

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> |
|-------------------------------------|---------------------|------------------------------------|---------------------|

Lot Detail Report

Report Date: 07-JUL-2004 01:41 PM

Page 1 of 1

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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