

Formulation and Evaluation of Glimepiride (GMP)-Solid Nanodispersion and Nanodispersed Tablets

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Abstract : Introduction: The major challenge with the design of oral dosage forms lies with their poor bioavailability. The most frequent causes of low oral bioavailability are attributed to poor solubility and low permeability. The aim of this study was to develop solid nanodispersed tablet formulation of Glimepiride for the enhancement of the solubility and bioavailability. Methodology: Solid nanodispersions of Glimepiride (GMP) were prepared using two different ratios of 2 different carriers, namely; PEG6000, pluronic F127, and by adopting two different techniques, namely; solvent evaporation technique and fusion technique. A full factorial design of 2³ was adopted to investigate the influence of formulation variables on the prepared nanodispersion properties. The best chosen formula of nanodispersed powder was formulated into tablets by direct compression. The Differential Scanning Calorimetry (DSC) analysis and Fourier Transform Infra-Red (FTIR) analysis were conducted for the thermal behavior and surface structure characterization, respectively. The zeta potential and particle size analysis of the prepared glimepiride nanodispersions was determined. The prepared solid nanodispersions and solid nanodispersed tablets of GMP were evaluated in terms of pre-compression and post-compression parameters, respectively. Results: The DSC and FTIR studies revealed that there was no interaction between GMP and all the excipients used. Based on the resulted values of different pre-compression parameters, the prepared solid nanodispersions powder blends showed poor to excellent flow properties. The resulted values of the other evaluated pre-compression parameters of the prepared solid nanodispersion were within the limits of pharmacopoeia. The drug content of the prepared nanodispersions ranged from 89.6 ± 0.3 % to 99.9 ± 0.5% with particle size ranged from 111.5 nm to 492.3 nm and the resulted zeta potential (ζ) values of the prepared GMP-solid nanodispersion formulae (F1-F8) ranged from -8.28 ± 3.62 mV to -78 ± 11.4 mV. The in-vitro dissolution studies of the prepared solid nanodispersed tablets of GMP concluded that GMP- pluronic F127 combinations (F8), exhibited the best extent of drug release, compared to other formulations, and to the marketed product. One way ANOVA for the percent of drug released from the prepared GMP-nanodispersion formulae (F1- F8) after 20 and 60 minutes showed significant differences between the percent of drug released from different GMP-nanodispersed tablet formulae (F1- F8), (P<0.05). Conclusion: Preparation of glimepiride as nanodispersed particles proven to be a promising tool for enhancing the poor solubility of glimepiride.

Keywords : glimepiride, solid Nanodispersion, nanodispersed tablets, poorly water soluble drugs

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