

Progesterone Transdermal Studies

Study

Evaluation of the Percutaneous Absorption of Progesterone, In Vitro, Using the Epiderm Skin Model

The study was designed to evaluate the percutaneous absorption pharmacokinetics of Humco's Vanishing Base II, HRT Botanical, HRT Heavy, AnhydrousBase and PenCream. Absorption was measured in human epidermal cultures, in vitro, using the finite dose technique and Franz Diffusion Cells.

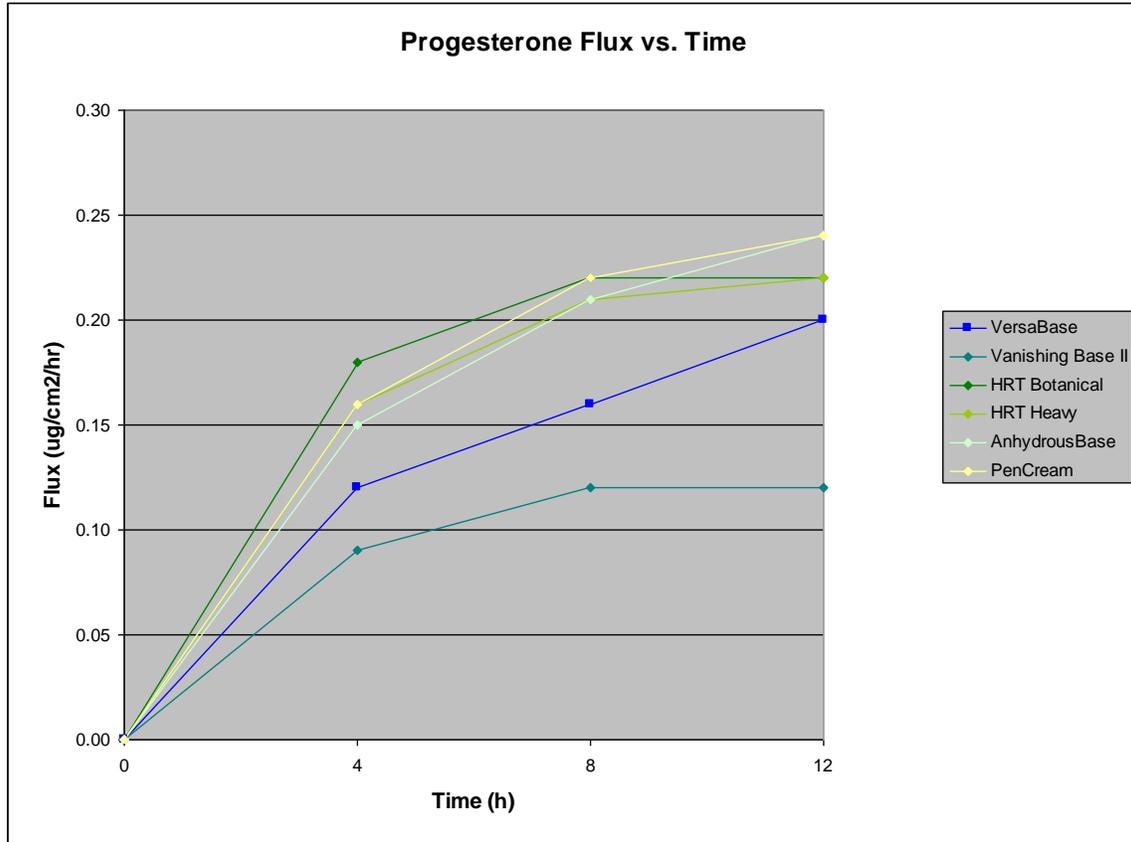
The formulas were tested on standardized sections for the percutaneous absorption of Progesterone over a 12-hour dose period. At pre-selected times after dose application, the dermal receptor solution was removed in its entirety, replaced with fresh receptor solution, and an aliquot saved for subsequent analysis. The samples were analyzed for Progesterone 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

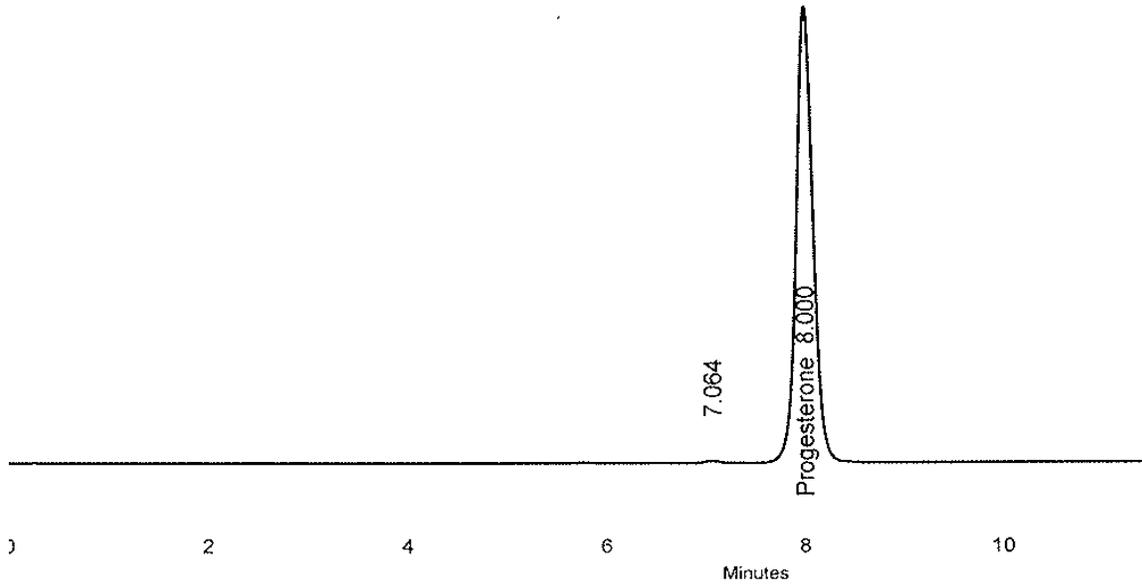
Progesterone

The data indicate that Progesterone did penetrate into and through human epidermal cultures, in vitro, from the test formulations provided. The absorption profiles indicate a steady penetration to a peak flux occurring at approximately 12 hours after dose application. The topical Humco base, Vanishing Base II, delivered less Progesterone than PCCA VersaBase, while the transdermal Humco bases, HRT Botanical, HRT Heavy, AnhydrousBase and PenCream, delivered more Progesterone than PCCA VersaBase.

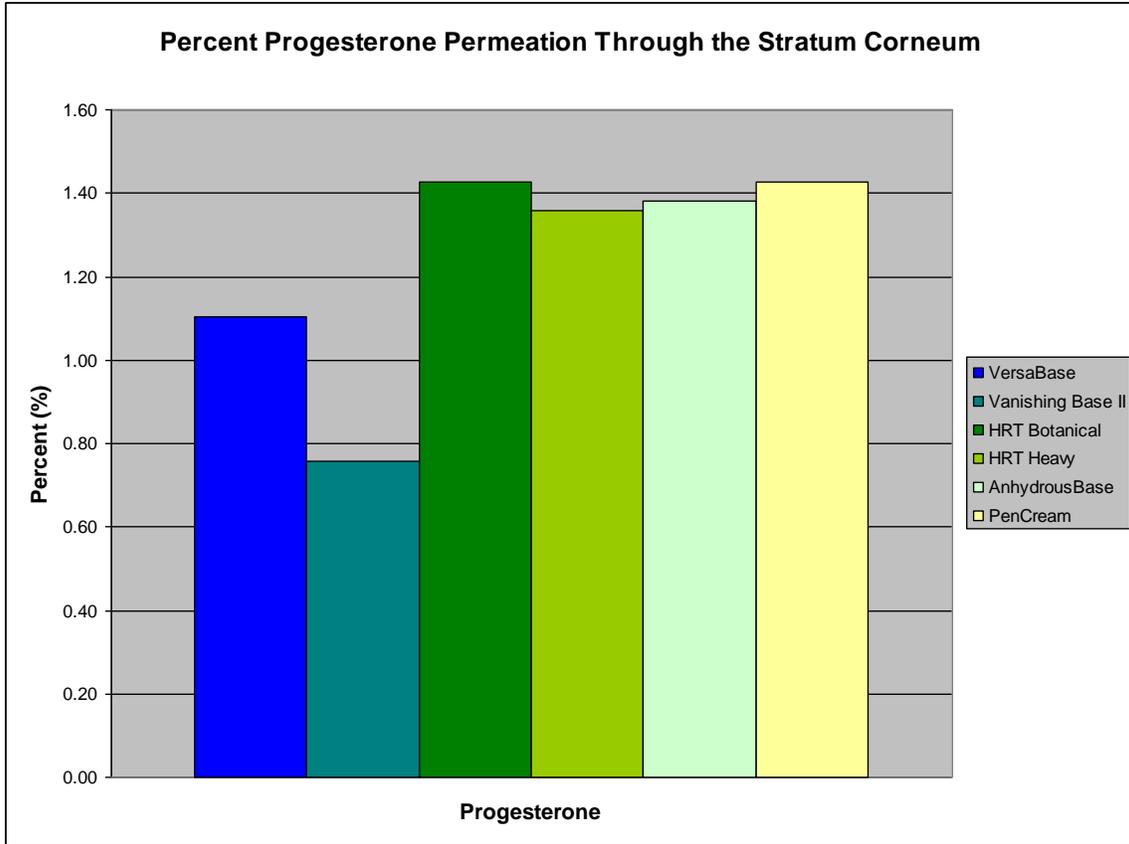


5% Progesterone

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), the data rank orders the test formulations as Humco PenCream, Humco AnhydrousBase, Humco HRT Heavy, Humco HRT Botanical > PCCA VersaBase > Humco Vanishing Base II.



Sample Chromatogram of 5% Progesterone



The total percent of applied dose that penetrated past the Stratum Corneum with PCCA VersaBase is 30% more than Humco Vanishing Base II, but 20% less than Humco HRT Botanical, Humco HRT Heavy, Humco AnhydrousBase and Humco PenCream.