

Product Quality Microbiology Review

23 October 2014

NDA: 206-814/N000

Drug Product Name

Proprietary: None

Non-proprietary: Potassium Chloride Oral Solution, USP

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
27 February 2014	27 February 2014	28 February 2014	28 February 2014
30 June 2014	30 June 2014	NA	NA
22 October 2014	22 October 2014	NA	NA

Submission History (for 2nd Reviews or higher) – NA

Applicant/Sponsor

Name: Pharma-Med, Inc.

Address: 941 Marcon Boulevard, Suite 301
Allentown, PA 18109

Representative: Melissa L. Goodhead
11705 Boyette Road, Suite 171
Riverview, Fl. 33569

Telephone: (813) 617-8570

Name of Reviewer: Denise A. Miller

Conclusion: Recommended for approval from a quality microbiology perspective. A post approval commitment was recommended.

Product Quality Microbiology Data Sheet

- A. 1. TYPE OF SUBMISSION:** Original New Drug Application
- 2. SUBMISSION PROVIDES FOR:** The manufacture and marketing of a non-sterile oral drug product.
- 3. MANUFACTURING SITE:**
Lehigh Valley Technologies, Inc.
514 N. 12th Street
Allentown, PA 18102
FEI number: 3003851100
- 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
- Dosage Form: Oral solution
 - Route of Administration: Oral
 - Strength/Potency: 20 mEq/15 mL, 40 mEq/15 mL in a (b) (4) bottle.
- 5. METHOD(S) OF STERILIZATION:** NA, not sterile
- 6. PHARMACOLOGICAL CATEGORY:** Indicated for the treatment of hypokalemia, (b) (4)
- B. SUPPORTING/RELATED DOCUMENTS:** NA
- C. REMARKS:**
The 74 day letter included an information request to provide the antimicrobial effectiveness testing. The AET report was provided in the amendment of 30 June 2014. Review of this report is located in the appropriate section of this review. A second information request was sent

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Executive Summary

I. Recommendations

- A. Recommendation on Approvability** - Recommended for approval from a quality microbiology perspective.
- B. Recommendations on Phase 4 Commitments and/or Agreements** – The antimicrobial preservative effectiveness testing (AET) data provided in the submission were for one of the formulations; AET was not performed on the second formulation. A post approval commitment for performing the AET on the second formulation was requested. See Section 3, List of Microbiology Deficiencies and Comments.

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – This is a non-sterile oral drug product and the application should provide for microbial quality of the drug product over the shelf life and during use.
- B. Brief Description of Microbiology Deficiencies** – None were identified in the information provided.
- C. Assessment of Risk Due to Microbiology Deficiencies** – NA
- D. Contains Potential Precedent Decision(s)**- Yes No

III. Administrative

- A. Reviewer's Signature** _____
Denise A. Miller
Microbiologist, OPS/NDMS
- B. Endorsement Block** _____
Neal J. Sweeney, Ph.D.
Senior Microbiologist, OPS/NDMS
- C. CC Block**
N/A

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/s/

DENISE A MILLER
10/24/2014

NEAL J SWEENEY
10/24/2014
I concur.

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 206-814 **Applicant:** PharmaMed Inc. **Letter Date:** 27 February 2014

Drug Name: Potassium chloride NDA Type: 505 (b)(2) **Stamp Date:** 27 February 2014
 Oral Solution, USP, 20 mEq per
 15 mL and 40 mEq per 15 mL

The following are necessary to initiate a review of the NDA application:

	Content Parameter	Yes	No	Comments
1	Is the product quality microbiology information described in the NDA and organized in a manner to allow substantive review to begin? Is it legible, indexed, and/or paginated adequately?	√		e-CTD format
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	√		
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	NA		Non-sterile product.
4	Are any study reports or published articles in a foreign language? If yes, has the translated version been included in the submission for review?		√	
5	Has the applicant submitted antimicrobial effectiveness testing (if applicable) and container-closure integrity studies?	√		AET: See additional comment #2. CCI: NA
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	√		Microbial limit per USP <61> and <62>  (b) (4)
7	Has the applicant submitted the results of analytical method verification studies?	√		Microbial Limit method suitability was submitted.
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?	NA		
9	If sterile, are extended post-constitution and/or post-dilution hold time in the draft labeling supported by microbiological data?	NA		
10	Is this NDA fileable? If not, then describe why.	√		

Additional Comments:

- 1) This an a non-sterile oral solution
- 2) A very brief summary of the Antimicrobial Effectiveness Testing (AET) was provided and it does not provide sufficient detail to allow a review. The complete report should be requested in the 74 day letter.

Denise A. Miller
Microbiologist, NDMS

Bryan S. Riley, Ph. D.
Senior Microbiologist, NDMS

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/s/

DENISE A MILLER
03/28/2014

BRYAN S RILEY
03/28/2014
I concur.