

(cont. from page N/A)

Date Initiated: 04-11-07

Purpose: To evaluate the preservative effectiveness of AL-37807 Vehicle, lots 07-47278 (FID 112294), 07-47249 (FID 112286) & 07-47250 (FID 112287) at Initial.

Method / Materials: PROC-0001139 (V-4.0)

Equipment: 12034: 091-2 Media: Media kitchen LIMS

PET Validation Summary: N/A

Test Samples

- ① AL-37807 Vehicle, Lot 07-47278 (FID 112294) LIMS# 200250592 at Initial.
- ② AL-37807 Vehicle, Lot 07-47249 (FID 112286) LIMS# 200250480 at Initial.
- ③ AL-37807 Vehicle, Lot 07-47250 (FID 112287) LIMS# 200250481 at Initial.

Cristina Gutierrez 4/11/07

Results / Summaries

Formulation pages: 12034: 091-3 - 091-5

Preservative Screen Data & Summaries: 12034: 091-6 - 091-8

LIMS Summaries: 12034: 091-9 - 091-11

Analytical Requests: 12034: 091-12 - 091-14

Lot 07-47278, ^{Projected to} Passes USP, JP & EPB; Projected to fail EPA (S_y, R_y, E_c, A_n) requirements at Initial.

Lot 07-47249, Projected to Pass USP & JP; Projected to Fail EPA (S_y, R_y, E_c, A_n) & EPB (S_y, E_c) requirements at Initial.

Lot 07-47250, Projected to Pass USP, JP & EPB; Projected to Fail EPA (S_y, R_y, E_c) requirements at Initial.

Cristina Gutierrez 4/30/07

EM 5-4-07

(cont. on page N/A)

Verified By:

Elise Miller

Date

5-4-07

Entered By:

Cristina Gutierrez

Date

4/30/07

EQUIPMENT FOR PET TESTING:

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

(2) Stock Cultures, Culture Transfers		(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:			
(4) Cristina Gutierrez (Aqua Tape)		(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 # <u>SN 51219199</u>		Thermometer # _____	
<input type="checkbox"/> Milliflex Unit #20 (check if necessary)	103169	<input type="checkbox"/> Milliflex Unit #17 (check if necessary)	10-2969
Other:		Other:	
(5) Elise Miller (Grey Tape)		(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 # _____		Thermometer # _____	
<input type="checkbox"/> Milliflex Unit #19 (check if necessary)	103168	<input type="checkbox"/> Milliflex Unit #21 (check if necessary)	103170
Other:		Other:	
(6) Kathleen Alford (Red Tape)		(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:	
(7) Na'Kedra Higgins (Pink Tape)		(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: Cristina Gutierrez

DATE: 4-27-07

VERIFIED BY: Elise Miller

DATE: 4-27-07

12034:091-3

Batch Number: 07-47278

Formulation ID: 112294 V. 1 AL-37807 vehicle with 0.012% Zinc Chloride at pH 7.5

Primary Purpose: MICROBIOLOGY

Reference Number: LN 13292.45

FID Life Cycle: Exploratory

Dosage Form: SOLUTION

Units: mL

Target pH: 7.5

Location: R&D FORT WORTH

Batch Size: 250 mL

Target Batch Weight (g): 250

Batch Density:

Jurisdiction: US Only

Comments:

Status: SCHEDULED

External: N

Batch Pre Approved By: *Aguel* Date: *4/10/07*

Component	Grade	Concentration	Calc Amt.	Actual Amt	Lot ID	Expiration Date	Weighted By/ Date	Witnessed by/ Date
PROPYLENE GLYCOL	USP	1.6% W/V %	4g	4.028g	00200777	28-Jun-2007	<i>Aguel</i> 4/10/07	<i>Aguel</i> 4/10/07
MANNITOL	USP	0.1% W/V %	25g	0.251g	00199672	05-May-2007	<i>Aguel</i> 4/10/07	<i>Aguel</i> 4/10/07
BORIC ACID	NF	0.25% W/V %	625g	0.627g	00202476	31-Oct-2008	<i>Aguel</i> 4/10/07	<i>Aguel</i> 4/10/07
ZINC CHLORIDE	USP	0.012% W/V %	03g	0.031g	00197505	31-Jul-2007	<i>Aguel</i> 4/10/07	<i>Aguel</i> 4/10/07
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	1.106g	07-46291-1	04-Jan-2008	<i>Aguel</i> 4/10/07	<i>Aguel</i> 4/10/07
PURIFIED WATER	USP	qs to 100%	qs to 100%	95.7g <i>10007</i>	20070409RD2 4	19-Apr-2007	<i>Aguel</i> 4/10/07	<i>Aguel</i> 4/10/07

Initial pH = 4.79 Final pH = 7.54 Osmolality: 261 Tare Wt.: 196.75g Final Wt.: 446.82g Batch Wt.: 250.07g

Compounded by: *Jason McMillen* Date: 4-10-07 Approved by: *Aguel* Date: 4/10/07

Record Created by: JASON MCMILLEN Date: 10-APR-2007

12034:091-4

Batch Number: 07-47249

Formulation ID: 112286 V. 1 AL-37807 vehicle with Zinc Chloride and Prop. Gly. at pH 5.5

Primary Purpose: MICROBIOLOGY Project Num: 225692

Dosage Form: SOLUTION Units: mL

Batch Size: 250 mL

Target Batch Weight (g): 250

Batch Density:

Reference Number: LN 13292:38

FID Life Cycle: Exploratory

Location: R&D FORT WORTH

Jurisdiction: US Only

Comments:

Status: SCHEDULED

External: N

Batch Pre Approved By: *[Signature]* Date: 4-6-07

Component	Grade	Concentration	Calc Amt	Actual Amt	Lot ID	Expiration Date	Weighed By/ Date	Witnessed by/ Date
PROPYLENE GLYCOL	USP	1.6% W/V %	4g	4.000g	C0201560	15-Aug-2007	<i>[Signature]</i> 4/6/07	<i>[Signature]</i> 4/6/07
MANNITOL	USP	0.1% W/V %	25g	2.250g	C0199672	05-May-2007	<i>[Signature]</i> 4/6/07	<i>[Signature]</i> 4/6/07
BORIC ACID	NF	0.25% W/V %	625g	0.625g	C0202476	31-Oct-2008	<i>[Signature]</i> 4/6/07	<i>[Signature]</i> 4/6/07
ZINC CHLORIDE	USP	0.025% W/V %	625g	0.0625g	C0197505	31-Jul-2007	<i>[Signature]</i> 4/6/07	<i>[Signature]</i> 4/6/07
HYDROCHLORIC ACID	NF	qs to pH 5.5	qs to pH 5.5	N/A	07-46293-1	04-Jan-2008	N/A	N/A
SODIUM HYDROXIDE	NF	qs to pH 5.5	qs to pH 5.5	(1M)	07-46291-1	04-Jan-2008	<i>[Signature]</i> 4/6/07	<i>[Signature]</i> 4/6/07
PURIFIED WATER	USP	qs to 100%	qs to 100%	45100L	20070327PD	06-Apr-2007	<i>[Signature]</i> 4/6/07	<i>[Signature]</i> 4/6/07

Initial pH = 4.84 Final pH = 5.56 Osmolality: 263 Tare Wt.: 205.54g Final Wt.: 455.55g Batch Wt.: 250.01g

Compounded by: *[Signature]* Date: 4-6-07 Approved by: *[Signature]* Date: 4/6/07

Record Created by: JASON MCMILLEN Date: 06-APR-2007

12034: 091-5

Batch Number: **07-47250**
 Formulation ID: 112287 V. 1 AL-37807 vehicle with Zinc Chloride and Prop. Gly. at pH 6.5
 Primary Purpose: MICROBIOLOGY Project Num: 225692 Reference Number: LN 13292-39 FID Life Cycle: Exploratory
 Dosage Form: SOLUTION Units: mL Target pH: 6.5 Location: R&D FORT WORTH
 Batch Size: 250 mL Target Batch Weight (g): 250 Batch Density: Jurisdiction: US Only External: N
 Comments: Status: SCHEDULED
 Batch Pre Approved By: *[Signature]* Date: 4-6-07

Component	Grade	Concentration	Calc Amt.	Actual Amt	Lot ID	Expiration Date	Weighted By/ Date	Witnessed by/ Date
PROPYLENE GLYCOL	USP	1.6% WV %	4g	4.004g	00201560	15-Aug-2007	<i>[Signature]</i> 4/6/07	<i>[Signature]</i> 4/6/07
MANNITOL	USP	0.1% WV %	.25g	0.250g	00199672	05-May-2007	<i>[Signature]</i> 4/6/07	<i>[Signature]</i> 4/6/07
BORIC ACID	NF	0.25% WV %	.625g	0.627g	00202476	31-Oct-2008	<i>[Signature]</i> 4/6/07	<i>[Signature]</i> 4/6/07
ZINC CHLORIDE	USP	0.025% WV %	.0625g	0.063g	00197505	31-Jul-2007	<i>[Signature]</i> 4/6/07	<i>[Signature]</i> 4/6/07
HYDROCHLORIC ACID	NF	qs to pH 6.5	qs to pH 6.5	NA	07-46293-1	04-Jan-2008	<i>[Signature]</i> 4/6/07	NA
SODIUM HYDROXIDE	NF	qs to pH 6.5	qs to pH 6.5	(IN)	07-46291-1	04-Jan-2008	<i>[Signature]</i> 4/6/07	<i>[Signature]</i> 4/6/07
PURIFIED WATER	USP	qs to 100%	qs to 100%	qs to 100%	20070327PD	06-Apr-2007	<i>[Signature]</i> 4/6/07	<i>[Signature]</i> 4/6/07

Initial pH = 4.86 Final pH = 6.57 Osmolality: 265 Tare Wt.: 187.44g Final Wt.: 437.34g Batch Wt.: 250.05g
 Compounded by: *[Signature]* Date: 4-6-07 Approved by: *[Signature]* Date: 4/6/07
 Record Created by: JASON MCMILLEN Date: 06-APR-2007

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