

CHAPTER V

CONCLUSIONS

1. Ketoprofen was rapidly released from conventional hydrophilic (PEG bases) rectal suppositories bases. On the other hand, a slower release of the drug was observed from suppositories prepared using a commercially available hydrophobic one, Suppocire[®]AM.

2. Two formulations of 100 mg prolonged release ketoprofen rectal suppositories were established using Eudragit S-100 and hydroxypropyl methylcellulose phthalate (HP55) as prolonged release carriers in hydrophilic suppository bases. The appropriate ratio of the drug to both carriers were 1:1 and 1:4 for Eudragit S-100 and HP55, respectively.

3. All formulations of ketoprofen rectal suppositories conformed to the British Pharmacopoeia 1993 specifications for uniformity of weight and uniformity of content.

4. Pharmacokinetics of ketoprofen in rabbits following single rectal administration of the three formulations of 100 mg prolonged release ketoprofen suppositories prepared using hydrophilic bases with each prolonged release carrier at a specified ratio and a hydrophobic bases appeared to follow multicompartement model. All corresponding pharmacokinetic parameters of ketoprofen obtained from these three formulations were not statistically significant difference ($p > 0.05$) among each other by mean of analysis of variance for a three way crossover design.

5. The two formulated 100 mg prolonged release ketoprofen rectal suppositories were bioequivalent with respect to both the rate and the extent of drug

absorption relative to the reference formulation prepared using Suppocire[®] AM. The 90% confidence intervals based on the log transformed data for the differences of C_{max} means of the formulation with Eudragit S-100 and that with HP55 were found to be 87.67-105.94%, and 87.21-105.48%, respectively. While those of AUC means of the formulation with Eudragit S-100 and that with HP55 were found to be 91.67-99.30%, and 92.01-99.65%, respectively.

6. Both Eudragit S-100 and HP55 were excellent prolonged release carriers for preparing prolonged release ketoprofen rectal suppositories but Eudragit S-100 appeared to be superior with respect to the amount being used was lesser and the ease of preparation to obtain the same quality and performance.

7. Further studies of these formulated products using human subjects are recommended before drawing a final conclusion for clinical efficacy.