

TITLE PET: USP/AL-6221 0.004% Oph Soln, lot 04-36405-2 (FID 106039) at Initial.

PROJECT # 224 270

(cont. from page N/A)

Date Initiated: 04-21-04

Purpose: To determine the preservative effectiveness of AL-6221 0.004% Oph Soln, lot 04-36405-2 (FID 106039) at Initial.

Methods/Materials: PROC-0001136 (V-2.0)

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

PET Validation Summary- N/A

C.P.D. 4/21/04

Test Samples

① AL-6221 0.004% Oph Soln, lot 04-36405-2, (FID 106039), LIMS# 200193447, at Initial.

Cristina Gutierrez 4/21/04

Results/Summary

Formulation page - 10750:021-2

Initial control data - 10750:021-3

Day 7 data - 10750:021-4

Day 14 data - 10750:021-5

Investigation Report - 10750:021-6

Day 28 data - 10750:021-7

Preservative Evaluation Summaries - 10750:021-8

Confirmation of ~~A. E. coli~~ raw data - 10750:021-9 — 021-10

C.P.D. 7/14/04

Confirmation of E. coli Summaries - 10750:021-11 — 021-12

LIMS Summaries - 10750:021-13

Analytical Requests - 10750:021-14 — 021-16

Passed USP & JP

C.P.D. 7/22/04

Lot 04-36405-2 Failed USP (Ec) & JP (Ec) requirements at Initial.

Cristina Gutierrez 7/14/04

OPR
7/27/04

(cont. on page N/A)

Verified By: *Ronald Berry*

Date 7/27/04

Entered By: *Cristina Gutierrez*

Date 7/14/04

Formulation ID: 106039

Vers. 2

Description: AL6221 0.004% Oph. Soln. (Preservative Free)

Target pH: 6.0

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	1%	Necessity
Zinc Chloride	0.0025%	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: 04/21/2004 Date of Sample: 04/21/2004

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				101	11	1.0 x 10 ⁶	C.H. 4/26/04
				103	14		
<i>P. aeruginosa</i> ATCC 9027				105	13	1.1 x 10 ⁶	C.H. 4/26/04
				116	15		
<i>E. coli</i> ATCC 8739				118	10	1.2 x 10 ⁶	C.H. 4/26/04
				120	15		
<i>C. albicans</i> ATCC 10231				104	9	1.1 x 10 ⁶	C.H. 4/26/04
				112	15		
<i>A. niger</i> ATCC 16404				TNTC	10	1.1 x 10 ⁶	C.H. 4/26/04
				TNTC	11		

MEDIA:

Peptone Lot (tubes): N/A Saline Lot (tubes): 04-36425-1 Polysaline Lot (tubes): 04-36451-1
 Peptone Lot (bulk): N/A Saline Lot (bulk): 04B070 Polysaline Lot (bulk): 04B024
 MCTA Lot: 04B075 Waterbath Asset No.: #22 (A0083) Waterbath Temp(°C): 45.6
 Lethen Lot: 04-36426-1 Other: N/A

ORGANISMS:

A. niger Preparation Reference: 10318:047-17(4/19/04) Transfer Log Reference: 10318:046-17(4/21/04)

Analyst: Cristina Gutierrez Date: 4/26/04
 Verified By: Na'kedra R. Higgins Date: 4/26/04

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PRESERVATIVE RAW DATA

Product: AL-6221 0.004%OPH. SOLN.

Lot number: 04-36405-2

Sample Timepoint: Day 7

On Test: 04/21/2004

Date of Sample: 04/28/2004

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	TNTC	72	11	0	/	8.0 x 10 ³	c.H. 5/3/04
	TNTC	88	18	1			
<i>P. aeruginosa</i> ATCC 9027	TNTC	25	0	0	/	2.9 x 10 ³	c.H. 5/3/04
	TNTC	32	3	0			
<i>E. coli</i> ATCC 8739	TNTC	221	22	3	/	2.3 x 10 ⁴	c.H. 5/3/04
	TNTC	240	23	4			
<i>C. albicans</i> ATCC 10231	TNTC	TNTC	TNTC	74	7	7.5 x 10 ⁵	c.H. 5/5/04
	TNTC	TNTC	TNTC	76	9		
<i>A. niger</i> ATCC 16404	TNTC	8	1	0	0	1.0 x 10 ³	c.H. 5/5/04
	TNTC	12	2	0	0		

MEDIA:

Peptone Lot (tubes): N/A Saline Lot (tubes): 04-36425-1 Polysaline Lot (tubes): 04-36451-1

Peptone Lot (bulk): N/A Saline Lot (bulk): N/A Polysaline Lot (bulk): N/A

MCTA Lot: 4091419 Waterbath Asset No.: #22 (A0083) Waterbath Temp(°C): 45.7

Lethen Lot: 04-36502-1 Other: N/A

ORGANISMS:

A. niger Preparation Reference: N/A Transfer Log Reference: N/A

Analyst: Cristina Gutierrez Date: 5/5/04

Verified By: NaKedra R Higgins Date: 5/7/04

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PRESERVATIVE RAW DATA

Product: AL-6221 0.004%OPH. SOLN.

Lot number: 04-36405-2

Sample Timepoint: Day 14

On Test: 04/21/2004

Date of Sample: 05/05/2004

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	19	5	/	/	/	2.2 x 10 ²	c.d. 5/10/04
	24	5	/	/	/		
<i>P. aeruginosa</i> ATCC 9027	2	0	/	/	/	2.5 x 10 ¹	c.d. 5/10/04
	3	0	/	/	/		
<i>E. coli</i> ATCC 8739	TNTC	55	/	/	/	6.7 x 10 ³	c.d. 5/10/04
	TNTC	78	/	/	/		
<i>C. albicans</i> ATCC 10231	TNTC	TNTC	TNTC	83	/	8.9 x 10 ⁵	c.d. 5/12/04
	TNTC	TNTC	TNTC	94	/		
<i>A. niger</i> ATCC 16404	TNTC	8	/	/	/	8.5 x 10 ²	c.d. 5/12/04
	TNTC	9	/	/	/		

MEDIA:

Peptone Lot (tubes): N/A Saline Lot (tubes): 04-36519-1 Polysaline Lot (tubes): 04-36501-1

Peptone Lot (bulk): N/A Saline Lot (bulk): N/A Polysaline Lot (bulk): N/A

MCTA Lot: 4091419 Waterbath Asset No.: #22(A0083) Waterbath Temp(°C): 46.1

Lethen Lot: 04-36590-1 Other: N/A

ORGANISMS:

A. niger Preparation Reference: N/A Transfer Log Reference: N/A

Analyst: Cristina Gutierrez Date: 5/12/04

Verified By: Na'kedra R. Higgins Date: 5/13/04

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