MEDISCA®

STABILITY ASSESSMENT OF COMPOUNDED PREPARATIONS

Bracketed Progesterone 1-40% in VersaPro™ Cream Base

Progesterone is an essential hormone produced endogenously in males and females. Progesterone deficiency is commonly noted in persons experiencing adrenal insufficiency, estrogen dominance, perimenopause, menopause, and andropause. Restoring progesterone levels through progesterone therapy can significantly improve the expression of these conditions. Transdermal delivery is a common route of progesterone administration.[1] Commercial availability of transdermal progesterone at various doses is limited, warranting the need for compounding. Determining the stability of a compounded medication is considered best practice and is highly sought after analytical data.

In this study, we evaluated the physical, chemical, and microbiological stability overtime of two different concentrations of Progesterone (1% and 40% w/w) compounded in VersaPro™ Cream Base (MEDISCA). The formulations underwent forced degradation studies to develop validated, stability-indicating methods. The stability of these formulations was evaluated in tightly-closed, light resistant containers at room temperature (25°C). Physicochemical characteristics were analyzed at predetermined time points (0, 30, 60, 90, 120 and 180 days) and each formula tested had the organoleptic properties inspected, the pH and viscosity measured, and the progesterone concentration assayed using a validated stability-indicating HPLC-UV method. The antimicrobial effectiveness of the preservative system was also tested using a validated method based on *USP <51>*. Our results showed that the concentration of the bracketed Progesterone formulations remained within the *United States Pharmacopeia* specification (90 to 110%) for at least 180 days at the tested condition. No changes in organoleptic properties were observed and there was no significant change in pH or viscosity (Table 1). Antimicrobial effectiveness of the preservative system also met the *USP* requirements for both concentrations (Table 2). In conclusion, Progesterone in VersaPro™ Cream Base with a bracketed range of 1 – 40% was found to be physically, chemically and microbiologically stable for up to 180 days when stored at room temperature in tightly-closed light resistant containers. Therefore, an extended beyond-use date of 180 days can be assigned to this bracketed range of Progesterone concentrations if the same vehicle and conditions are respected.

Table 1. Stability of Progesterone 1% and 40% in VersaPro™ Cream Base at 25 °C for 180 days.

Time Points	Progesterone LOW Concentration	Progesterone HIGH Concentration
	1%	40%
	Hormone Concentrations (%)[a]	
Initial	100 ± 0.11	100 ± 0.08
30 days	103.95 ± 0.17	97.34 ± 0.01
60 days	103.74 ± 0.00	101.66 ± 0.03
90 days	100.81 ± 0.05	97.35 ± 0.06
120 days	103.98 ± 0.08	95.52 ± 0.03
180 days	101.89 ± 0.01	98.29 ± 0.09
	pH	
Initial	5.00	5.30
30 days	4.72	5.08
60 days	4.73	4.84
90 days	4.70	4.96
120 days	4.95	4.77
180 days	4.49	4.62
	Viscosity (cPs)	
Initial	824,824	815,451
30 days	815,451	793,581
60 days	890,435	843,570
90 days	787,332	843,570
120 days	784,208	843,570
180 days	784,208	843,570

[a] Reported as Mean ± SD of duplicate determinations.

Table 2. Antimicrobial Preservative Effectiveness of Progesterone 1% and 40% in VersaPro™ Cream Base.

Identification	Method	Test Performed	Specification[a]	Result[b]
Progesterone 1% in VersaPro™ Cream Base	USP <51>	Antimicrobial Effectiveness Testing	Category 2	Pass
Progesterone 40% in VersaPro™ Cream Base	USP <51>	Antimicrobial Effectiveness Testing	Category 2	Pass

[a] Category 2 includes topically used products made with aqueous bases or vehicles, such as emulsions.
[b] Product must meet the following for (i) Bacteria: NLT 2.0 log reduction from initial count at 14 days; no increase from 14 days count to 28 days. (ii) Yeast and mold: No increase from the initial calculated count at 14 and 28 days.

MEDISCA Network Formula:

F 008 567 Progesterone 1% to 40% Topical Cream (Emulsion, 100g). www.medisca.com/studies/buds?tab=bud-databank

References:
1 Du JY, Sanchez P, Kim L, et al. Percutaneous progesterone delivery via cream or gel application in postmenopausal women: a randomized cross-over study of progesterone levels in serum, whole blood, saliva, and capillary blood. *Menopause*. 2013. 20(11):1169-1175.

FOR MORE INFORMATION
USA 1-800-932-1039 | CAN 1-800-665-6334 | WWW.MEDISCA.COM