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OBJECTIVE: Make 250ml of AL-37807 Vehicle containing 0.025% Zinc Chloride at pH 5.5 and submit a portion for PET - ASSUMPTIVE DATA

h 7/6/07

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REF LN 13292-38

Equipment:

Corning Stir Plate		
Advanced Micro-Osmometer 3320	room:C125	Asset# 000519462
Laminaire horizontal flow hood	room:C125	Asset#:13324-00
Balance-Mettler B240	room:C125	Asset#:A0129
Balance-Sartorius LP6200S	room:C125	Asset#:A1721
pH Meter-Orion 350	room:C125	Asset#:A1722

Formulation:

AL-37807 Vehicle at PH 5.5
with Zn Chloride & Prop. Gly.
FID: 112286 BATCH: 07-47249
MADE: 6-APR-07 EXP: 6-OCT-07
STORAGE: RT

h
4-6-07

h
4-6-07

Compounding Procedure: 250 mL batch size

1. Tare weighed a clean 400mL pyrex beaker with stirbar.
2. Added 80% batch quantity of purified water and began mixing.
3. Weighed and added Boric Acid, Mannitol, Propylene Glycol, and Zinc Chloride.
4. QS'ed to 95% with purified water.
5. Stirred until completely dissolved
6. Checked initial pH and recorded on batch sheet. pH= 4.84
7. Adjusted pH to 5.5 with 1N HCl and/or 1N NaOH. Amount used 0.032g
8. Qs'ed to 100% with purified water.
9. Mixed until homogenous.
10. Filter through 2-150mL 0.2micron Millipore filter units.
(150mL in one for PET and 100mL in the other to store at RT)
11. Moved to Laminaire Flow Hood for remainder of batch preparation.
12. Removed a small amount for the following tests:
13. Final pH pH= 5.56
14. Final tonicity Osmolality= 263
15. Visual Observations= clear solution

Submit 07-47249 for PET Screen:

1. Submit a copy of the Batch Report, an FID sheet and the AR along with the sample.
Submission ID number: 100096141 amount 150ml

COMMENTS: Remaining 100ml is being stored at RT in C125.

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Verified By: <i>Lynnda Loren</i>	Date: <i>4/13/07</i>	Entered By: <i>Jason Merrill</i>	Date: <i>4-6-07</i>
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OBJECTIVE: Make 250ml of AL-37807 vehicle containing 0.025% Zinc Chloride at pH 6.5 and submit a portion for PET ADJUNCTIVE DATA 4-6-07

Equipment:

Corning Stir Plate
Advanced Micro-Osmometer 3320 room:C125
Laminaire horizontal flow hood room:C125
Balance-Mettler B240 room:C125
Balance-Sartorius LP6200S room:C125
pH Meter-Orion 350 room:C125

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REF LN13292: 39

Asset# 000519462

Asset#:13324-00

Asset#:A0129

Asset#:A1721

Asset#:A1722

4-6-07

Formulation:

AL-37807 Vehicle at PH 6.5
with Zn Chloride & Prop. Gly.
FID: 112287 BATCH: 07-47250
MADE: 6-APR-07 EXP: 6-OCT-07
STORAGE: RT

4-6-07

Compounding Procedure: 250 mL batch size

1. Tare weighed a clean 400mL pyrex beaker with stirbar.
2. Added 80% batch quantity of purified water and began mixing.
3. Weighed and added Boric Acid, Mannitol, Propylene Glycol, and Zinc Chloride.
4. QS'ed to 95% with purified water.
5. Stirred until completely dissolved
6. Checked initial pH and recorded on batch sheet. pH= 4.86
7. Adjusted pH to 6.5 with 1N HCl and/or 1N NaOH. Amount used 0.261g
8. Qs'ed to 100% with purified water.
9. Mixed until homogenous.
10. Filter through 2-150mL 0.2micron Millipore filter units.
(150mL in one for PET and 100mL in the other to store at RT)
11. Moved to Laminare Flow Hood for remainder of batch preparation.
12. Removed a small amount for the following tests:
13. Final pH pH= 6.57
14. Final tonicity Osmolality= 265
15. Visual Observations= clear solution

Submit 07-47250 for PET Screen:

1. Submit a copy of the Batch Report, an FID sheet and the AR along with the sample.
Submission ID number: 100096142 (150ml submitted)

COMMENTS: The remaining 100ml is being stored at RT in C125

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Verified By:

Date

Entered By:

Date