



Formulation Development and Optimization of Cefuroxime Axetil tablets by Direct Compression Method and its Stability Studies

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SUMMARY. Cefuroxime axetil (CA) immediate release (IR) tablets were developed and optimized by direct compression method. Ten formulations were designed and optimized using central composite design with two main variables, microcrystalline cellulose PH 102 and croscarmellose. Pharmaceutical evaluation of the formulations was conducted emphasizing on dissolution profile of the drug by USP dissolution test using apparatus II in 0.07 N HCl and in medium of pH 1.2, 4.5 and 6.8 to determine the dissolution pattern of the low soluble drug. Test formulations were compared against reference brand using f_2 similarity factor. Test formulations were assayed by a validated HPLC method, with acetonitrile and 10 mM ammonium acetate solution (pH = 5.2) in a ratio of 15:85 as mobile phase. Stability studies under stress were conducted on selected formulations according to ICH guidelines. It was conclusive that stable CA formulations could be developed by direct compression method.

KEY WORDS: Cefuroxime axetil, Centre composite design, Formulation development, Formulation optimization, Similarity factor f_2 , Stability under stress conditions.

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