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Stability Assessment of Compounded Cyclobenzaprine Hydrochloride 5%, Diclofenac Sodium 10% and Lidocaine 5% in Medisca VersaPro™ Cream Base

The physical, chemical, and microbiological stability of Cyclobenzaprine Hydrochloride 5%, Diclofenac Sodium 10% and Lidocaine 5% compounded in VersaPro Cream Base were evaluated over time. The formulation was 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 and 180 days) and the 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 Cyclobenzaprine Hydrochloride, Diclofenac Sodium and Lidocaine formulation 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 the formulation *(Table 2)*. In conclusion, Cyclobenzaprine Hydrochloride 5%, Diclofenac Sodium 10% and Lidocaine 5% in VersaPro Cream Base was 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 formulation if the same vehicle and conditions are respected.

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Product No.: 2529

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Table 1. Stability of Cyclobenzaprine Hydrochloride, Diclofenac Sodium and Lidocaine in VersaPro Cream Base at 25°C for 180 days

Time Points	Cyclobenzaprine Hydrochloride 5%	Diclofenac Sodium 10%	Lidocaine 5%
		Assay (%)[a]	
Initial	100 ± 0.03	100 ± 0.02	100 ± 0.03
30 days	96.81 ± 0.02	98.22 ± 0.03	97.55 ± 0.01
60 days	98.47 ± 0.01	99.90 ± 0.02	99.27 ± 0.06
90 days	101.30 ± 0.07	102.62 ± 0.08	101.76 ± 0.15
120 days	96.84 ± 0.01	98.35 ± 0.06	99.13 ± 0.01
180 days	99.41 ± 0.00	100.44 ± 0.03	101.23 ± 0.01
		pH	
Initial		9.14	
30 days		9.03	
60 days		9.03	
90 days		9.01	
120 days		9.11	
180 days		8.91	

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

Table 2. Antimicrobial Preservative Effectiveness of Cyclobenzaprine Hydrochloride, Diclofenac Sodium and Lidocaine in VersaPro Cream Base.

Identification	Method	Test Performed	Specification[a]	Result[b]
Cyclobenzaprine Hydrochloride 5%, Diclofenac Sodium 10% and Lidocaine 5% 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 009 715 Cyclobenzaprine Hydrochloride 5%, Diclofenac Sodium 10%, Lidocaine 5% Topical Cream (Emulsion, 100g)

For More Information
CAN 1-800-665-6334 medisca.ca

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