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Design and development of dual release oral reconstitutable suspension of Cefpodoxime proxetil

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Objectives: The aim of present research work was undertaken with the objective of design and development of dual release oral reconstitutable suspension of Cefpodoxime proxetil for pediatric patients.

Experimental work: Pellets were prepared by extrusion – spheronization technique. Immediate release pellets were prepared and evaluated by using varying concentration of Sodium starch glycolate, Croscarmellose sodium and Crospovidone whereas sustained release pellets were prepared and evaluated by using different concentration of HPMC K100M, Eudragit RSPO & Kollidon SR. From the preliminary studies, optimize the batch of immediate release pellets and which are used for further preparation of dual release reconstitutable suspension but in SR pellets, optimization is carried out by using 32 factorial design in which HPMC K100M (X1) and Eudragit RSPO (X2) were selected as independent variables, while t50 (hr), t90 (hr), Q2 (%), and Q10 (%), were selected as dependent variable. Dissolution data were fitted to various kinetic models on drug release of SR pellets and optimize the SR pellet formulation for dual release oral reconstitutable suspension. The prepared dual release oral reconstitutable suspensions were evaluated for rheological and sedimentation behavior.

Results & Discussion: Result of preliminary studies of P1-P18 batches indicated that, Combination of sodium starch glycolate (5%) and Croscarmellose sodium (5%) containing P10 batch shows minimum disintegration time (22 sec), minimum wetting time (16 sec) and maximum % water absorption ratio (124.7%), desirable particle size (990 µm) and gave 98.7% drug release at the end of 2 hrs which are used for preparation of dual release reconstitutable suspension while results of statistical data was indicated that concentration of HPMC K100M and Eudragit RSPO had significant influence on Q2 (%), Q10 (%), t50 (hr) and t90 (hr). Form the study of factorial batches (F1-F9) of SR pellets, the optimized formulation (F6) showed 98.6% drug release at the end of 12 hrs with concentration of HPMC K100M (20%) and concentration of Eudragit RSPO (15%). SEM showed that optimized batch of IR pellets (P10 batch) and SR pellets (F6 batch) both were in spherical shape with smooth surface. The dissolution profile of optimize batch of SR pellet exhibits similarity factor (f2=86.36) and dissimilarity factor (f1=2.72) with theoretical release profile of Cefpodoxime proxetil. So, P10 batch of IR pellets and F6 batch of SR pellets were selected for the preparation of dual release oral reconstitutable suspension. Result of dissolution study of reconstitutable suspension indicated that there is no significant difference in % CPR on 1st day and after 15 day which indicates the stability of dual release reconstitutable suspension.

Conclusion: It was concluded that liquid pharmaceutical preparation for oral administration capable for providing a dual release of Cefpodoxime proxetil was successfully obtained and it was most suitable for pediatric patients due to reduce dosing frequency, masking the bitter taste of drug and increase patient compliance.

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