



DESIGN AND EVALUATION OF DOMPERIDONE SUBLINGUAL TABLETS

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Abstract:

Objective: The aim of this work was to enhance the bioavailability of poorly soluble, anti-emetic drug; domperidone (DMP) having a poor oral bioavailability (13-17%) due to extensive first pass metabolism. The goal of this study was achieved through solubilization of DMP using solid dispersion technology followed by incorporation of solid dispersions into sublingual tablets to bypass pre-systemic metabolism. **Methods:** Solid dispersions of DMP with Pluronic F-68 were prepared in different weight ratios by fusion method and they were evaluated for their in vitro dissolution rate to select the best ratio for final formulation. Then, solid dispersions were formulated into sublingual tablets in combination with various soluble excipients. Sublingual tablets were prepared by direct compression technique and evaluated for their physical properties, in vitro dissolution rate and kinetics of drug release. The best formulae were selected for in vivo studies in rabbits in comparison with marketed oral tablets; Motinorm®. **Results:** Solid dispersions of DMP with Pluronic F-68 in a weight ratio of 1:7 (w/w) showed the highest dissolution rate and were selected for sublingual tablets formulation. Sublingual tablets formulae S16 (containing Fructose and 10% w/w Ac-Di-Sol) and S20 (containing Fructose and 10% w/w Explotab) showed the best results and were selected for in vivo studies in rabbits. The selected formulae showed marked enhancement of DMP bioavailability compared with the commercial oral tablets; Motinorm®, with relative bioavailability values of $432.49 \pm 10.13\%$ and $409.32 \pm 11.59\%$ for S16 and S20, respectively. **Conclusion:** The results confirmed that sublingual tablets were an effective tool for DMP delivery with marked enhancement of bioavailability.

Keywords:

Domperidone, Solubility, Solid dispersions, Sublingual tablets, First-pass metabolism, Bioavailability

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