

(cont. from page N/A) Date Initiated - 3/21/07

Purpose - To evaluate the preservative effectiveness of AL37807 Vehicle Lot 07-46930-1 (FID 112147), Lot 07-46931-1 (FID 112148) at initial.

Methods/Materials - PROC-0001139 (v4.0)

Equipment - 12586:063-2 Media - Media Kitchen/LIMS

PET Validation Summary - N/A

Test Samples -

① AL37807 Vehicle Lot 07-46930-1 (FID 112147) LIMS # 200249213 at initial.

② AL37807 Vehicle Lot 07-46931-1 (FID 112148) LIMS # 200249214 at initial. Elise Miller 3/22/07

Results/Summary -

Formulation pages - 12586:063-3,4

Preservative Screen Data + Summaries - 12586:063-5,6

LIMS Summaries - 12586:063-7,8

Analytical Requests - 12586:063-9,10

Lot 07-46930-1 is projected to Pass USP, JP, EPB; Fail EPA (Sa, Pa, Ca, An) requirements at initial.

Lot 07-46931-1 is projected to Pass USP, JP, EPB; Fail EPA (An) requirements at initial.

Elise Miller 4/6/07

SJ 4/13/07

(cont. on page N/A)

Verified By:

Maren Swale

Date

4/13/07

Entered By:

Elise Miller

Date

4/6/07

EQUIPMENT FOR PET TESTING:

(1) General Equipment

Name:	Asset #	Name:	Asset #
<input type="checkbox"/> Spectrophotometer #12	A1692	<input type="checkbox"/> Microscope # 13	A0885
<input checked="" type="checkbox"/> Refrigerator # 22	10-1367	<input type="checkbox"/> Balance # 10	13900

<input type="checkbox"/> (2) Stock Cultures, Culture Transfers		<input type="checkbox"/> (3) A. niger: Weekly & Daily Preparations	
Name:	Asset #	Name:	Asset #
Incubator # 15 (30-35°C)	10-1177	Incubator # 16 (20-25°C)	10-1023
Incubator # 19 (20-25°C)	102619	Centrifuge # 3	1-3832
Refrigerator # 22	10-1367	Laminar Flow Hood #1	13606
Refrigerator # 19	A0762	Spectrophotometer # 12	A-1692
<input type="checkbox"/> Other:		Refrigerator # 19	A0762
<input type="checkbox"/> Other:		Electronic Repeater Pipettor Model Plus (# 41)	A1442
<input type="checkbox"/> Other:		Refrigerator # 22	

Individual Equipment:

<input type="checkbox"/> (4) Cristina Gutierrez (Aqua Tape)		<input type="checkbox"/> (8) Sharon Fowler (Purple Tape)	
Name:	Asset #	Name:	Asset #
Water Bath #22	A0083	Water Bath #25	A0328
Incubator #19 (20-25°C)	102619	Incubator #19 (20-25°C)	102619
Incubator #15 (30-35°C)	10-1177	Incubator #20 (30-35°C)	102620
Electronic Repeater Pipettor Model Plus (#46)	A1594	Electronic Repeater Pipettor Model Plus (#48)	A1596
Thermometer # _____		Thermometer # _____	
<input type="checkbox"/> Milliflex Unit #20 (check if necessary)	103169	<input type="checkbox"/> Milliflex Unit #17 (check if necessary)	10-2969
Other:		Other:	

<input checked="" type="checkbox"/> (5) Elise Miller (Grey Tape)		<input type="checkbox"/> (9) LaFonda Somerville (Rose Tape)	
Name:	Asset #	Name:	Asset #
Water Bath #26	A0329	Water Bath #6	32523
Incubator #19 (20-25°C)	102619	Incubator # 16 (20-25°C)	10-1023
Incubator #15 (30-35°C)	10-1177	Incubator #20 (30-35°C)	102620
Electronic Repeater Pipettor Model Plus (#34)	A0975	Electronic Repeater Pipettor Model Plus (#49)	A1793
Thermometer # <u>SIN 5122262</u>		Thermometer # _____	
<input type="checkbox"/> Milliflex Unit #19 (check if necessary)	103168	<input type="checkbox"/> Milliflex Unit #21 (check if necessary)	103170
Other:		Other:	

<input type="checkbox"/> (6) Kathleen Alford (Red Tape)		<input type="checkbox"/> (10) Cade Pippin (Orange Tape)	
Name:	Asset #	Name:	Asset #
Water Bath #30	A2595	Water Bath #21	A0038
Incubator #19 (20-25°C)	102619	Incubator # 16 (20-25°C)	10-1023
Incubator #15 (30-35°C)	10-1177	Incubator #20 (30-35°C)	102620
Electronic Repeater Pipettor Model Plus (#42)	A1443	Electronic Repeater Pipettor Model Plus (#47)	A1595
Thermometer # _____		Thermometer # _____	
<input type="checkbox"/> Milliflex Unit #18 (check if necessary)	102970	<input type="checkbox"/> Milliflex Unit #2 (check if necessary)	1-7716
Other:		Other:	

<input type="checkbox"/> (7) Na'Kedra Higgins (Pink Tape)		<input type="checkbox"/> (11) Other:	
Name:	Asset #	Name:	Asset #
Water Bath #29	A2594	_____	_____
Incubator # 16 (20-25°C)	10-1023	_____	_____
Incubator #20 (30-35°C)	102620	_____	_____
Electronic Repeater Pipettor Model Plus (#74)	A2591	_____	_____
Thermometer # _____		_____	_____
Other:		_____	_____

Comments:

ANALYST: Elise Miller

DATE: 4-5-07

VERIFIED BY: Cristina Gutierrez

DATE: 4-6-07

Batch Number: 07-46930

Formulation ID: 112147 V. 1 AL-37807 vehicle with Zinc Chloride and NaCl at pH7.5

Primary Purpose: MICROBIOLOGY

Project Num: 225692

Reference Number: LN 13160:67

FID Life Cycle: Exploratory

Dosage Form: SOLUTION

Units: mL

Target pH: 7.5

Location: R&D FORT WORTH

Batch Size: 300 mL

Target Batch Weight (g): 300

Batch Density:

Jurisdiction: US Only

Comments:

Status: SCHEDULED

External: N

Batch Pre Approved By: Lyndal Coslin Date: 3/12/07

Component	Grade	Concentration	Calc Amt.	Actual Amt	Lot ID	Expiration Date	Weighted By/ Date	Witnessed by/ Date
SODIUM CHLORIDE	USP	0.71% WV %	2.13g	2.130g	C0196937	02-Dec-2007	pc 3/13/07	pc 3/13/07
MANNITOL	USP	0.1% WV %	.3g	0.302g	C0199672	05-May-2007	pc 3/13/07	pc 3/13/07
BORIC ACID	NF	0.25% WV %	.75g	0.750g	C0196730	16-Nov-2007	pc 3/13/07	pc 3/13/07
ZINC CHLORIDE	USP	0.025% WV %	.075g	0.074g	C0197505	31-Jul-2007	pc 3/13/07	pc 3/13/07
HYDROCHLORIC ACID	NF	qs to pH 7.5	qs to pH 7.5		07-46293-1	04-Jan-2008		
SODIUM HYDROXIDE	NF	qs to pH 7.5	qs to pH 7.5	1.332g	07-46291-1	04-Jan-2008	pc 3/13/07	pc 3/13/07
PURIFIED WATER	USP	qs to 100%	qs to 100%	1/5 to 100%	20070309PD	19-Mar-2007	pc 3/13/07	pc 3/13/07

Initial pH = 4.84 Final pH = 7.52 Osmolality: 282 Tare Wt.: 184.30g Final Wt.: 484.60g Batch Wt.: 300.30g

Compounded by: Jason McMillen Date: 3-13-07 Approved by: [Signature] Date: 3/13/07

Record Created by: JASON MCMILLEN Date: 12-MAR-2007

12586:063-3

12586:063-4

Batch Number: 07-46931

Formulation ID: 112148 V. 1 AL-37807 vehicle with Zinc Chloride and Prop. Gly. at pH7.5

Primary Purpose: MICROBIOLOGY

Reference Number: LN 13160:68

FID Life Cycle: Exploratory

Dosage Form: SOLUTION

Units: mL

Target pH: 7.5

Location: R&D FORT WORTH

Batch Size: 300 mL

Target Batch Weight (g): 300

Batch Density:

Jurisdiction: US Only

Comments:

Status: SCHEDULED

External: N

Batch Pre Approved By: Lyndal Wren Date: 3/12/07

Component	Grade	Concentration	Calc Amt.	Actual Amt	Lot ID	Expiration Date	Weighted By/ Date	Witnessed by/ Date
PROPYLENE GLYCOL	USP	1.6% WV %	4.8g	4.800g	00200777	28-Jun-2007	PC 3/12/07	PC 3/13/07
MANNITOL	USP	0.1% WV %	.3g	0.303g	00199672	05-May-2007	PC 3/12/07	PC 3/13/07
BORIC ACID	NF	0.25% WV %	.75g	0.750g	00196730	16-Nov-2007	PC 3/12/07	PC 3/13/07
ZINC CHLORIDE	USP	0.025% WV %	.075g	0.076g	00197505	31-Jul-2007	PC 3/12/07	PC 3/13/07
HYDROCHLORIC ACID	NF	qs to pH 7.5	qs to pH 7.5		07-46293-1	04-Jan-2008		
SODIUM HYDROXIDE	NF	qs to pH 7.5	qs to pH 7.5	1.586g	07-46291-1	04-Jan-2008	PC 3/12/07	PC 3/13/07
PURIFIED WATER	USP	qs to 100%	qs to 100%	95.7g	20070309PD	19-Mar-2007	PC 3/12/07	PC 3/13/07

Initial pH = 4.85 Final pH = 7.53 Osmolality: 265 Tare Wt: 186.41g Final Wt: 486.41g Batch Wt: 300.00g
 Compounded by: Jason Mynh Date: 3-12-07 Approved by: [Signature] Date: 3/13/07
 Record Created by: JASON MCMILLEN Date: 12-MAR-2007

PRESERVATIVE SCREEN DATA AND SUMMARY

Formulation/Product **112147 AL-37807 VEHICLE WITH ZINC CHLORIDE** Date Assayed **3/21/2007**
 Preservative **None**
 Project No. **225692** Proc No. **PROC-0001139 V4.0** LIMS No **200249213**
 Age initial Project CFU/mL Log₁₀ Reduction Entered by (Initials/Date)

Test Organism	Date of Sample	Sampling Time	Organism Counts at Dilutions					CFU/mL	Log ₁₀ Reduction	Entered by (Initials/Date)
			10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻⁵			
<i>S. aureus</i> ATCC 6538	3-21-07	Initial	TNTC	TNTC	TNTC	113	1.1 x 10 ⁶		EM 3-26-07	
	3-21-07	6 hour	TNTC	TNTC	TNTC	43	4.3 x 10 ⁵	0.4	EM 3-26-07	
	3-23-07	24 hour	TNTC	TNTC	33	2	3.3 x 10 ⁴	1.5	EM 3-26-07	
	3-28-07	Day 7	0	0	0	0	<10	5.0	EM 4-2-07	
<i>S. aeruginosa</i> ATCC 9027	3-21-07	Initial	TNTC	216	16	138	1.4 x 10 ⁶		EM 3-26-07	
	3-21-07	6 hour	0	0	0	2	2.2 x 10 ⁴	1.8	EM 3-26-07	
	3-23-07	24 hour	0	0	0	0	<10	5.1	EM 3-26-07	
	3-28-07	Day 7	0	0	0	0	<10	5.1	EM 4-2-07	
<i>E. coli</i> ATCC 8739	3-21-07	Initial	TNTC	TNTC	TNTC	112	1.1 x 10 ⁶		EM 3-26-07	
	3-21-07	6 hour	TNTC	TNTC	TNTC	29	2.9 x 10 ⁵	0.6	EM 3-26-07	
	3-23-07	24 hour	0	0	0	7	9.6 x 10 ⁴	1.1	EM 3-26-07	
	3-28-07	Day 7	0	0	0	0	<10	5.0	EM 4-2-07	
<i>C. albicans</i> ATCC 10231	3-21-07	Initial	TNTC	TNTC	TNTC	91	9.1 x 10 ⁵		EM 3-26-07	
	3-23-07	Day 7	TNTC	TNTC	79	8	7.9 x 10 ⁴	1.1	EM 4-4-07	
	3-21-07	Initial	TNTC	TNTC	TNTC	TNTC	8.0 x 10 ⁵		EM 3-26-07	
	3-28-07	Day 7	TNTC	TNTC	TNTC	8	8.0 x 10 ⁴	1.0	EM 4-4-07	

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Media/Org. References	Leitheen	Peptone (tubes)	Peptone (bulk)	Polysaline (tubes)	Polysaline (bulk)	MCTA	Waterbath Asset No.	Waterbath Temp (°C)	Transfer Log Ref.	A. niger Prep. Ref.
Initial	07-46924-1	07-46920-1	07-46723-1	07-46919-1	07-46493-2	7046807	A0329	47.1	12941-01-13	12941-01-5(3/19/07)
3 hours	07-47014-1	07-46920-1				7046807	A0329	47.0		
24 hours	07-47014-1	07-46911-1				7046807	A0329	47.2		
Day 7	07-47112-1	07-47111-1		07-47015-1		7046807	A0329	45.8		

For Filtration Tests only:

MCTA Cassettes	Funnel	Peptone Rinse

PROJECTED TO:

Pass USP
 Pass JP
 Pass PhEur A
 Pass PhEur B

Fail USP
 Fail JP
 Fail PhEur A
 Fail PhEur B

Analyst: Elise Miller Date: 4-5-07
 Verified by: Sharon Swider Date: 4/13/07

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