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Stability Assessment of Compounded Bracketed Estradiol 0.025 - 0.5%, Estriol 0.025 - 0.5% and Progesterone 1-20% in Medisca VersaPro™ Cream Base

The physical, chemical, and microbiological stability of two different concentrations of combined Estradiol (0.025% and 0.5% w/w), Estriol (0.025% and 0.5% w/w) and Progesterone (1% and 20% w/w) compounded in VersaPro Cream Base were evaluated over time. The formulations were packaged in tightly-closed, light resistant, plastic containers and stored at controlled room temperature (25°C) for the duration of the study. Physicochemical characteristics were analyzed at predetermined time points (0, 30, 60, 90, 120, 150 and 180 days) and each formula tested had the organoleptic properties inspected, the pH measured, and the API concentrations assayed using a validated, stability-indicating HPLC-UV method. The antimicrobial preservative effectiveness was also tested using a validated method according to USP <51>. The results showed that the concentration of the bracketed Estradiol, Estriol and Progesterone formulations remained within USP specification (90 to 110%) for at least 180 days at the tested conditions *(Table 1)*. No significant changes in organoleptic properties or pH were observed. Antimicrobial preservative effectiveness also met USP <51> requirements for both concentrations *(Table 2)*. In conclusion, Estradiol 0.025%, Estriol 0.025%, Progesterone 1% in VersaPro Cream Base and Estradiol 0.5%, Estriol 0.5%, Progesterone 20% in VersaPro Cream Base were found to be physically, chemically and microbiologically stable for up to 180 days at the tested conditions. Therefore, an extended beyond-use date of 180 days may be assigned to this bracketed range of active concentrations if the same vehicle and conditions are respected.

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Table 1. Stability of Estradiol, Estriol and Progesterone Combinations in VersaPro Cream Base at 25°C for 180 days.

Time Points	E2 0.025%	E3 0.025%	P 1%	E2 0.5%	E3 0.5%	P 20%
			Assay (%)[a]			
Initial	100 ± 0.26	100 ± 0.05	100 ± 0.11	100 ± 0.61	100 ± 0.06	100 ± 0.05
30 days	100.58 ± 2.06	101.31 ± 0.09	102.60 ± 0.03	99.13 ± 0.05	100.87 ± 0.01	102.77 ± 0.10
60 days	97.65 ± 0.04	100 00 ± 0.02	101.53 ± 0.07	98.22 ± 0.13	101.01 ± 0.04	101.81 ± 0.02
90 days	100.75 ± 0.38	103.28 ± 0.00	103.55 ± 0.07	98.05 ± 0.61	100.96 ± 0.07	101.92 ± 0.00
120 days	97.21 ± 0.02	101.31 ± 0.03	101.14 ± 0.05	99.98 ± 0.82	102.78 ± 0.12	102.93 ± 0.02
150 days	95.76 ± 0.11	101.29 ± 0.06	100.93 ± 0.03	98.41± 0.57	102.35 ± 0.15	102.17 ± 0.02
180 days	96.95 ± 0.15	100.56 ± 0.16	100.95 ± 0.05	99.05 ± 1.20	100.95 ± 0.01	101.90 ± 0.00
			pH			
Initial		5.16			5.12	
30 days		5.01			4.97	
60 days		4.96			4.79	
90 days		5.01			4.85	
120 days		5.03			4.80	
150 days		5.02			4.71	
180 days		5.03			4.68	

[a] Reported as Mean ± SD of duplicate determinations.
E2 = Estradiol, E3 = Estriol, P = Progesterone

Table 2. Antimicrobial Preservative Effectiveness of Estradiol, Estriol and Progesterone Combinations in VersaPro Cream Base.

Identification	Method	Test Performed	Specification[a]	Result[b]
Estradiol 0.025%, Estriol 0.025%, Progesterone 1% in VersaPro Cream Base	USP <51>	Antimicrobial Effectiveness Testing	Category 2	Pass
Estradiol 0.5%, Estriol 0.5%, Progesterone 20% 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 Formula

F 008 995 Estradiol 0.025%-0.5%, Estriol 0.025%-0.5%, Progesterone 1%-20% Topical Cream (Emulsion, 200g)

For More Information

CAN 1-800-665-6334 medisca.ca

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