



## Stability Assessment of Compounded Bracketed Methimazole 1-10% in Medisca PLO Gel MediFlo™ 30

The physical, chemical, and microbiological stability of two different concentrations of Methimazole (1% and 10% 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 and 120 days) and each formula tested had the organoleptic properties inspected, the pH measured, and the Methimazole 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 Methimazole formulations remained within USP specification (90 to 110%) for at least 120 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, Methimazole 1% and 10% in PLO Gel MediFlo 30 were found to be physically, chemically and microbiologically stable for up to 120 days at the tested conditions. Therefore, an extended beyond-use date of 120 days may be assigned to this bracketed range of Methimazole concentrations if the same vehicle and conditions are respected.



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Product No.: 2501



**Table 1. Stability of Methimazole 1% and 10% in PLO Gel MediFlo 30 at 25°C for 120 days.**

Time Points	Methimazole 1%	Methimazole 10%
<b>Assay (%)<sup>a</sup></b>		
Initial	100 ± 0.00	100 ± 0.03
30 days	97.94 ± 0.09	99.39 ± 0.03
60 days	96.53 ± 0.04	98.78 ± 0.06
90 days	95.89 ± 0.09	99.41 ± 0.01
120 days	95.32 ± 0.46	99.95 ± 0.12
<b>pH</b>		
Initial	4.53	4.53
30 days	4.54	4.54
60 days	4.57	4.59
90 days	4.47	4.57
120 days	4.52	4.58

<sup>a</sup> Reported as Mean ± SD of duplicate determinations.

**Table 2. Antimicrobial Preservative Effectiveness of Methimazole 1% and 10% in PLO Gel MediFlo 30.**

Identification	Method	Test Performed	Specification <sup>a</sup>	Result <sup>b</sup>
Methimazole 1% in <a href="#">PLO Gel MediFlo 30</a>	USP <51>	Antimicrobial Effectiveness Testing	Category 2	Pass
Methimazole 10% in <a href="#">PLO Gel MediFlo 30</a>	USP <51>	Antimicrobial Effectiveness Testing	Category 2	Pass

<sup>a</sup> Category 2 includes topically used products made with aqueous bases or vehicles, such as emulsions.

<sup>b</sup> 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 008 996](#) Methimazole 1% to 10% Transdermal PLO Gel (Emulsion, 100 g)

### For More Information

CAN 1-800-665-6334 [medisca.ca](http://medisca.ca)

