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Stability Assessment of Compounded Bracketed Diclofenac Sodium 1-15% in Medisca VersaPro™ Gel Base

The physical, chemical, and microbiological stability of two different concentrations of Diclofenac Sodium (1% and 15% w/w) compounded in VersaPro Gel 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 Diclofenac Sodium 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 Diclofenac Sodium 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, Diclofenac Sodium 1% and 15% in VersaPro Gel 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 Diclofenac Sodium concentrations if the same vehicle and conditions are respected.

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Table 1. Stability of Diclofenac Sodium 1% and 15% in VersaPro Gel Base at 25°C for 180 days.

Time Points	Diclofenac Sodium 1%	Diclofenac Sodium 15%
	Assay (%)[a]	
Initial	100 ± 0.24	100 ± 0.03
30 days	101.49 ± 0.13	96.54 ± 0.02
60 days	104.72 ± 0.00	97.75 ± 0.01
90 days	104.77 ± 0.00	97.75 ± 0.03
120 days	102.21 ± 0.42	97.10 ± 0.01
150 days	104.70 ± 0.40	97.47 ± 0.04
180 days	102.15 ± 0.10	99.31 ± 0.01
	pH	
Initial	7.43	7.83
30 days	7.38	7.81
60 days	7.38	7.83
90 days	7.33	7.78
120 days	7.32	7.76
150 days	7.37	7.79
180 days	7.36	7.69

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

Table 2. Antimicrobial Preservative Effectiveness of Diclofenac Sodium 1% and 15% in VersaPro Gel Base.

Identification	Method	Test Performed	Specification[a]	Result[b]
Diclofenac Sodium 1% in VersaPro Gel Base	USP <51>	Antimicrobial Effectiveness Testing	Category 2	Pass
Diclofenac Sodium 15% in VersaPro Gel 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 008 946 Diclofenac Sodium 1%-15% Topical Gel (Suspension, 100g)

For More Information

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