SAMPLE SUMMARY

Formulation Development and Optimization of Paracetamol Fast Dissolving Tablets for Pediatrics

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INTRODUCTION

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Paracetamol is well known Antipyretic and Anti-inflammatory drug, used in the management of fever and pain. Difficulty in swallowing (dysphagia) is common among paediatric patients. Although unpleasant taste may be masked for paediatric administration, the accurate dose administration cannot be ensured through liquid formulation.

OBJECTIVE

The aim of the present investigation was to formulate Paracetamol Fast Dissolving Tablet (FDT), which may be dissolved in a glassful of milk or water by parents of the paediatric patient and medicated milk or water may be administered orally to paediatric patients. Hence the taste of the tablets and disintegration are the crucial parameters to be optimised. The efforts were made in the present study to formulate the Paracetamol Fast Dissolving Tablets by optimization of critical excipients, which offers patient compliance and regulatory compliance.

MATERIALS AND METHODS

Analytical Estimation of Drug

The purity of Paracetamol was analysed using UV Spectrophotometry, Raman Spectrophotometry as well as FTIR Spectroscopy. The standard curve of Paracetamol was generated in Distilled water, Methanol, 0.1 N HCl, 0.01N HCl (Fed state) and Phosphate buffer pH 5.8. The solubility of Paracetamol was determined in above media.

Formulation and evaluation of Paracetamol tablets

The Fast dissolving tablets of Paracetamol were formulated by wet granulation technique. The concentration of mannitol and sucralose as sweetener as well as diluent were optimized based on taste masking capacity in solution form. The taste masking and solubility improvement of paracetamol was attempted by complexing of drug at various ratios with complexing agents like β-cyclodextrine and KyronT-314. The disintegration time was reduced by incorporation of Sodium Starch Glycolate (SSG) as a super-disintegrant. Further reduction of disintegration time to desired time limit was tried by incorporation of non-aqueous solvent like Ethanol at varied proportions with water during wet granulation process. The FDTs were also formulated by vacuum drying of tablet containing camphor as well as the combination approach was executed by incorporation of super-disintegrant and sublimating agent. The tablets were dispersed in 100 mL of milk or water along with stirring using spoon at 25 rpm, and the dispersion time were noted by regular sampling and visual inspection. The tablets were also evaluated for hardness, disintegration, friability, weight variation and in-vitro dissolution testing. Taste of the formulation was also checked by human volunteers. The optimized batch was re-evaluated after short term stability testing.

RESULTS AND DISCUSSIONS

Formulation component were selected based on their apparent capacity to improve solubility, taste masking and dissolution of the drug. β-cyclodextrine in 1:1 ratio was found to give complete taste masking. The FTIR spectra of paracetamol, β-cyclodextrine and complex indicate the absences of finger print region of paracetamol in the complex, which justify complete complex formation. The reduction of disintegration time was observed with higher proportion of ethanol in solvent mixture. The FDT formulated by sublimation approach could not offer any significant outcome and the process found to be non-economic. The best formulation batch was evaluated for in-vitro dissolution study with different dissolution media and the drug release profile was found to be independent of pH. The optimized FDT formulation ensured disintegration in 100 mL of milk & water within 60 sec as well as more than 85% drug released in first 15 min and complete dissolution in 25 min.(Figure 1) The optimized formulation was found to be stable after short term stability study.

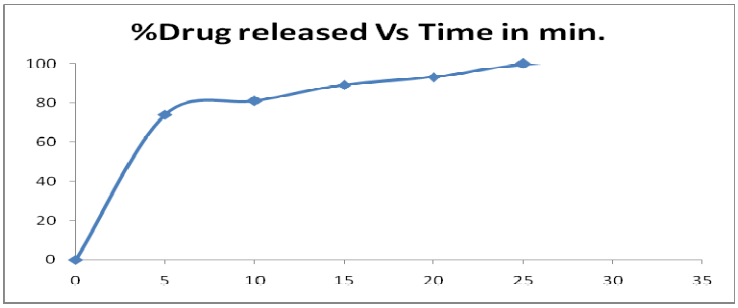

Figure 1: Dissolution profile of Optimized Batch

CONCLUSION

The results of the present study revealed that the Paracetamol FDT for paediatric patients with desired formulation characteristics can be prepared by systemic optimization of critical excipients, and higher patient compliance can be expected.

REFERENCES

1) Krishna R, Srinivas P, Sadanandam. Paediatric formulation development challenges and opportunities. International Journal of drug formulation and Research. 2010;2(1):58-79.

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3) Rowe RC, Sheskey PG, Quinn NE. Handbook of pharmaceutical excipients, pharmaceutical press, 6th edition;2009:663-667.

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