Sanare Advanced Scar Base Transdermal Studies – Flurbiprofen + Lidocaine

Study

Evaluation of the Percutaneous Absorption of Flurbiprofen + Lidocaine

The study was designed to evaluate the percutaneous absorption pharmacokinetics of Humco's Sanare Advanced Scar Base. Absorption was measured in human epidermal cultures, in vitro, using the finite dose technique and Franz Diffusion Cells.

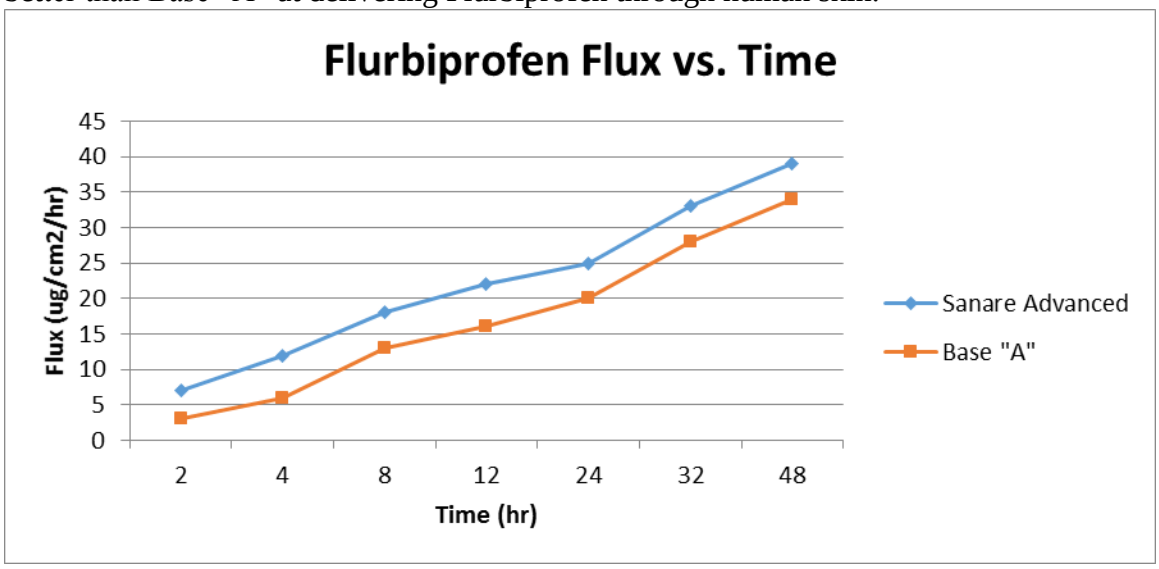
The formula was tested on standardized sections with two different transdermal compounding bases, for the percutaneous absorption of Flurbiprofen + Lidocaine over a 48-hour dose period. At pre-selected times after dose application, the dermal receptor solution was removed in its entirety, replaced with fresh receptor solution, and an aliquot saved for subsequent analysis. The samples were analyzed for Flurbiprofen and Lidocaine content by High Performance Liquid Chromatography (HPLC).

The in vitro human Epiderm skin model has proven to be a valuable tool for the study of percutaneous absorption and the determination of the pharmacokinetics of topically applied drugs. The model uses human epidermal skin mounted in specially designed diffusion cells that allow the skin to be maintained at a temperature and humidity that match typical in vitro conditions. A finite dose of formulation is applied to the outer surface of the skin and drug absorption is measured by monitoring the rate of appearance in the receptor solution bathing the inner surface of the skin. Data defining total absorption, as well as rate of absorption can be accurately determined in this model.

Results

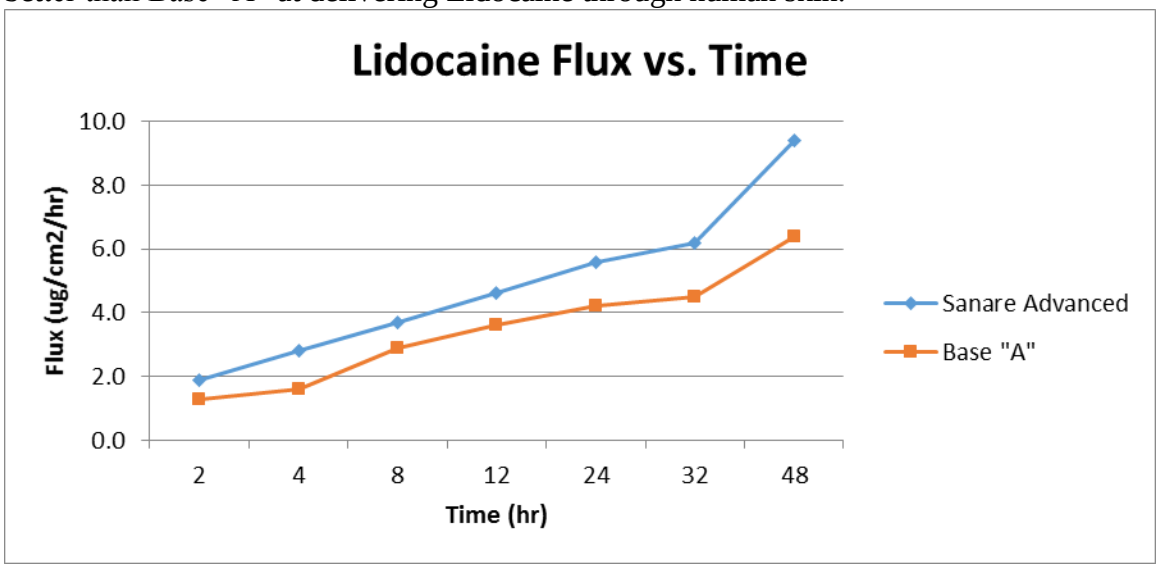
Flurbiprofen

The data indicate that Flurbiprofen did penetrate into and through human epidermal cultures, in vitro, from the test formulations provided. The absorption profiles indicate a steady penetration for 48 hours after dose application of both Humco Sanare Advanced Scar Base and Base “A”. Humco Sanare Advanced Scar Base performed significantly better than Base “A” at delivering Flurbiprofen through human skin.



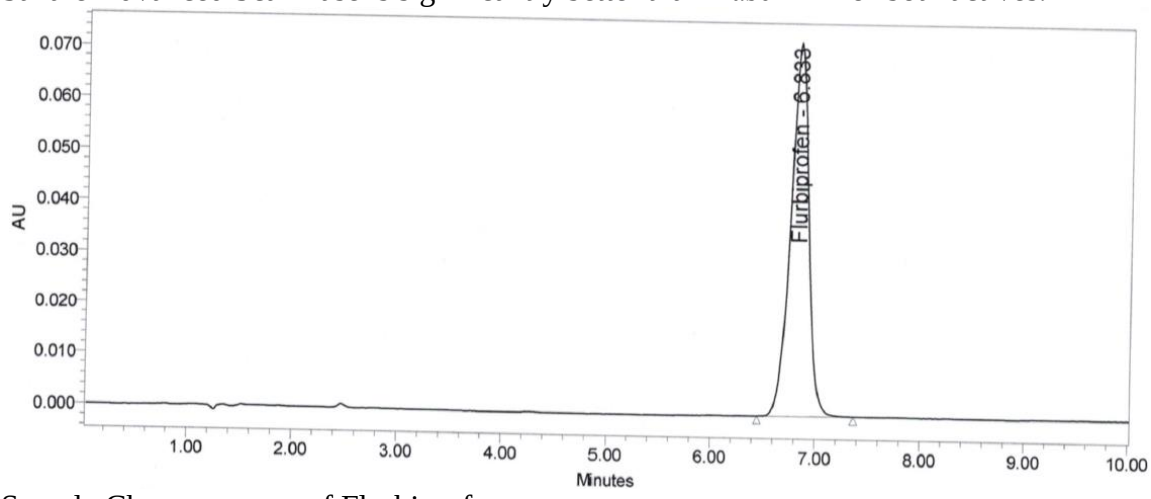
Lidocaine

The data indicate that Lidocaine did penetrate into and through human epidermal cultures, in vitro, from the test formulations provided. The absorption profiles indicate a steady penetration for 48 hours after dose application of both Humco Sanare Advanced Scar Base and Base “A”. Humco Sanare Advanced Scar Base performed significantly better than Base “A” at delivering Lidocaine through human skin.

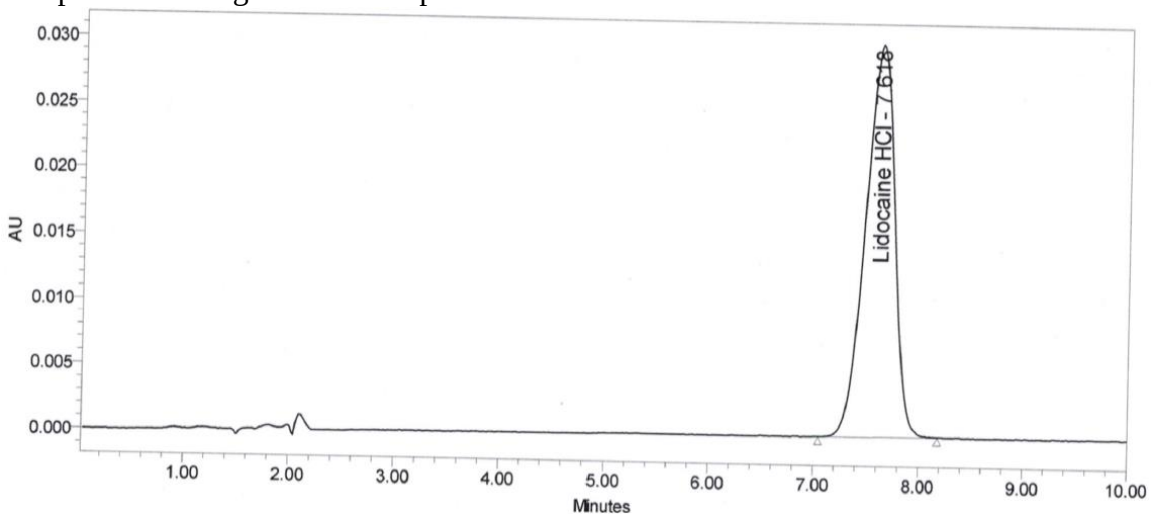


10% Flurbiprofen / 5% Lidocaine

The data indicate that the actives do penetrate into and through human epidermal cultures. Based on total penetration (through the skin into the reservoir solution), Humco Sanare Advanced Scar Base is significantly better than Base "A" for both actives.

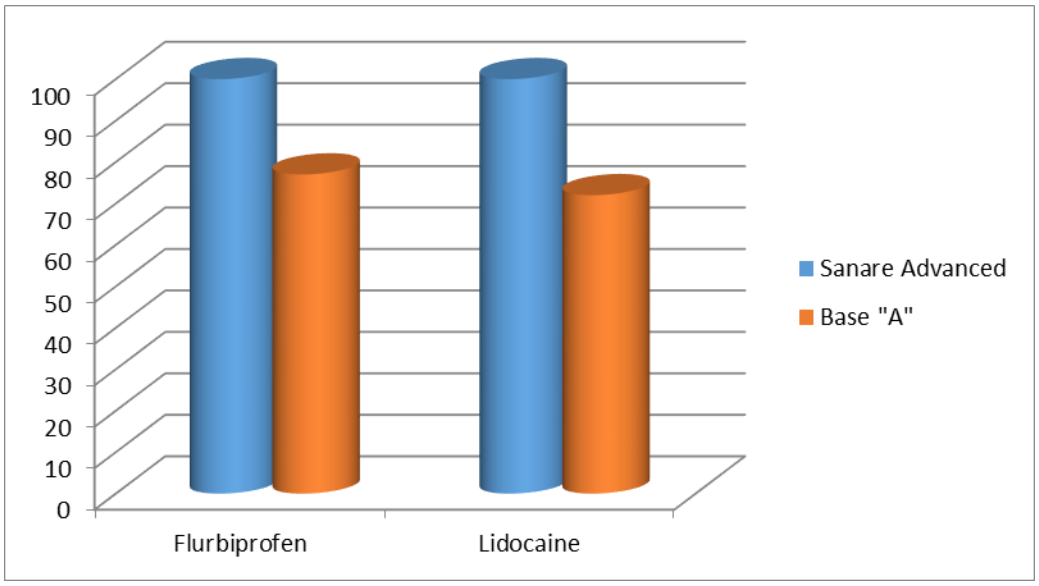


Sample Chromatogram of Flurbiprofen



Sample Chromatogram of Lidocaine

Study conducted by Humco Holding Group, Inc. with all results specific to this study.



The total percent of applied dose that penetrated past the Stratum Corneum with Humco Sanare Advanced Scar Base was significantly better than Base “A”.

Study conducted by Humco Holding Group, Inc. with all results specific to this study.