

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205649Orig1s000

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: 4 November 2013

TO: NDA 205649

FROM: Bryan S. Riley, Ph.D.
Team Leader (Acting)
OPS/New Drug Microbiology Staff

THROUGH: Stephen E. Langille, Ph.D.
Master Review Microbiologist
OPS/New Drug Microbiology Staff

cc: Elizabeth R. Chen
Regulatory Project Manager
OND/DMEP

SUBJECT: Product Quality Microbiology assessment of Microbial Limits for
Dapagliflozin/Metformin XR Fixed Dose Combination Tablet
[Submission Date: 29 October 2013]

The Microbial Limits specification for Dapagliflozin/Metformin XR Fixed Dose Combination Tablet is acceptable from a Product Quality Microbiology perspective. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.

Dapagliflozin/Metformin XR Fixed Dose Combination is a Tablet for 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).

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Table 1 – Microbial Limits Specifications

Test	Acceptance Criteria
Total Aerobic Microbial Count (USP <61>)	NMT ^{(b) (4)} CFU/g
Total Yeast and Mold Count (USP <61>)	NMT ^{(b) (4)} CFU/g
<i>E. coli</i> (USP <62>)	Absent in 1 g

The Microbial Limits test methods were verified to be appropriate for use with the drug product following procedures consistent with those in USP Chapter <61> and <62>.

ADEQUATE

Reviewer Comments – The microbiological quality of the drug product is controlled via a suitable testing protocol.

END

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/s/

BRYAN S RILEY
11/04/2013

STEPHEN E LANGILLE
11/04/2013