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Stability Assessment of Compounded Bracketed Ketamine Hydrochloride 0.5-10% in Medisca VersaPro™ Cream Base

The physical, chemical, and microbiological stability of two different concentrations of Ketamine Hydrochloride (0.5% and 10% w/w, equivalent to Ketamine 0.435% and 8.695% respectively) 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 and 180 days) and each formula tested had the organoleptic properties inspected, the pH measured, and the Ketamine Hydrochloride concentration 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 Ketamine Hydrochloride 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, Ketamine Hydrochloride 0.5% and 10% 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 Ketamine Hydrochloride concentrations if the same vehicle and conditions are respected.

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Product No.: 2529

Updated March 2023

Table 1. Stability of Ketamine Hydrochloride 0.5% and 10% in VersaPro Cream Base at 25°C for 180 days.

Time Points	Ketamine Hydrochloride 0.5%	Ketamine Hydrochloride 10%
	Assay (%)[a]	
Initial	100 ± 0.20	100 ± 0.15
30 days	103.02 ± 0.11	100.95 ± 0.08
60 days	99.79 ± 0.07	100.96 ± 0.10
90 days	100.41 ± 0.10	101.00 ± 0.09
120 days	100.66 ± 0.11	100.47 ± 0.04
180 days	100.29 ± 0.07	100.43 ± 0.11
	pH	
Initial	4.37	4.62
30 days	4.84	4.48
60 days	4.83	4.34
90 days	4.83	4.47
120 days	4.85	4.45
180 days	4.39	4.79

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

Table 2. Antimicrobial Preservative Effectiveness of Ketamine Hydrochloride 0.5% and 10% in VersaPro Cream Base.

Identification	Method	Test Performed	Specification[a]	Result[b]
Ketamine Hydrochloride 0.5% in VersaPro Cream Base	USP <51>	Antimicrobial Effectiveness Testing	Category 2	Pass
Ketamine Hydrochloride 10% 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 009 687 Ketamine Hydrochloride 0.5%-10% Topical Cream (Emulsion, 100g)

For More Information

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Updated March 2023