

BOOK NO: 10750

PAGE NO: 81-1

TITLE PET: USP / Travatan BAC Free, lots 05-40452-1, 05-40453-1, 05-40454-1 @ Initial

PROJECT # 225719

(cont. from page N/A)

Date Initiated: 05-05-05

Purpose: To determine the preservative effectiveness of Travatan BAC Free, lots 05-40452-1 (FID 109032), 05-40453-1 (FID 109033), and 05-40454-1 (FID 109034) at Initial.

Method / Materials: PROC-0001136 (V-3.0)

Equipment: 11673:001 Media- Media Kitchen/LIMS

PET Validation Summary: n/a

Test Samples

- ① Travatan BAC Free, 0.004%, lot 05-40452-1, (FID 109032), LIMS# 200213082, at Initial.
- ② Travatan BAC Free, 0.004%, lot 05-40453-1, (FID 109033), LIMS# 200213084, at Initial.
- ③ Travatan BAC Free, 0.004%, lot 05-40454-1, (FID 109034), LIMS# 200213085, at Initial.

Cristina Gutierrez 05-05-05

Results / Summary

Formulation pages: 10750:081-2 — 081-4

Initial control data: 10750:081-5

6 Hour data @ C.H. 6-9-05

24 Hour data @ C.H. 6-9-05

Day 7 data- 10750:081-6 — 081-8

Day 14 data- 10750:081-9 — 081-11

Day 28 data- 10750:081-12 — 081-14

Preservative Evaluation Summaries- 10750:081-15 — 081-17

LIMS Summaries- 10750:081-18 — 081-20

Analytical Requests- 10750:081-21 — 081-23

Lots 05-40452-1, 05-40453-1, and 05-40454-1 Passes USP & JP requirements at Initial.

Cristina Gutierrez 6-9-05

✓
6/13/05

(cont. on page N/A)

Verified By: <i>Kathleen Alford</i>	Date: <i>6/13/05</i>	Entered By: <i>Cristina Gutierrez</i>	Date: <i>6-9-05</i>
--	-------------------------	--	------------------------

Formulation ID: 109032**Vers. 1****Description:** TRAVATAN BAC Free, 0.004% - pH 5.5**Target pH:** 5.5**Units:** W/V %**Dosage Form:** SOLUTION

Component	Concentration	Purpose
Al06221	0.004%	Active Ingredient
Polyoxyl 40 Hydrogenated Castor Oil	0.5%	Surfactant
Boric Acid	1%	Buffering Agent
Sorbitol	0.25%	Excipient
Propylene Glycol	0.75%	Excipient
Zinc Chloride	0.0025%	Excipient
Sodium Hydroxide	adjust pH	Ph Adjust
Hydrochloric Acid	adjust pH	Ph Adjust
Purified Water	q.s. 100%	Vehicle

Formulation ID: 109033

Vers. 1

Description: TRAVATAN BAC Free, 0.004% - pH 6.5

Target pH: 6.5

Units: W/V %

Dosage Form: SOLUTION

Component	Concentration	Purpose
Al06221	0.004%	Active Ingredient
Polyoxyl 40 Hydrogenated Castor Oil	0.5%	Surfactant
Boric Acid	1%	Buffering Agent
Sorbitol	0.25%	Excipient
Propylene Glycol	0.75%	Excipient
Zinc Chloride	0.0025%	Excipient
Sodium Hydroxide	adjust pH	Ph Adjust
Hydrochloric Acid	adjust pH	Ph Adjust
Purified Water	q.s. 100%	Vehicle

Formulation ID: 109034 Vers. 1

Description: TRAVATAN BAC Free, 0.004% -pH 5.5 w/ 85% of zinc, boric acid

Target pH: 5.5

Units: W/V %

Dosage Form: SOLUTION

Component	Concentration	Purpose
Al06221	0.004%	Active Ingredient
Polyoxyl 40 Hydrogenated Castor Oil	0.5%	Surfactant
Boric Acid	0.85%	Buffering Agent
Sorbitol	0.25%	Excipient
Propylene Glycol	0.75%	Excipient
Zinc Chloride	0.002125%	Excipient
Sodium Hydroxide	adjust pH	Ph Adjust
Hydrochloric Acid	adjust pH	Ph Adjust
Purified Water	q.s. 100%	Vehicle

PRESERVATIVE RAW DATA

Product: _____ Controls _____ Lot number: _____
 Sample Timepoint: Initial
 On Test: 5/5/2005 Date of Sample: 05/05/2005

Test Organism	Organism Counts at Dilutions					Plate Count Average	Initials -Date
	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻⁵		
<i>S. aureus</i> ATCC 6538	/	/	/	60	5	6.9 x 10 ⁵	C.H. 5-9-05
	/	/	/	77	9		
<i>P. aeruginosa</i> ATCC 9027	/	/	/	65	7	7.2 x 10 ⁵	C.H. 5-9-05
	/	/	/	78	7		
<i>E. coli</i> ATCC 8739	/	/	/	85	13	8.7 x 10 ⁵	C.H. 5-9-05
	/	/	/	88	16		
<i>C. albicans</i> ATCC 10231	/	/	/	76	5	7.8 x 10 ⁵	C.H. 5-9-05
	/	/	/	80	17		
<i>A. niger</i> ATCC 16404	/	/	/	TNTC	13	1.3 x 10 ⁶	C.H. 5-9-05
	/	/	/	TNTC	13		

MEDIA:

Peptone Lot (tubes): N/A Saline Lot (tubes): 05-40408-1 Polysaline Lot (tubes): 05-40426-1
 Peptone Lot (bulk): N/A Saline Lot (bulk): 05-40076-1 Polysaline Lot (bulk): 04-38477-2
 MCTA Lot: 5101273 Waterbath Asset No.: #22(A0083) Waterbath Temp(°C): 46.1
 Lethen Lot: 05-40311-1 Other: N/A

ORGANISMS:

A. niger Preparation Reference: 11673:007-19 (5/2/05) Transfer Log Reference: 11673:006-19 (5/5/05)

Analyst: Cristina Gutierrez Date: 5-9-05
 Verified By: Elise Miller Date: 5-16-05

M40.02
Rev. 10

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.