Medisca®
PARTNERS IN WELLNESS

# Stability assessment

## Compounded Baclofen 2%, Cyclobenzaprine Hydrochloride 2%, Diclofenac Sodium 3%, Lidocaine Hydrochloride 2% and Ketoprofen 10% in Medisca Transdermal Pain Base

The physical, chemical, and microbiological stability of Baclofen 2%, Cyclobenzaprine Hydrochloride 2%, Diclofenac Sodium 3%, Lidocaine Hydrochloride 2% and Ketoprofen 10% compounded in Transdermal Pain 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 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 at the final time point using a validated method according to USP <51>. The results showed that the concentration of the Baclofen, Cyclobenzaprine Hydrochloride, Diclofenac Sodium, Lidocaine Hydrochloride and Ketoprofen formulation remained within USP specification (90 to 110 %) for 60 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, Baclofen 2%, Cyclobenzaprine Hydrochloride 2%, Diclofenac Sodium 3%, Lidocaine Hydrochloride 2% and Ketoprofen 10% in Transdermal Pain Base was found to be physically, chemically and microbiologically stable for up to 60 days at the tested conditions. Therefore, an extended beyond-use date of 60 days may be assigned to this formulation if the same vehicle and conditions are respected.


Scan QR code to learn more

Product No.: 2493

## Table 1. Stability of Baclofen, Cyclobenzaprine Hydrochloride, Diclofenac Sodium, Lidocaine Hydrochloride and Ketoprofen in Transdermal Pain Base at 25 °C for 60 days.

| Time points | Baclofen 2% | Cyclobenzaprine Hydrochloride 2% | Diclofenac Sodium 3% | Lidocaine Hydrochloride 2% | Ketoprofen 10% |
|---|---|---|---|---|---|
| | | | Assay (%)[a] | | |
| **Initial** | 100 ± 0.08 | 100 ± 0.15 | 100 ± 0.05 | 100 ± 0.08 | 100 ± 0.11 |
| **30 days** | 93.92 ± 0.17 | 93.70 ± 0.03 | 91.75 ± 0.10 | 98.93 ± 0.05 | 97.86 ± 0.12 |
| **60 days** | 91.26 ± 0.10 | 95.58 ± 0.15 | 91.27 ± 0.12 | 100.84 ± 0.12 | 98.46 ± 0.11 |
| | | | pH | | |
| **Initial** | | | 4.73 | | |
| **30 days** | | | 4.76 | | |
| **60 days** | | | 4.75 | | |

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

## Table 2. Antimicrobial Preservative Effectiveness of Baclofen, Cyclobenzaprine Hydrochloride, Diclofenac Sodium, Lidocaine Hydrochloride and Ketoprofen in Transdermal Pain Base.

| Identification | Method | Test performed | Specification[a] | Result[b] |
|---|---|---|---|---|
| Baclofen 2%, Cyclobenzaprine Hydrochloride 2%, Diclofenac Sodium 3%, Lidocaine Hydrochloride 2% and Ketoprofen 10% in Transdermal Pain 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 010 096 Baclofen 2%, Cyclobenzaprine Hydrochloride 2%, Diclofenac Sodium 3%, Ketoprofen 10%, Lidocaine Hydrochloride 2% Topical Cream (Emulsion, 100 g)

**For more information** 1-800-932-1039 medisca.com



Updated January 2024