ADVANCING CEFDITOREN PIVOXIL TABLET MANUFACTURING: A QUALITY BY DESIGN APPROACH FOR SOLVENT-FREE PRODUCTION AND ENHANCED PHARMACEUTICAL PROPERTIES THROUGH SURFACE OPTIMIZATION

Vikram S. Gharge[a*], Vishal B. Hol[a] and Umesh R. Chavan[a]

(Received 06 May 2025) (Accepted 24 June 2026)

ABSTRACT

This study focuses on optimizing the dry granulation process for cefditoren pivoxil tablets (400 mg) to enhance their dissolution performance, addressing the challenges posed by the drug's high insolubility (BCS Class IV). Using a Quality by Design approach [QbD] and Response Surface Methodology [RSM], the research evaluated the impact of key formulation ingredients: % granules ratio, mannitol (PEARLITOL SD® 200), and magnesium stearate, on tablet properties like friability, hardness and Carr's index. The final optimized formulation featured a granule ratio of 60 %, 240 mg tablet^{-1} of mannitol and 24 mg tablet^{-1} of magnesium stearate. This formulation demonstrated significant improvements in tablet performance metrics, with dissolution studies and bioequivalence showing results similar to the innovator product Meiact® 400. These findings indicate that the optimized dry granulation process can produce high-quality cefditoren pivoxil tablets with enhanced bioavailability.

Keywords: Cefditoren pivoxil, dry granulation, quality by design, response surface methodology, tablet formulation, bioavailability.

high dose and is moisture, sensitive which adds to challenges during manufacturing process selection and development.