

04-37150-1
04-37152-1
04-37156-1
04-37157-3
04-37160-1

TITLE DET: USP/Trovatan BAC Control of Elements

PROJECT # 225719

(cont. from page 11A)

Date Initiated - 7/13/04

Purpose - To determine the preservative effectiveness of Trovatan BAC Free, Lot 04-37150-1 (FID 107337), Lot 04-37152-1 (FID 107339), Lot 04-37156-1 (FID 107341), Lot 04-37157-3 (FID 107047), Lot 04-37160-1 (FID 107340) at initial. This is a contribution of elements study.

Methods / Materials - PROC-0001136, V-2 0

Equipment - 10318:038 Media - LIMS / media kitchen

Test Validation Summary - N/A

Test Samples

- ① Trovatan BAC Free, no ZnCl₂, Lot 04-37150-1 (FID 107337), LIMS# 200198154 at initial.
- ② Trovatan BAC Free, no Boric acid, Lot 04-37152-1 (FID 107339), LIMS# 200198155 at initial.
- ③ Trovatan BAC Free, 85% ZnCl₂ + Boric acid, Lot 04-37156-1 (FID 107341), LIMS# 200198156 at initial.
- ④ Trovatan BAC Free, 0.004%, Lot 04-37157-3, (FID 107047), LIMS# 200197918 at initial.
- ⑤ Trovatan BAC Free, no Sorbitol or Propylene Glycol, Lot 04-37160-1, (FID 107340), LIMS# 200198273, at initial.

Kathleen Alford 7/15/04

Results Summary

Formulation Passes	10545:051-2,3,4,5,6
Initial Control Data	10545:051-7
Day 7 Data	10545:051-8,9,10,11,12
Day 14 Data	10545:051-13,14,15,16,17
Day 28 Data	10545:051-18,19,20,21,22
Preservative Evaluation Summaries	10545:051-23,24,25,26,27
LIMS Summaries	10545:051-28,29,30,31,32
Analytical Requests @ 8/19/04	10545:051-33,34,35,36,37

Lot 04-37150-1 fails 5 USP (Sa, Pa, Ec) and JP (Sa, Pa, Ec). Lots 04-37152-1, 04-37156-1, 04-37157-3, and 04-37160-1 pass USP and JP at initial. Kathleen Alford 8/19/04

OKB
8/31/04

(cont. on page _____)

Verified By: <u>Ronald F. Barry</u>	Date <u>8/31/04</u>	Entered By: <u>Kathleen Alford</u>	Date <u>8/19/04</u>
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Lot Number: 04-37150-1 Lot Status: SCHEDULED External Lot: N
 Formulation ID: 107337 V. 1 TRAVATAN BAC Free, 0.004%-no ZnCl2
 Lot Purpose: Microbiology Lot Description: 0.004% TRavatan BAC Free no Zinc chloride
 Mfg Lot Number: Target pH: 6.0 Project: 225719
 Reference Num: LN 11246:008 Dosage Form: Solution Batch Made by: Sandhya Rugwani
 Expiration Date: Retest Period: Storage Cond.: 2-25C

FORMULATION

Description	Concentration	Units	Purpose
AI06221,	0.004%	W/V %	Active Ingredient
Polyoxyl 40 Hydrogenated Castor Oil,	0.5%	W/V %	Surfactant
Boric Acid,	1%	W/V %	Buffering Agent
Sorbitol,	0.25%	W/V %	Excipient
Propylene Glycol,	0.75%	W/V %	Excipient
Sodium Hydroxide,	adjust pH	W/V %	Ph Adjust
Hydrochloric Acid,	adjust pH	W/V %	Ph Adjust
Purified Water,	q.s. 100%	W/V %	Vehicle

Formulation Comments:

Batch Comments:

Lot Comments:

PACKAGING

Package BOM #: 94 Descr: FORMULATION DEV BOM 19, BULK POLYSTYRENE PLASTIC CONTAINER

Component Description	Sterilization Method	Package Lot No.	Expiration Date	Alcon Part #	Packaging Operation Performed/ Witnessed by	Perform & Witness Date
NON-SPECIFIED POLYSTYRENE BULK CONTAINER FOR RESEARCH BOM'S	Non-Specified	0060400	01/07	-	SR jsh	7-7-04 7-7-04

Lot Filled by: SANDHYA RUGWANI Lot Fill Date: 07-Jul-2004 Fill Location: R&D Fort Worth
 Fill Volume: 200mL Num Units Filled: 1

Approved by: Ruma Sarkar Date: 7/8/04

Lot Number: 04-37152-1 **Lot Status:** SCHEDULED **External Lot:** N
Formulation ID: 107339 V. 1 TRAVATAN BAC Free, 0.004%-No Boric Acid
Lot Purpose: Microbiology **Lot Description:** 0.004% TRavatan BAC Free,no Boric Acid
Mfg Lot Number: **Target pH:** 6.0 **Project:** 225719
Reference Num: LN 11246:009 **Dosage Form:** Solution **Batch Made by:** Sandhya Rugwani
Expiration Date: **Retest Period:** **Storage Cond.:** 2-25C

FORMULATION

Description	Concentration	Units	Purpose
AI06221,	0.004%	W/V %	Active Ingredient
Polyoxyl 40 Hydrogenated Castor Oil,	0.5%	W/V %	Surfactant
Sorbitol,	0.25%	W/V %	Excipient
Propylene Glycol,	0.75%	W/V %	Excipient
Zinc Chloride,	0.0025%	W/V %	Excipient
Sodium Hydroxide,	adjust pH	W/V %	Ph Adjust
Hydrochloric Acid,	adjust pH	W/V %	Ph Adjust
Purified Water,	q.s. 100%	W/V %	Vehicle

Formulation Comments:

Batch Comments:

Lot Comments:

PACKAGING

Package BOM #: 94 **Descr:** FORMULATION DEV BOM 19, BULK POLYSTYRENE PLASTIC CONTAINER

Component Description	Sterilization Method	Package Lot No.	Expiration Date	Alcon Part #	Packaging Operation Performed/ Witnessed by	Perform & Witness Date
NON-SPECIFIED POLYSTYRENE BULK CONTAINER FOR RESEARCH BOM'S	Non-Specified	0050400	01107	-	Sr JMM	7/7/04 7-7-04

Lot Filled by: SANDHYA RUGWANI **Lot Fill Date:** 07-Jul-2004 **Fill Location:** R&D Fort Worth
Fill Volume: 200mL **Num Units Filled:** 1

Approved by: Rema Karan **Date:** 7/8/04

10545:051-4

Lot Number: 04-37156-1 Lot Status: SCHEDULED External Lot: N
 Formulation ID: 107341 V. 1 TRAVATAN BAC Free, 0.004%-85% ZnCl₂ & Boric Acid
 Lot Purpose: Microbiology Lot Description: 0.004% Travatan BAC Free, 85% ZnCl₂ & Boric Acid
 Mfg Lot Number: Target pH: 6.0 Project: 225202
 Reference Num: LN 11246: 010 Dosage Form: Solution Batch Made by: Sandhya Rugwani
 Expiration Date: Retest Period: Storage Cond.: 2-25C

FORMULATION

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

Formulation Comments:

Batch Comments:

Lot Comments:

PACKAGING

Package BOM #: 94 Descr: FORMULATION DEV BOM 19, BULK POLYSTYRENE PLASTIC CONTAINER

Component Description	Sterilization Method	Package Lot No.	Expiration Date	Alcon Part #	Packaging Operation Performed/ Witnessed by	Perform & Witness Date
NON-SPECIFIED POLYSTYRENE BULK CONTAINER FOR RESEARCH BOM'S	Non-Specified	00504001	01/07	—	SR JMD	7/7/04 7-7-04

Lot Filled by: SANDHYA RUGWANI Lot Fill Date: 07-Jul-2004 Fill Location: R&D Fort Worth

Fill Volume: 200mL Num Units Filled: 1

Approved by: Reema Sankar Date: 7/8/04

Formulation ID: 107047

Vers. 2

Description: TRAVATAN BAC Free, 0.004%

Target pH: 6.0

Units: W/V %

Dosage Form: SOLUTION

<u>Component</u>	<u>Concentration</u>	<u>Purpose</u>
A106221	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

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