Formulation Development and Optimization of Paracetamol Fast Dissolving Tablets for Pediatrics

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Oral formulations have carved a niche amongst the different drug delivery systems. Ease of administration and patient compliance are gaining significant importance in the design of dosage form. Paracetamol is an orally administered Antipyretic and Anti-inflammatory drug, used in the management of fever and pain. Difficulty in swallowing (dysphagia) is a common problem among paediatric patients. Although unpleasant taste is masked for pediatrics administration, the accurate dose administration is difficult to ensure through syrup. In light of all above facts and challenges, the formulation of fast dissolving tablets (FDT) for pediatric patients could provide patient compliance as well as accurate dose with desirable taste masking. The FDT were evaluated for friability, dispersion time study, taste masking in solution form and in-vitro dissolution study. The excipients like diluents, sweetener, taste masking agent and super-disintegrants were found to play an important role in formulation of FDT and were systematically optimized. Mannitol and sucralose as diluents as well sweeteners were optimized. The sodium starch glycolate optimized as super-disintegrant and β-cyclodextrine & KyronT-314 were evaluated as taste masking agents. The optimum batch showed drug release more than 85% within 15 min and disintegration time less than 60 sec, along with the desired organoleptic properties. The optimized batches showed substantial stability when subjected to short term stability study (room temperature). Developed fast dissolving tablets were found to be best in terms of dispersion time, drug release profile, stability, operational skills, and process cost.

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