In Vitro Evaluation of the Percutaneous Absorption of Progesterone in Anhydrous Permeation-Enhancing Base Using the Franz Skin Finite Dose Model and Mass Spectrometry

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This study, published in the Archives of Dermatological Research, reveals the exceptional permeation of progesterone in a topical preparation using Anhydrous VersaBase® HRT. The in vitro study compared progesterone permeation between two formulations – one with Anhydrous VersaBase HRT gel and the other with water-based, non-ionic cream. A stability-indicating UPLC assay method was employed to evaluate the stability of progesterone in Anhydrous VersaBase HRT.

Methods

The Franz Skin Finite Dose Model

Rigorously tests the rate of drug absorption and permeation into and through layers of human skin.

Mass Spectrometry Imaging

Delivers multi-layered, high-resolution and detailed images of molecular distribution in and through the skin's stratum corneum, epidermis and dermis layers.

Stability Analysis

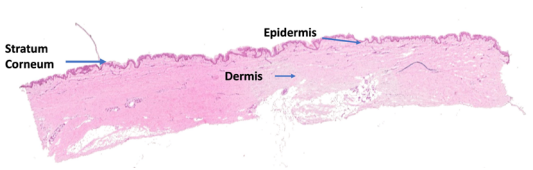
Ensures the progesterone maintained consistent performance throughout multiple tests.

Key Findings

Figures 1 & 2: Mass spectrometry imaging shows progesterone penetration into the stratum corneum, epidermis and dermis layers of skin.

Visible Permeation of Progesterone

1



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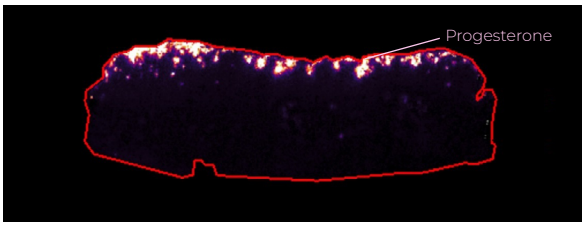


Figure 3: Note the 3.2-fold increase in optical density ($p = 0.029$) in progesterone skin permeation with Anhydrous VersaBase HRT vs. non-ionic cream.

3

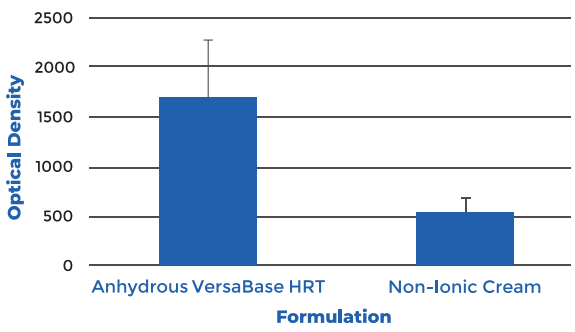
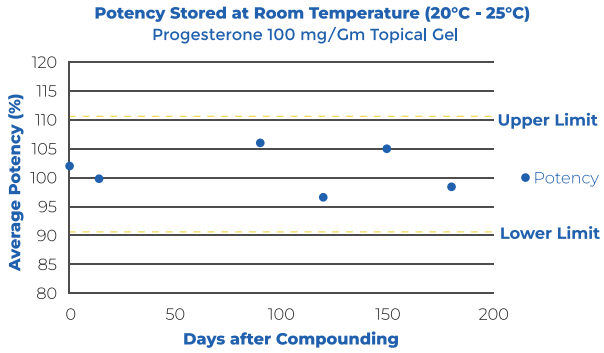


Figure 4: Stability of progesterone in Anhydrous VersaBase HRT at room temperature.

4



Study Conclusion

Anhydrous VersaBase HRT is a promising base for topical delivery of progesterone. The tested formulation remained stable at room temperature and offers the potential for longer beyond-use dates (BUDs)* of 180 days, benefiting patients and compounding pharmacies.

In addition, mass spectrometry imaging is an effective method for the quantitative analysis of progesterone permeation through the skin. Combining the Franz Skin Finite Dose Model with mass spectrometry imaging offers a robust framework for evaluating and optimizing topical formulations.

**USP 795 establishes BUD limits by type of preparation in the absence of a USP–NF Compounded Preparation Monograph or CNSP-specific stability information.*

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As of September 2024, VersaBase Anhydrous HRT is known as Anhydrous VersaBase HRT. The name change is designed to help our members' pharmacy staff more easily differentiate products on the shelf.

Scan the QR code or go to bit.ly/HRTStudy to access the study.

The Absorption of Progesterone in a Compounded Anhydrous Cream

What does the study say?

Progesterone in a topical preparation using Anhydrous VersaBase® HRT exhibits exceptional delivery of the hormone through the skin compared to another standard non-ionic cream base. The stability and potency of progesterone in this base was consistent over 180 days.

What does it mean for patients?

Bioidentical progesterone therapy can be formulated in Anhydrous VersaBase HRT, a cream base with proven and consistent drug delivery results. It can be theorized that consistent hormone delivery can only improve a patient's chances for optimal prescription outcomes.

What does “Anhydrous” mean?

Anhydrous by definition means “containing no water.” When a compound is formulated without water or with low water activity it is less likely to degrade or become contaminated therefore giving it a convenient and longer beyond-use-date of 90-180 days in most cases.

Examples of applicable compounded formulas:

Progesterone 50 mg/Gm in Anhydrous VersaBase HRT
Progesterone 100 mg/Gm in Anhydrous VersaBase HRT
**Anhydrous VersaBase HRT is not intended for vaginal use.*

Scan to learn more about anhydrous bases.

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