

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208019Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

MEMORANDUM



DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 05 March 2015

TO: NDA 208019

FROM: Erika Pfeiler, Ph.D.
Microbiologist
CDER/OPQ/OPF/DMA

THROUGH: Stephen Langille, Ph.D.
Branch Chief (Acting)
CDER/OPQ/OPF/DMA

cc: Yvonne Knight
Regulatory Health Project Manager
CDER/OPS/ONDQA

SUBJECT: Product Quality Microbiology assessment of Microbial Limits for Potassium Chloride Powder for Oral Solution, 20 mEq [Submission Date: 24 October 2014]

The Microbial Limits specification for Potassium Chloride Powder for Oral Solution is acceptable from a Product Quality Microbiology perspective. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.

This product is a nonsterile powder intended for reconstitution immediately prior to oral administration.

The drug product is tested for Microbial Limits at release using a method consistent with USP Chapter <61> (Microbiological Examination of Non-sterile Products: Microbial Enumeration Tests) and <62> (Microbiological Examination of Non-sterile Products: Tests for Specified Microorganisms). The Microbial Limits acceptance criteria are consistent with USP Chapter <1111> (Microbiological Examination of Non-sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use).

The drug product will also be tested for Microbial Limits annually as part of the post-approval stability protocol.

MEMORANDUM

ADEQUATE

Reviewer Comments – No statement of method suitability for USP <61> and USP <62> was provided in the application. However, the formulation of the product does not contain ingredients that are inhibitory to microbial growth, nor would the resulting concentrations in the test medium be inhibitory to growth. Therefore, information pertaining to method suitability was not requested. The microbiological quality of the drug product is controlled via a suitable testing protocol.

END

74-day letter information request

You have proposed

(b) (4)

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If you cannot provide this information, you should plan to minimally perform microbial limits testing for product release.

05 February 2015 Response

The applicant stated that microbial limits testing will be adopted for product release and stability. A revised release specification was provided, as well as a revised stability testing schedule.

MEMORANDUM

Erika A. Pfeiler -S

Digitally signed by Erika A. Pfeiler -S
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Date: 2015.03.05 09:19:10 -05'00'

Stephen E. Langille -A

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Langille -A
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