CHAPTER V

CONCLUSION

1. In vitro studies, all three commercial brands of 1 g. ceftriaxone met the United States Pharmacopoeia XXIII requirements for weight variation and content of active ingredient (% L.A.).

2. Following reconstitution with sterile water for injection, all three brands of ceftriaxone intramuscular injection were stable for 7 days when refrigerated at 4°C. While at 30°C the products were not. However, to recommend that the products should be kept refrigerated at 4°C not more than 3 days.

3. The bioequivalence of ceftriaxone IM, brands A, B and C, were studied. The values of relevant pharmacokinetic paramaters, C_{max}, T_{max} and AUC, were observed as follows :

The mean peak plasma ceftriaxone concentration of all treatments ranged from 145.9 to 150.34 μg/ml.

The average times to peak plasma concentrations ranged from 1.48 to 2.08 hr. for the three brands.

The area under the plasma concentration-time curves of all brands ranged from 1769.51 to 1982.50 μg.hr/ml.

There were no statistically significant difference of the pharmacokinetic parameters among the corresponding values of all brands studied ($p>0.05$). These domonstrated that all of the test products were bioequivalent with equal rates and amounts of absorption. Therefore, all bronds could be used interchangeably.

4. The pharmacokinetics of 1g. ceftriaxone following intramuscular injection was described by a mean of one compartment open model with first order input and first order output.

The average absorption rate constants obtained from the PCNONLIN program output for brands A, B and C were 3.3, 2.34 and 3.01 $hr.^{-1}$, respectively.

The mean elimination rate constants also obtained from the PCNONLIN program were 0.12 $hr.^{-1}$ for brands A and B, and was 0.09 $hr.^{-1}$ for brand C.

The average biological half-life of ceftriaxone for all three brands ranged from 6.36 to 8.18 hr.

5. The values of C_{max} and AUC from this study were almost two times higher than those previously reported. This suggest that the dose of ceftriaxone used in Thais could be reduced in half. However, further studies must be conducted.