

(cont. from page N/A)

Date Initiated - 4/6/04

Purpose - To determine the preservative effectiveness of AL6221 0.004%, Lot 04-36174-1 (FID106756), Lot 04-36176-1 (FID106757), and Lot 04-36177-1 (FID106758) at initial.

Methods/Materials - PROC-0001136, V-2.0

Equipment - 10318:038 Media - 10318:040

PET Validation Summary - N/A

Test Samples

- ① AL-6221 Preserv. Free, 0.004%, Lot 04-36174-1, (FID106756) LIMS# 200191981 at initial.
- ② AL-6221 Preserv. Free, 0.004%, Lot 04-36176-1, (FID106757) LIMS# 200191982 at initial.
- ③ AL-6221 Preserv. Free, 0.004%, Lot 04-36177-1, (FID106758) LIMS# 200191983 at initial.

Stellen Alford 4/6/04

Results Summary

Formulation pages	10545:041-2,3,4
Initial Control Data	10545:041-5
Day 7 Data	10545:041-6,7,8
Day 14 Data	10545:041-9,10,11
Day 28 Data	10545:041-12,13,14
Preservative Evaluation Summary	10545:041-15,16,17
LIMS Summary	10545:041-18,19,20
Analytical Requests	10545:041-21,22,23

Lots 04-36174-1, 04-36176-1 and 04-36177-1 fail USP and JP (Sa, Ec) at initial. Stellen Alford 5/11/04

ATP 5/28/04

(cont. on page N/A)

Verified By : <u>Ronaldt Berry</u>	Date <u>5/28/04</u>	Entered By : <u>Stellen Alford</u>	Date <u>5/11/04</u>
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10545:041-2

# Alcon<sup>®</sup>

R&D LIMS

## Lot Report

Report Date: 25-MAR-2004 09:50 AM

Page 1 of 1

Lot Number: 04-36174-1

Formulation ID: 106756 V. 1 AL6221 0.004% Oph Sol (Isotonic Sodium Chloride)

Lot Purpose: Exploratory

Lot Description: PET

Mfg Lot Number:

Target pH: 6.0

Project: 106464

Reference Num: LN 11068:20 M

Dosage Form: Solution

Batch Made by: Wayne Schneider

Expiration Date: 23-MAR-2005

Retest Period: 1 year

Storage Cond.: 2-25C

### FORMULATION

Description	Concentration	Units	Purpose
Al06221, NOC	0.004%	W/V %	Active Ingredient
Polyoxyl 40 Hydrogenated Castor Oil, NF, EUR, JPE	0.5%	W/V %	Surfactant
Boric Acid, NF	1%	W/V %	Buffering Agent
Sorbitol, NF	1%	W/V %	Tonicity Agent
Sodium Chloride, USP, PH, EUR, JP	0.26%	W/V %	Tonicity Agent
Zinc Chloride, USP	0.0025%	W/V %	Excipient
Sodium Hydroxide, NF	adjust pH	W/V %	Ph Adjust
Hydrochloric Acid, NF	adjust pH	W/V %	Ph Adjust
Purified Water, USP	q.s. 100%	W/V %	Vehicle

Formulation Comments:

Batch Comments:

Lot Comments:

### PACKAGING

Package BOM #: 549 Descr: RESEARCH BOM 30, NONSPECIFIC PACKAGING TBD BY THE FORMULATOR

Lot Filled by: WAYNE SCHNEIDER

Lot Fill Date: 24-MAR-2004

Fill Location: R&D Fort Worth

Fill Volume: 90mL

Num Units Filled 1

Approved by:

*W Schneider*

Date:

*3-25-04*

*Jul 3-25-04*  
ADJUNCTIVE DATA TO  
BOOK 11068 PAGE 21

Lot Number: 04-36176-1

Formulation ID: 106757 V. 1 AL6221 0.004% Oph Sol (Hypotonic; 1/2 Boric/Sorbitol)

Lot Purpose: Exploratory

Lot Description: PET

Mfg Lot Number:

Target pH: 6.0

Project: 106464

Reference Num: LN 11068:20 N

Dosage Form: Solution

Batch Made by: Wayne Schneider

Expiration Date: 23-MAR-2005

Retest Period: 1 year

Storage Cond.: 2-25C

**FORMULATION**

Description	Concentration	Units	Purpose
AI06221, NOC	0.004%	W/V %	Active Ingredient
Polyoxyl 40 Hydrogenated Castor Oil, NF, EUR, JPE	0.5%	W/V %	Surfactant
Boric Acid, NF	0.5%	W/V %	Buffering Agent
Sorbitol, NF	3.2%	W/V %	Tonicity Agent
Zinc Chloride, USP	0.0025%	W/V %	Excipient
Sodium Hydroxide, NF	adjust pH	W/V %	Ph Adjust
Hydrochloric Acid, NF	adjust pH	W/V %	Ph Adjust
Purified Water, USP	q.s. 100%	W/V %	Vehicle

Formulation Comments:

Batch Comments:

Lot Comments:

**PACKAGING**

Package BOM #: 549 Descr: RESEARCH BOM 30, NONSPECIFIC PACKAGING TBD BY THE FORMULATOR

Lot Filled by: WAYNE SCHNEIDER

Lot Fill Date: 24-MAR-2004

Fill Location: R&D Fort Worth

Fill Volume: 90mL

Num Units Filled 1

Approved by:

*W Schneider*

Date:

*3-25-04*

*W Schneider*  
ADJUNCTIVE DATA TO  
BOOK 11068 PAGE 21

10545:041-4

Lot Number: 04-36177-1

Formulation ID: 106758 V. 1 AL6221 0.004% Oph Sol (Ethanol / No Zinc)

Lot Purpose: Exploratory

Lot Description: PET

Mfg Lot Number:

Target pH: 6.0

Project: 106464

Reference Num: LN 11068:20 O.

Dosage Form: Solution

Batch Made by: Wayne Schneider

Expiration Date: 23-MAR-2005

Retest Period: 1 year

Storage Cond.: 2-25C

**FORMULATION**

Description	Concentration	Units	Purpose
Al06221, NOC	0.004%	W/V %	Active Ingredient
Polyoxyl 40 Hydrogenated Castor Oil, NF, EUR, JPE	0.5%	W/V %	Surfactant
Boric Acid, NF	1%	W/V %	Buffering Agent
Sorbitol, NF	3.5%	W/V %	Tonicity Agent
Dehydrated Alcohol (Ethyl Alcohol), USP	0.1%	W/V %	Vehicle
Sodium Hydroxide, NF	adjust pH	W/V %	Ph Adjust
Hydrochloric Acid, NF	adjust pH	W/V %	Ph Adjust
Purified Water, USP	q.s. 100%	W/V %	Vehicle

Formulation Comments:

Batch Comments:

Lot Comments:

**PACKAGING**

Package BOM #: 549 Descr: RESEARCH BOM 30, NONSPECIFIC PACKAGING TBD BY THE FORMULATOR

Lot Filled by: WAYNE SCHNEIDER

Lot Fill Date: 24-MAR-2004

Fill Location: R&D Fort Worth

Fill Volume: 90mL

Num Units Filled 1

Approved by: W Schneider

Date: 3-25-04

ADJUNCTIVE DATA TO  
BOOK 11068 PAGE 21

**PRESERVATIVE RAW DATA**

Product: \_\_\_\_\_ Controls \_\_\_\_\_ Lot number: \_\_\_\_\_

Sample Timepoint: \_\_\_\_\_ Initial \_\_\_\_\_

On Test: 4/6/2004 Date of Sample: 04/06/2004

Test Organism	Organism Counts at Dilutions					Plate Count Average	Initials -Date
	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>	10 <sup>-4</sup>	10 <sup>-5</sup>		
<i>S. aureus</i> ATCC 6538	X	X	X	84	1	8.3 x 10 <sup>5</sup>	Ka 4/9/04
				81	7		
<i>P. aeruginosa</i> ATCC 9027				76	9	8.2 x 10 <sup>5</sup>	↓
				88	8		
<i>E. coli</i> ATCC 8739				80	6	7.8 x 10 <sup>5</sup>	
				75	7		
<i>C. albicans</i> ATCC 10231	95	5	1.0 x 10 <sup>6</sup>				
	107	6					
<i>A. niger</i> ATCC 16404	TNTC	10	1.0 x 10 <sup>6</sup>				
	TNTC	10					

**MEDIA:**

Peptone Lot (tubes): N/A Saline Lot (tubes): 04B074 Polysaline Lot (tubes): 04B067  
 Peptone Lot (bulk): N/A Saline Lot (bulk): 04B025 Polysaline Lot (bulk): 04B024  
 MCTA Lot: 04B041 Waterbath Asset No.: A0096 Waterbath Temp(°C): 46.5  
 Lethen Lot: 04B068 Other: \_\_\_\_\_

**ORGANISMS:**

*A. niger* Preparation Reference: 10318:047-15 <sup>4/5/04</sup> Transfer Log Reference: 10318:046-15

Analyst: Kathleen Alford Date: 4/9/04  
 Verified By: Lafonda Joneshill Date: 5/10/04

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