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Stability Assessment of Compounded Bracketed Ketoprofen 2.5 - 30% in Medisca PLO Gel MediFlo™ 30

The physical chemical and microbiological stability stability of two different concentrations of Ketoprofen (2.5% and 30% w/w) compounded in PLO Gel MediFlo 30 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 Ketoprofen 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 Ketoprofen formulations remained within USP specification (90 to 110%) for at least 180 days at the tested conditions *(Table 1)*. Antimicrobial preservative effectiveness also met USP <51> requirements for both concentrations *(Table 2)*. No significant changes in organoleptic properties or pH were observed. In conclusion, Ketoprofen 2.5% and 30% in PLO Gel MediFlo 30 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 Ketoprofen concentrations if the same formulation and conditions are respected.

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Product No.: 2501

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Table 1. Stability of Ketoprofen 2.5% and 30% in PLO Gel MediFlo 30 at 25°C for 180 days.

Time Points	Ketoprofen 2.5%	Ketoprofen 30%
	Assay (%)[a]	
Initial	100 ± 0.03	100 ± 0.07
30 days	97.4 ± 0.02	99.6 ± 0.08
60 days	97.4 ± 0.07	100.1 ± 0.08
90 days	98.6 ± 0.11	101.4 ± 0.07
120 days	99.4 ± 0.03	102.5 ± 0.07
180 days	100.5 ± 0.04	102.0 ± 0.00
	pH	
Initial	4.67	4.87
30 days	4.71	4.90
60 days	4.67	4.90
90 days	4.64	4.88
120 days	4.66	4.87
180 days	4.66	4.83

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

Table 2. Antimicrobial Preservative Effectiveness of Ketoprofen 2.5% and 30% in PLO Gel MediFlo 30.

Identification	Method	Test Performed	Specification[a]	Result[b]
Ketoprofen 2.5% in PLO Gel MediFlo 30	USP <51>	Antimicrobial Effectiveness Testing	Category 2	Pass
Ketoprofen 30% in PLO Gel MediFlo 30	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 009 560 Ketoprofen 2.5% to 30% Transdermal PLO Gel (Emulsion, 100g)

For More Information

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