

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205353Orig1s000

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: 29 May 2014

TO: NDA 205353

FROM: Erika Pfeiler, Ph.D.
Microbiologist
CDER/OPS/NDMS

THROUGH: John Metcalfe, Ph.D.
Senior Review Microbiologist
CDER/OPS/NDMS

cc: Diane Hanner
Senior Program Manager
CDER/OND/OHOP/DHP

SUBJECT: Product Quality Microbiology assessment of Microbial Limits for FARYDAK® (proposed) [Submission Date: 22 March 2014]

The microbial limits specification for FARYDAK® (proposed) is acceptable from a Product Quality Microbiology perspective and is recommended for approval from the standpoint of product quality microbiology.

FARYDAK® (proposed) is a capsule for oral administration with 10 mg, 15 mg, and 20 mg presentations.

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). Recommended acceptance criteria in USP <1111> for product of this type include a total aerobic microbial count of 10^3 CFU/g, a total yeast and mold count of 10^2 CFU/g, and the absence of *Escherichia coli* per gram.

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>.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ERIKA A PFEILER
05/29/2014

JOHN W METCALFE
05/29/2014
I concur.