diagnosis of COVID-19, disease management by resource allocation, facilitating training, record maintenance and pattern recognition for studying the disease trend. As the healthcare sector across the globe is growing, it has opened great career opportunities to thousands of students of pharmaceutical science because the rate of growth of the pharmaceutical sector is interlinked and is directly proportional to the growth of the healthcare sector.

H024

Regulations of 3D printed devices

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Advances in 3D printing, also called additive manufacturing, are capturing attention in the health care field because of their potential to improve treatment for certain medical conditions. A radiologist, for instance, might create an exact replica of a patient's spine to help plan a surgery; a dentist could scan a broken tooth to make a crown that fits precisely into the patient's mouth. In both instances, the doctors can use 3D printing to make products that specifically match a patient's anatomy. 3D printing is a process that creates a three-dimensional object by building successive layers of raw material. Each new layer is attached to the previous one until the object is complete. 3D printing is a new consept in medical field and that's why it required a specific regulations and provisions to regulate the manufacturing process for protecting the human health. China, U.S and EU these are the country's leading in the implementation and regulation of 3DP. India has no particular provisions and guidelines related to 3DP. In case of USA, the US FDA approved the first 3D printed pill in 2015. USFDA has given the process and material which are used for the manufacturing of 3D printing medical devices. In 2016, FDA issued the draft guidance on the Technical Considerations for Additive Manufactured Devices to advise manufacturers who are producing devices through 3D printing techniques.

H025

Leaky gut syndrome: An emerging stress induced disorder

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Intestinal permeability is a major aspect of intestinal barrier function, and it serves as the interface between the body's external and internal environment, by preventing potentially harmful luminal antigens from entering the blood streams. Altered intestinal barrier due to disruption of tight junction or imbalance of gut microbiota causes increase in intestinal permeability which allows toxins, antigens and bacteria from the lumen to flow into the blood stream resulting into 'Leaky gut syndrome' (LGS). LGS has been linked to a number of intestinal diseases such as and irritable bowel syndrome (IBD), celiac disease as well as extra-intestinal diseases such autoimmune disease, liver conditions, hypersensitivity, food allergies and autism. Many clinical evidence has suggested that the use of probiotics and tight junction modulators are highly effective in reversing the intestinal permeability. Intestinal permeability is also affected by 'stress' diseases such as intense exercise, use of NSAIDs and Pregnancy which can be reverse by the use of dietary fibers. Other therapeutics treatments which have been shown a promising effect on LGS are Zinc, L-glutamine, Collagen peptide, curcumin, berberine and Deglycyrrhizinated licorice. The intestinal permeability can be measured by recording the passage of permeability biomarkers over the epithelium via paracellular or transcellular route such as Zonulin, Fluorescein isothiocyanate -dextran, LPS. This review will define and analyse the current understanding of how diverse factors affect intestinal permeability, emerging therapeutic options, and how permeability is assessed along with the current problems that need to be address in the future.

H026

Phloretin treatment prevent Arsenic Trioxide induced Nephrotoxicity in Swiss Albino Mice

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Introduction: Arsenic trioxide (As_2O_3) is known to cause toxicity to kidney, the mechanistic link for toxicity is through generation of reactive oxygen species. Phloretin is a phytoconstituents, known for the inhibition of inflammatory mediators and oxidative stress by scavenging ROS. The objective of study is to determine nephroprotective effect of Phloretin on As_2O_3 induced nephrotoxicity in mice.

Method: As_2O_3 was administered in drinking water via specially designed feed tube to assess acute and chronic effect of As_2O_3 ingestion to Swiss albino mice. Phloretin (20,40, and 80 mg/kg) was given via oral gavage in both the model. The serum and urinary kidney function parameters and oxidative stress parameters in kidney were assessed and renal histopathology was performed to assess the pathological alterations using H&E staining.

Result: As_2O_3 treated group significantly increases serum creatinine, BUN, ALP and decreases serum level of albumin. As_2O_3 treated group shown significant decreased urinary level of creatinine and BUN and increased in urinary albumin excretion. AS_2O_3 treated group shown significant decrease in antioxidant enzymes like GSH, SOD,CAT and increased LPO Level. Histologically, As_2O_3 treated animals showed damaged to glomerular region in kidney. Phloretin show significant protective effect in all parameters.

Conclusion: Present study demonstrated that Phloretin can be developed as effective therapy to prevent As_2O_3 induced functional and pathological changes in kidney.

H027

Emergence of Immunotherapy to Combat Cytokine Storm in COVID-19

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Coronavirus disease, also known as COVID-19, has been a point of discussion since its outbreak. Known to be caused by a deadly virus, SARS-COV-2, it has affected around 38 Cr people worldwide. The death toll has reached almost 57 L to date. The life-threatening virus is a source of mild enteric and respiratory diseases in both animals and humans. Clinical manifestations of COVID-19 include high fever, advanced inflammatory response, and increased lung damage. The virus has a deleterious effect on an individual's immune system leading to a sudden rise in inflammatory mediators such as CRP and cytokines. There occurs a rapid release of interleukins like IL-6 and tumor necrosis factors. Many times it provokes a condition called a "cytokine storm"! That causes blood clots, finally triggering multi-organ failure. A differentiating point behind it is the easy ability of the virus to penetrate the lungs causing difficulty in breathing. Thereby, the patient immediately requires ventilation. Timely treatment and proper medication in such cases become an essential aspect. Research suggests the use of various immunomodulators along with antiviral drugs. From hydroxychloroquine to siltuximab, scientists have come a long way. Still, there is a lot of scope where immunotherapy can play a pivotal role in preventing lethal conditions like COVID-19.

H028

Effect of Covid-19 on Pregnancy and Related Outcomes

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Pregnant Women were one of the major concerns in the COVID-19 pandemic. The impact of Covid-19 on Pregnancy is studied by many researchers. It is reported that the inflammatory cytokines are majorly involved in different trimester of pregnancy as well as maternal and perinatal mortality. It is also observed that SARS-CoV-2 activates immunologic state especially, Th-1 and Th-2 components. During pregnancy, COVID-1 virus causes severe inflammation via cytokine-storm. ACE-2 (Angiotensin converting Enzyme) is the functional receptor present on cell from where SARS-CoV-2 enters in the host cell. During pregnancy, ACE-2 receptor expression increases and affects the placenta too. During pregnancy in respiratory system, the tidal volume gets affected and 20-30 % reduction can be observed in functional residual capacity. The effect on foetus is dependent on the particular trimester phase of pregnancy. This review discusses the impact of covid-19 on pregnancy and related outcomes.

H029

A Review on Nano-polymer formulation and Characterization for Drug Delivery System

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Nanomedicine and Nano-scale drug delivery systems are still under development, apart from that this area is one of the rapidly evaluating filed of research. Materials in the nanoscale are employed to serve as diagnostic tools or drivers of therapeutic ingredients to the specific site and in a controlled manner. Nanotechnology offers multiple benefits in treating chronic human diseases by site-specific, and target-oriented delivery of precise medicines. Recently, there are many outstanding applications of nanomedicine (chemotherapeutic agents, biological agents, immunotherapeutic agents, etc.) in the treatment of various diseases. In this review, different formulation methods for nano-polymers, factors affecting preparation, and characterization methods are briefed. The formulation of nano-polymer for drug delivery is not as simple, as it involves several issues like immunogenicity, clinical acceptance, and environmental hazards. Moreover, a basic understanding of constituent materials like therapeutic moieties, polymers, and stabilizing is the prerequisite. These components directly affect various attributes like size, shape, surface morphology, surface charge, drug loading/encapsulation efficiency and drug release profile, and consequently pharmacokinetics and biodistribution, thus efficacy and safety profiles.

H030

Cardiorenal Syndrome: New Development in the Understanding and Pharmacological Management and diagnosis

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Cardiorenal syndromes (CRSs) with bidirectional heart-kidney signaling are increasingly being recognized for their association with increased morbidity and mortality. The term CRS implies acute or chronic injury to the heart and kidneys that often involves a temporal sequence of disease initiation and progression. Classification of CRS is divided into five subtypes: Types 1 and 2 involve acute and chronic cardiovascular disease (CVD) scenarios leading to acute kidney injury (AKI) or accelerated chronic kidney disease (CKD). Types 3 and 4, describe AKI and CKD, respectively, leading primarily to heart failure. Finally, CRS type 5 describes a systemic insult to both heart and the kidneys, such as sepsis, where both organs are injured simultaneously in persons with previously normal heart and kidney function at baseline. The presence of a group of interactive maladaptive factors including hypertension, insulin resistance, metabolic dyslipidemia, obesity, microalbuminuria, and/or reduced renal function constitute the CRS. Large population-based investigations have confirmed that these interacting variables cause heart and kidney illness. The involvement of fluid overload and venous congestion, in particular, has sparked interest in the most effective use of diuretic medication to improve heart failure symptoms while also protecting renal function. In recent years, various innovative vasoactive treatments have been investigated in the hopes of enhancing heart function, alleviating symptoms, and improving patient outcomes while preserving or increasing kidney function.

E098

Design and Development of pH-Sensitive In-Situ Ophthalmic Gel for Open-Angle Glaucoma

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Glaucoma is a condition in the eye that damages the optic nerve and the main reason behind the damage is high intraocular pressure. According to WHO glaucoma is the leading cause of vision loss and in India, over 12 million are affected. Currently, there are different marketed formulations are present in the form of solutions. However poor retention time of the drug, washout, fast dilution causes a less therapeutic effect of the drug when it is used as a conventional eye drop. The in-situ gel is the formulation having the ability to convert from sol. This study aims to design and develop a pH-sensitive in-situ ophthalmic gel for sustained release of timolol. The gel was characterized for, in-vitro and in-vivo study. Timolol maleate is popularly used as a beta-blocker. The drug is used to treat open-angle glaucoma as it can decrease intraocular pressure. Gellan gum is the polymer used to prepare pH-sensitive in-situ gel. The developed novel in-situ gel was characterized for texture analysis, viscosity, gelling capacity, DSC, FTIR, and drug release study. Timolol maleate in-situ gel-based system is the novel approach to improve bioavailability and improve therapeutic effect and provide advantages in the treatment of open-angle glaucoma. . In the present study, the pH in-situ gel is developed using gellan gum. It shows that sustained drug release upto two hours in the ocular region and it is expecte that it will reduce dose frequency and improve patient compliance.

F007

Design, Molecular Docking, Microwave Synthesis of 2-Substituted Benzothiazole derivatives and study of their antioxidant and anticancer activities targeting DHFR Enzyme

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Background: A series of 2-Substituted Benzothiazole derivatives was developed and its chemical scaffolds were authenticated by NMR, IR, elemental analyses, and physicochemical properties. The Molecular docking studies, synthesized 2-Substituted Benzothiazole compounds were screened for their in-vitro antioxidant activities and were preliminary screened against two breast cancer MDA-MB-231 and MCF 7 breast cancer cell lines which were compared with Methotrexate. Potent compounds were further evaluated against L929 (noncancerous skin fibroblast) cell line and found highly selective for MCF-7 cells over L929 cells.

Results and discussion: The synthesized benzimidazole compounds were evaluated for their antioxidant activity using the DPPH, Hydrogen Peroxide Radical Scavenging activity, Nitric oxide, FRAP Assay method were found to exhibit good antioxidant potential against selected. The compounds were also assessed for their anticancer activity exhibited using the MTT assay and were found to elicit antiproliferative activity against the MDA-MB-231 and MCF7 breast cancer cell line, which was comparable to the standard drug.

Conclusion: Antioxidant activity results indicated that compounds 7a, 7c, and 7e to be promising Antioxidant activity and comparable to standard drugs. The anticancer screening results revealed that compounds 7a, 7c, and 7e to show the highest activity against MCF7. There is still scope for more research in this field to discover a novel agent

DISCLAMIER

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