SOUVANEE KITTISOPEE, POL.CAP. : COMPARATIVE BIOAVAILABILITY OF PIROXICAM CAPSULES COMMERCIALLY AVAILABLE IN THAILAND. THESIS ADVISOR : ASSO. PROF. UTHAI SUVANAKOOT. THESIS CO-ADVISOR:ASS.PROF. SARINEE KRITTIYANUNT 124 pp. ISBN 974-581-509-8

Piroxicam 10 mg capsules commercially available in Thailand were investigated in order to assess the bioequivalence of the local manufactured brands relatively to the innovator's product, Feldene(R). These capsules were evaluated both in vitro and in vivo.

In vitro studies included weight variation, content of active ingredient, content uniformity, disintegration time and dissolution profile. Results showed that all brands met the requirements of B.P. 1988 and USP XXII, except dissolution test, of which only three out of eight brands met the requirements of USP XXII. Statistical comparisons for disintegration time showed that two brands were significantly different from the innovator's product ($p < 0.05$), and all brands were significantly different from the innovator's one for the dissolution rate constants. ($p < 0.05$)

The comparative bioavailability of four brands of piroxicam capsules including Feldene(R) , with difference in dissolution characteristics, were selected to study in 24Thai healthy male volunteers using an incomplete crossover design. A single dose of two 10 mg piroxicam capsules was orally administered to overnight fasted subjects. Plasma piroxicam levels at predetermined time intervals were assayed by HPLC. Data analysis by CSTRIP computer program demonstrated that there were no statistically significant difference for the relevant pharmacokinetic parameters (C_{max} ,t_{max} and AUC) among the four brands ($p > 0.05$). This refered that the four brands were bioequivalent in terms of both rate and extent of drug absorption. The relative bioavailability of brands B, C and D with respect to the innovator's product (brands A) were 103.23, 106.35 and 111.35% respectively. No statistical correlation between the in vitro and the in vivo data were observed.

The pharmacokinetics of piroxicam following oral administration of two 10 mg capsules were described by mean of a one-compartment open model with first order absorption and elimination. The absorption rate constants ranged from 1.19-1.82 hr^{-1}. The peak plasma concentrations were in thr range of 2.60-2.75 mcg/ml and reached within 3.07-3.97 hr., and the biological half-life was about 52.75-54.53 hr.