CHAPTER V

CONCLUSIONS

In this study, controlled release gliclazide tablets formulated using hydrophilic matrix system was successfully prepared by direct compression method. Hydroxypropyl methylcellulose or xanthan gum was used as retarding polymer. The important factors, such as the quantity of polymers and the effect of pH of dissolution medium, were investigated. In addition, the mechanism of drug release was also examined. The suitable formulation should produce sufficient sustained release and should be similar to commercial product. After that a single dose of each formulation was administered to rabbit. Pharmacokinetic parameters of gliclazide were studied after an oral administration of gliclazide tablets in rabbits. The following conclusions could be drawn:

1. Sustained release of gliclazide was achieved from hydrophilic matrices containing hydroxypropyl methylcellulose or xanthan gum.

2. The influence of polymer concentration on drug release rate was observed. An increase in concentration of polymer resulted in slower rate and extent release of the drug from the tablet. This might be due to an augmentation of polymer chain entanglement in hydrated gel layer around the matrix comprising higher polymer content. This resulted in a more concentrated gel and increased gel tortuosity.

3. The effect of pH of dissolution medium on gliclazide release resulted in the difference in drug release rate in these dissolution media. However, diluent in formulation might play a more important role on drug release rate. The stronger gel

layer of diluent around the matrices and the lower solubility of the drug in the dissolution medium resulted in the slower drug release rate.

4. The formulations produced drug release profiles similar to that of commercial product based on difference factor and similarly factor were those with 20 % HPMC and 7 % XG. All two formulations had difference factor less than 15 and similarly factor more than 50.

5. In vivo study of gliclazide matrix tablet formualtion with 20 % HPMC, 7 % XG and commercial product were performed using rabbits. The pharmacokinetic parameters, C_{max}, t_{max} and AUC obtained from 20 % HPMC and 7 % XG formulations were statistically significant difference. In addition, it was found that 20 % HPMC and 7% XG formulation were as comparable as commercial product because all pharmacokinetic parameters obtained from this formulation were not statistically significant difference.

This study could be employed as a useful basic knowledge for further development of gliclazide controlled release tablet using two different hydrophilic matrix systems. The further investigation should be studied scale up in vitro and in vivo.

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