

BOOK NO: 10750

PAGE NO: 19-1

TITLE PET: USP /AL-6221 0.004%, Lot 04-36171-1 (106737), 04-36172-1 (106738), 04-36173-1 (106755) at Initial PROJECT # 225202

(cont. from page. N/A)

Date Initiated: 04-06-04

Purpose: To determine the preservative effectiveness of AL-6221 0.004%, lots 04-36171-1 (106737), 04-36172-1 (106738), and 04-36173-1 (106755) at Initial.

Method / Materials- PROC-0001134 (V-2.0)

Equipment - 10318:038 Media- ~~10318:004~~ + 10318:040, Media Kitchen/LIMS

PET Validation Summary- N/A

Test Samples

- ① AL-6221 0.004%, Lot 04-36171-1, (FID 106737), LIMS# 200191978, at Initial.
- ② AL-6221 0.004%, Lot 04-36172-1, (FID 106738), LIMS# 200191979, at Initial.
- ③ AL-6221 0.004%, Lot 04-36173-1, (FID 106755), LIMS# 200191980, at Initial.

Cristina Gutierrez 4/6/04

Results/Summary

Formulation pages- 10750:019-2 — 019-4

Initial control data- 10750:019-5 — ~~019-6~~ 5/12/04

Day 7 data- 10750:019-6 — 019-8

Day 14 data- 10750:019-9 — 019-11

Day 28 data- 10750:019-12 — 019-14

Preservative Evaluation Summaries- 10750:019-15 — 019-17

LIMS Summaries- 10750:019-18 — 019-20

Analytical Requests- 10750:019-21 — 019-23

Lot 04-36171-1 Failed USP & JP (S_a, E_c) requirements at Initial.

Lot 04-36172-1 Failed USP & JP (P_a) requirements at Initial.

Lot 04-36173-1 Failed USP & JP (E_c) requirements at Initial.

Cristina Gutierrez 5/12/04

Va 6/9/04

(cont. on page N/A)

Verified By:

Ruthie [Signature]

Date

6/9/04

Entered By:

Cristina Gutierrez

Date

5/12/04

Alcon[®]

R&D LIMS

Lot Report

Report Date: 25-MAR-2004 09:23 AM

Page 1 of 1

Lot Number: 04-36171-1

Formulation ID: 106737 V. 1 AL6221 0.004% Oph Sol (Isotonic Sorbitol, Pres. Free)

Lot Purpose: Exploratory

Lot Description: PET

Mfg Lot Number:

Target pH: 6.0

Project: 106464

Reference Num: LN 11068:20 H

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	1%	W/V %	Buffering Agent
Sorbitol, NF	3.8%	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 3-25-04
 ADJUNCTIVE DATA TO
 BOOK 11068 PAGE 21

Alcon®

R&D LIMS

Lot Report

Report Date: 25-MAR-2004 09:41 AM

Page 1 of 1

Lot Number: 04-36172-1

Formulation ID: 106738 V. 1 AL6221 0.004% Oph Sol (Isotonic Glycine, Pres. Free)

Lot Purpose: Exploratory

Lot Description: PET

Mfg Lot Number:

Target pH: 6.0

Project: 106464

Reference Num: LN 11068:20 I

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
Glycine, USP	0.65%	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 SchneiderDate: 3-25-04

W Schneider
 ADJUNCTIVE DATA TO
 BOOK 11068 PAGE 21

Lot Number: 04-36173-1

Formulation ID: 106755 V. 1 AL6221 0.004% Oph Sol (Isotonic Propylene Glycol)

Lot Purpose: Exploratory

Lot Description: PET

Mfg Lot Number:
Target pH: 6.0

Project: 106464

Reference Num: LN 11068:20 L

Dosage Form: Solution

Batch Made by: Wayne Schneider

Expiration Date: 23-MAR-2005

Retest Period: 1 year

Storage Cond.: 2-25C

FORMULATION

<u>Description</u>	<u>Concentration</u>	<u>Units</u>	<u>Purpose</u>
AI06221, 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
Propylene Glycol, USP	0.6%	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

PRESERVATIVE RAW DATA

Product: _____ Controls _____ Lot number: _____
 Sample Timepoint: Initial
 On Test: 04/06/2004 Date of Sample: 04/06/2004

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				144	10	1.5 x 10 ⁶	c.d. 4/9/04
				148	14		
<i>P. aeruginosa</i> ATCC 9027				121	18	1.2 x 10 ⁶	c.d. 4/9/04
				123	19		
<i>E. coli</i> ATCC 8739				150	14	1.6 x 10 ⁶	c.d. 4/9/04
				173	20		
<i>C. albicans</i> ATCC 10231				151	13	1.6 x 10 ⁶	c.d. 4/9/04
				170	18		
<i>A. niger</i> ATCC 16404				TNTC	10	1.1 x 10 ⁶	c.d. 4/9/04
				TNTC	11		

MEDIA:

Peptone Lot (tubes): N/A Saline Lot (tubes): 04B074 Polysaline Lot (tubes): 04B067
 Peptone Lot (bulk): N/A Saline Lot (bulk): 04B070 Polysaline Lot (bulk): 04B024
 MCTA Lot: 04B041 Waterbath Asset No.: #22(A0083) Waterbath Temp(°C): 45.5
 Lethen Lot: 04B068 Other: N/A

ORGANISMS:

A. niger Preparation Reference: 10318: 047-15 (4/5/04) Transfer Log Reference: 16318: 046-15 (4/6/04)

Analyst: Cristina Dutieroy Date: 4/9/04
 Verified By: Na'Keetra R. Higgins Date: 4/12/04

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