

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205060Orig1s000

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: 19 July 2013

TO: NDA 205060

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

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

cc: Kati Johnson
Senior Regulatory Project Manager
OND/DMEP

SUBJECT: Product Quality Microbiology assessment of Microbial Limits for Epanova™ Capsules [Submission Date: 3 July 2013]

The Microbial Limits specification for Epanova Capsules is acceptable from a Product Quality Microbiology perspective. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.

Epanova™ is a Capsule” 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).

MEMORANDUM

Table 1 – Microbial Limits Specification

Test	Acceptance Criteria	Method
Total Aerobic Microbial Count	NMT (b) (4) CFU/g	HMR/2K/M57 (EP 2.6.12)
Total Yeast and Mold Count	NMT (b) (4) CFU/g	
<i>E. coli</i>	Absent (b) (4)g	HMR/2K/M58 (EP 2.6.13)
<i>Salmonella</i>	Absent/ (b) (4)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>.

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

ADEQUATE

Reviewer Comments – The microbiological quality of the drug product is controlled via a suitable testing protocol. The test methods used are the microbial limits chapters in the European Pharmacopeia which have been harmonized with USP Chapters <61> and <62>.

END

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/s/

BRYAN S RILEY
07/19/2013

STEPHEN E LANGILLE
07/19/2013