Project Title : Formulation and Availability of Piroxicam Gel

Name of the Investigators :

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ABSTRACT

Formulation of piroxicam gel 0.5 % was conducted by first searching for 5 suitable formulation of gel bases containing different gelling agents with various concentrations. The suitable gel bases based on clarity, gel mass and viscosity of formulation, were found to be those with carbopol 940 1 %, carbopol 934 1 %, hydroxyethyl cellulose 2.4 %, hydroxypropylmethyl cellulose 2.8 %, and hydroxymethyl cellulose 2.6 %, respectively Piroxicam was later incorporated into the gel base using geometric dilution.

The quality of piroxicam gel was *in vitro* evaluated using the percent content of active ingredient in preparation and drug released from formulation data. Drug

contents were analysed following the method of the United States Pharmacopoeia XXII. Release of the drug was determined according to diffusion technique. Results showed that all formulations including the innovator's product contained the percent labeled amount of active ingredient as specified in the monograph and they also provided the same patterns of drug released characteristics, indicating equally drug-product quality. However, based on percent drug released establishment, piroxicam gel with carbopol 940 1 % demonstrated the best results.

Piroxicam gel availability was *in vivo* tested in 8 Thai male subjects according to a two-way crossover design. Each subject received a single topical dose of 10 g. of piroxicam gel 0.5 % at the back thoroughly 1 sq-ft. Blood samples were collected at predetermined time intervals. Data analysis showed that the relevant pharmacokinetic parameters C_{max}, t_{max} and AUC produced by the best formulation and the innovator's product were not statistically significant differences ($p>0.05$), referring that they could provide the same availability with respect to the rate and the extent of drug absorption. Moreover, the biological half-life of piroxicam was found to be about 55 hr.

Although a formulation of piroxicam gel 0.5 % with equal quality and availability to the innovator's product was accomplished, stability of this product should be further studied in order to establish a suitable formulation for use elsewhere.