

The effect of PEG molecular weight and concentration on properties of gliclazide solid dispersion systems

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Background and Aims: Gliclazide (GL) is a potent antidiabetic agent which is used in the treatment of non-insulin-dependent diabetes mellitus. The oral bioavailability of GL is low and variable due to its low water solubility and slow intrinsic dissolution rate in the gastrointestinal fluids. Therefore, in the present study, the effect of polyethylene glycol (PEG) molecular weight and concentration on dissolution rate of gliclazide solid dispersion systems was investigated.

Methods: Solid dispersions (SDs) of GL with various PEGs (6000, 10000 and 20000) were prepared by solvent evaporation method at drug: PEG ratios of 1:1 to 1:7. Physical mixtures (PMs) related to the optimal SD formulations were also prepared. In vitro dissolution studies were carried out on all prepared samples and the amount of drug in aliquots were analysed spectrophotometrically. Samples with the best dissolution rate were characterized by differential scanning calorimetry (DSC), infrared spectrophotometry (IR) and x-ray diffractometry (XRD). In addition, solubility studies were performed on SD samples.

Results: According to the results, the dissolution rate of GL from all solid dispersion systems prepared by PEGs, as soluble carriers, was increased compared to pure drug and related physical mixtures. However, PEG with molecular weight of 6000 showed better results and the highest dissolution rate was obtained with the GL: PEG6000 ratio of 1:7. FTIR and DSC studies demonstrated the absence of any chemical interactions between the components of system. Based on XRD analysis a slightly reduction in GL crystallinity nature in solid dispersions was observed.

Conclusions: PEG molecular weight had an important role in the achievement of desirable dissolution of GL solid dispersion systems. Reduced particle size, deaggregation of particles and slightly decreased crystallinity of the drug could be responsible for enhancing drug dissolution profile.

Keywords: Gliclazide; Solid dispersion; Dissolution; PEG