Development of Gliclazide Matrix Tablets from Pure and Blended Mixture of Glycerol Monostearate and Stearic Acid

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SUMMARY. The present study was undertaken to evaluate the effect of glyceryl monostearate (GMS) and stearic acid (SA) on the release profile of gliclazide from the matrix. Matrix tablets for the controlled delivery of gliclazide were prepared by hot melt method using pure and blended mixture of glycerol monostearate and stearic acid in different drug to polymer and polymer to polymer ratios. In vitro release characteristics of gliclazide from these hydrophobic matrices were studied over 8 h in phosphate buffer media of pH 7.4. The release kinetics of drug was evaluated for zero order, first order, Higuchi and Peppas kinetic models. It was observed that the release of drug from the matrix was greatly retarded by GMS and retarding effect increased with increasing polymer to drug ratios. On the other hand SA appeared to channel the drug from the wax matrix and release was greatly increased with increasing polymer to drug ratios. The kinetic evaluation of release profile indicated that the Higuchi model was the most appropriate model for describing the release profile of gliclazide. The application of Peppas biexponential equation indicated that non-Fickian release was the predominant mechanism of drug release. The FTIR results showed no interaction between the drug and the polymers and DSC results indicated that both the drug and polymers are in amorphous state and no significant complexes were formed. The results indicated that proper selection of drug to polymer and polymer to polymer ratios were important in order to achieve the desired dissolution profile in these matrix tablets.

KEY WORDS: Gliclazide, Glycerol monostearate, Matrix tablets, Stearic acid, Sustained-release.

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