IJARSCT



International Journal of Advanced Research in Science, Communication and Technology

International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal

Volume 5, Issue 6, June 2025



Improvement of Bioavailability of Poorly Soluble Drugs by Solid Dispersion Technology

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Abstract: The present study aimed to enhance the oral bioavailability of metoclopramide (MCZ), a poorly soluble drug, through solid dispersion-based fast dissolving tablets (FDTs). Preformulation assessments determined the λ max of MCZ at 232 nm in 0.1 N HCl, distilled water, and pH 7.4 phosphate buffer, and solubility profiling revealed limited inherent solubility. Solid dispersions were prepared via solvent evaporation and fusion methods using polyethylene glycols (PEG 4000, PEG 6000, PEG 20000) and Gelucire® carriers in drug-to-carrier ratios ranging from 1:0.5 to 1:6. Phase solubility (Higuchi-Connors), FTIR, DSC, and XRD analyses confirmed enhanced solubility, the absence of drug-carrier interactions, and conversion of MCZ to a more amorphous state. Selected dispersions exhibiting optimal physicochemical properties were compressed into FDTs using crospovidone (5%) as superdisintegrant, spray-dried lactose as filler, magnesium stearate (1%) as lubricant, and talc (2%) as glidant. Tablet batches (MCZ1–MCZ58) demonstrated acceptable weight variation (200.58 \pm 1.94 to 202.63 \pm 1.63 mg), hardness $(3.0-3.1 \text{ kg/cm}^2)$, friability (<0.4%), rapid disintegration (117–123 s), wetting time (27–41 s), and drug content (98.13–99.63%). In vitro dissolution in pH 7.4 buffer at 37 ± 0.5 °C (USP II, 50 rpm) revealed that batch MCZ22 achieved $99.12 \pm 1.35\%$ release within 15 min, significantly outperforming the marketed product (Diligan-25: 45.71 \pm 1.23% at 15 min). Stability studies at 40 \pm 2 °C/75 \pm 5% RH for six months showed no significant change in assay or dissolution profile (p > 0.05; similarity factor $F \square = 85.74$). These findings demonstrate that solid dispersion strategies effectively improve MCZ solubility and dissolution rate, enabling development of robust FDTs for enhanced patient compliance and therapeutic efficacy.

Keywords: Metoclopramide; Solid dispersion; Fast dissolving tablets; Bioavailability enhancement; PEG; Gelucire; Crospovidone; Dissolution efficiency

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DOI: 10.48175/568

