



## Stability Assessment of Compounded Benzocaine 20%, Lidocaine 6% and Tetracaine 4% in Medisca VersaPro™ Cream Base

The physical, chemical, and microbiological stability of Benzocaine 20%, Lidocaine 6% and Tetracaine 4% 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, 150 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 Benzocaine, Lidocaine and Tetracaine 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, Benzocaine 20%, Lidocaine 6% and Tetracaine 4% 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



**Table 1. Stability of Benzocaine, Lidocaine and Tetracaine in VersaPro Cream Base at 25°C for 180 days.**

Time Points	Benzocaine 20%	Lidocaine 6%	Tetracaine 4%
<b>Assay (%)<sup>a</sup></b>			
Initial	100 ± 0.01	100 ± 0.14	100 ± 0.04
30 days	99.8 ± 0.05	101.3 ± 0.08	98.0 ± 0.07
60 days	100.6 ± 0.11	104.7 ± 0.95	96.8 ± 0.05
90 days	101.3 ± 0.01	100.1 ± 0.09	97.1 ± 0.02
120 days	100.4 ± 0.06	101.0 ± 0.01	94.5 ± 0.04
150 days	98.8 ± 0.10	101.5 ± 0.33	95.2 ± 0.04
180 days	99.6 ± 0.04	101.2 ± 0.40	95.2 ± 0.08
<b>pH</b>			
Initial	8.09		
30 days	8.16		
60 days	8.19		
90 days	8.37		
120 days	8.43		
150 days	8.45		
180 days	8.47		

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

**Table 2. Antimicrobial Preservative Effectiveness of Benzocaine, Lidocaine and Tetracaine in VersaPro Cream Base.**

Identification	Method	Test Performed	Specification <sup>a</sup>	Result <sup>b</sup>
Benzocaine 20%, Lidocaine 6%, Tetracaine 4% in <a href="#">VersaPro Cream Base</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.009.529](#) Benzocaine 20%, Lidocaine 6%, Tetracaine 4% Topical Cream (Emulsion, 100g)

### For More Information

USA 1-800-932-1039 [medisca.com](http://medisca.com)

