MEDISCA®

YOUR TRUSTED PARTNER IN COMPOUNDING

IN VITRO SKIN STUDIES AND BUD RESULTS

Versatility. Permeation. Elegance.

Scientifically Proven Moisturizer

BASES

VERSAPRO™ CREAM BASE

With its great carrying capacity and excellent emollient characteristics, MEDISCA's **VersaPro™ Cream Base** is ideal for both pharmaceutical and cosmetic purposes. Its versatility relates in part to its increased pH stability and excellent compatibility with a wide range of active pharmaceutical ingredients. This unique oil-in-water emulsion is non-greasy, non-irritant and paraben-free. **VersaPro™** is a highly moisturizing cream formulated with excellent penetrating properties.

FEATURES & BENEFITS

SCIENTIFIC DATA	– Increased permeation of Progesterone through the skin *(DPSI, January 2010)* – Validated Beyond-Use-Dates (BUDs) Available – Scientifically Classified as an All-Day Moisturizer
API COMPATIBILITY	For lipophilic and hydrophilic drugs (hormones, analgesics, etc.)
APPEARANCE	White, smooth, versatile cream
INTENDED USE	– Pharmaceutical : Highly penetrating transdermal delivery vehicle – Cosmetic : Non-comedogenic moisturizer containing Vitamin E and Aloe Vera
pH STABILITY	pH 2 to 12
TOLERANCE TO API BASE & SALT FORMS	Excellent
APPLICATION TO MUCOUS MEMBRANES	Yes
HEAT SENSITIVITY	Stable at 45°C (113°F)
PRESERVATIVE EFFECTIVENESS	Passes USP microbial challenge test <51>

In vitro skin studies on MEDISCA formulations

SUPERIOR PERFORMANCE OF VERSAPRO™ COMPARED TO COMPETITOR'S CREAM BASE

INTRODUCTION

Figure 1. *Bronaugh Flow-Through Cells.* 2010 DPSI. Available at www.dowpharmasci.com

Realizing the critical role of drug penetration and skin retention involved in transdermal applications, MEDISCA has taken a unique approach towards formulation development by testing and comparing its products to today's leading cream bases. To achieve this goal, MEDISCA partnered up with Dow Pharmaceutical Sciences Inc. (DPSI), a topical product development company with 25+ years of experience interpreting *in vitro* data. DPSI specifically studied the *in vitro* percutaneous absorption of (^{14}C)-Progesterone from nine transdermal delivery vehicles, including MEDISCA's own **VersaPro™ Cream Base**. The study was conducted by using the Bronaugh flow-through diffusion cell method *(see Figure 1)* and human excised skin from a single Caucasian female donor following elective abdominal surgery. In fact, results from *in vitro* studies using this particular tissue preparation are typically less variable and more reproducible than *in vitro* studies using human cadaver skin preparations.

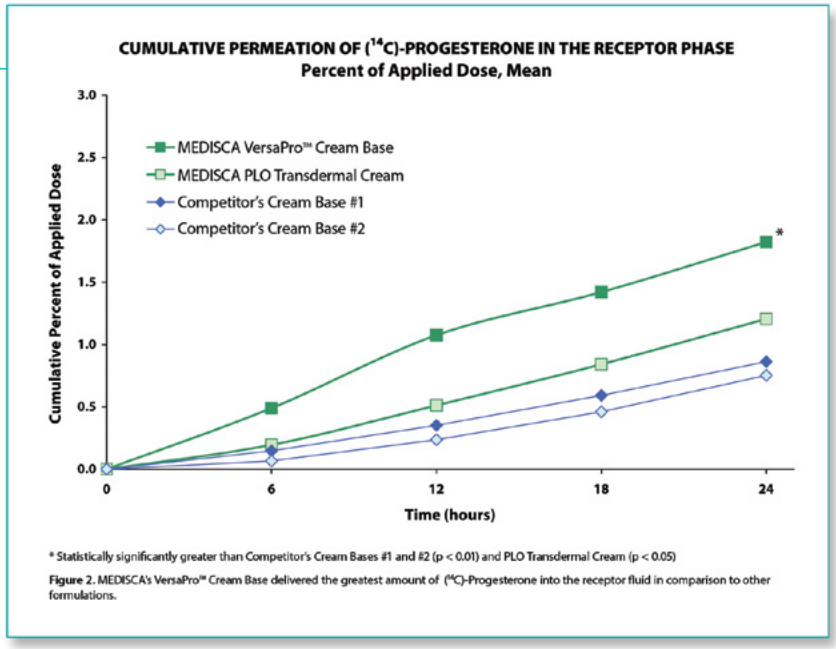
METHODS

All formulations evaluated in this study were equally spiked with sufficient (^{14}C)-Progesterone to achieve a nominal formulation dose of 1.0µCi/3.2mg per diffusion cell, which corresponds to a topical application of 5mg formulation per cm^2 of tissue. This clinically relevant dose was dispensed onto dermatomed skin tissue (0.028 ± 0.004 inches), and was left undisturbed for a 24-hour exposure period. The 54 flow-through diffusion cells were maintained at a constant temperature of 32°C by use of recirculating water baths. Fresh receptor phase buffered solution was continuously pumped under the tissue at a flow rate of 1.0mL/hr and collected in 6-hour intervals. Over the 24-hour period, the amount of (^{14}C)-Progesterone residing in the receptor phase samples was quantified using liquid scintillation analyzing techniques to determine the cumulative permeation of (^{14}C)-Progesterone.

RESULTS

Following a 24-hour period, MEDISCA's **VersaPro™ Cream Base** delivered significantly more (^{14}C)-Progesterone relative to the Competitor's Cream Bases and PLO Transdermal Cream (1.82% of the applied dose).

In addition, **VersaPro™ Cream Base** displayed a more rapid rate of (^{14}C)-Progesterone delivery over the exposure period.



* Statistically significantly greater than Competitor's Cream Bases #1 and #2 ($p < 0.01$) and PLO Transdermal Cream ($p < 0.05$)

Figure 2. MEDISCA's VersaPro™ Cream Base delivered the greatest amount of (^{14}C)-Progesterone into the receptor fluid in comparison to other formulations.