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TITLE

APPLICATION OF DERMAL MICRODIALYSIS FOR THE DETERMINATION OF BIOAVAILABILITY / BIOEQUIVALENCE OF TOPICAL DRUG PRODUCTS NOT INTENDED FOR SYSTEMIC CIRCULATION

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Dermal microdialysis (DMD) was used to assess the bioavailability of a topical gel formulation containing ketoprofen and subsequently evaluated as a tool for the determination of bioequivalence. Four microdialysis probes were inserted into the dermis on the volar aspect of the forearms of 18 human subjects and the probes were perfused with normal saline for 60 min. A ketoprofen (2.5%, m/m) gel formulation (50 mg) was applied to the skin directly overlying the probes and samples were collected at 30 min intervals for 5h. With the probes still in place in the dermis each site was scanned by ultrasound to determine the implantation depth of these probes. Ketoprofen concentration in the dialysate samples was determined by LC–MS/MS. The area under the curve obtained from the concentration–time profiles from pairs of application sites in each subject was evaluated in order to assess bioequivalence. Ninety percent confidence intervals were calculated using the two one-sided test procedure and limits of 80–125% based on log-transformed data were used as acceptance criteria to declare bioequivalence. The intra-subject variability was 10% between probes whereas inter-subject variability was 68% (n = 18). Bioequivalence was confirmed with a power greater than 90%.