

**IN VITRO  
SKIN  
STUDIES**

See reverse for details



## **NEW** **VERSAPRO Cream Base**

*Versatility. Permeation. Elegance.*

With its great carrying capacity and excellent emollient characteristics, MEDISCA's NEW **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 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.

FEATURE	DESCRIPTION
SCIENTIFIC DATA	<ul style="list-style-type: none"><li>• Increased permeation of Progesterone through the skin (DPSI, January 2010)</li><li>• Validated 60 day Beyond-Use-Dates</li></ul>
API COMPATIBILITY	Anti-inflammatory, Hormone replacement, Pain management, Diabetic neuropathy, etc.
APPEARANCE	White, smooth, versatile cream
INTENDED USE	<ul style="list-style-type: none"><li>• Pharmaceutical: Highly penetrating transdermal delivery vehicle</li><li>• Cosmetic: Non-comedogenic moisturizer containing Vitamin E and Aloe Vera</li></ul>
pH STABILITY	pH 2 to 12
TOLERANCE TO API BASE & SALT FORMS	Excellent
APPLICATION TO MUCOUS MEMBRANES	Yes
HEAT SENSITIVITY	Stable at 45°C
PRESERVATIVE EFFECTIVENESS	Passes USP microbial challenge test <51>

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# IN VITRO SKIN STUDIES ON MEDISCA FORMULATIONS

## SUPERIOR PERFORMANCE OF **VERSA**PRO COMPARED TO COMPETITOR'S CREAM BASES

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 (<sup>14</sup>C)-Progesterone from nine transdermal delivery vehicles, including MEDISCA's own **VERSA**PRO 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.



Figure 1. Bronaugh Flow-Through Cells. 2010 DPSI. Available at [www.dowpharmsci.com](http://www.dowpharmsci.com)

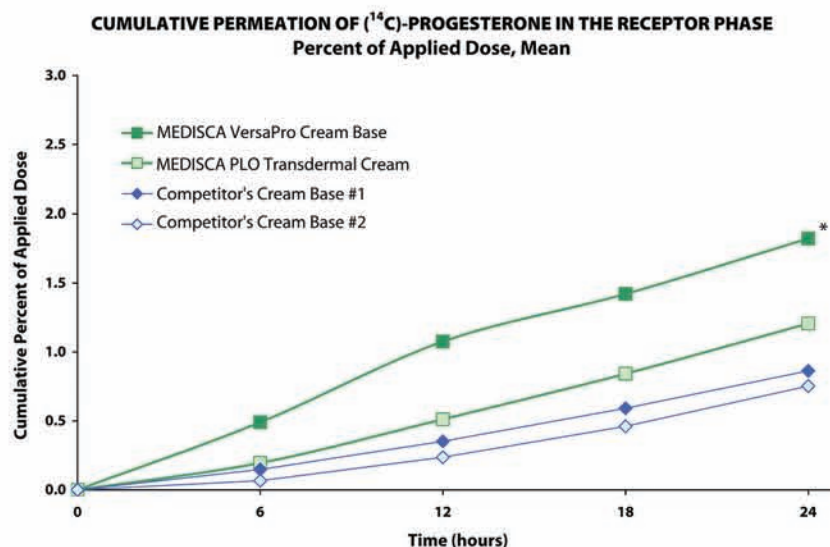
### METHODS

All formulations evaluated in this study were equally spiked with sufficient (<sup>14</sup>C)-Progesterone to achieve a nominal formulation dose of 1.0 $\mu$ Ci/3.2mg per diffusion cell, which corresponds to a topical application of 5mg formulation per cm<sup>2</sup> of tissue. This clinically relevant dose was dispensed onto dermatomed skin tissue (0.028  $\pm$  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 (<sup>14</sup>C)-Progesterone residing in the receptor phase samples was quantified using liquid scintillation analyzing techniques to determine the cumulative permeation of (<sup>14</sup>C)-Progesterone.

### RESULTS

Following a 24-hour period, MEDISCA's **VERSA**PRO Cream Base delivered significantly more (<sup>14</sup>C)-Progesterone relative to the Competitor's Cream Bases and PLO Transdermal Cream (1.82% of the applied dose).

In addition, **VERSA**PRO Cream Base displayed a more rapid rate of (<sup>14</sup>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 (<sup>14</sup>C)-Progesterone into the receptor fluid in comparison to other formulations.

Supporting innovative  
formulation with the  
finest chemicals and  
equipment

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