

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205750Orig1s000

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: 3 December 2013

TO: NDA 205750

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: Anissa Davis-Williams, RN, B.S.N., M.P.H., C.P.H.M.
Senior Regulatory Project Manager
OND/DGIEP

SUBJECT: Product Quality Microbiology assessment of Microbial Limits for Cholic Acid Capsules (50 mg and 250 mg) [Submission Date: 21 November 2013]

The Microbial Limits specification for Cholic Acid Capsules (50 mg and 250 mg) is acceptable from a Product Quality Microbiology perspective. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.

The drug product 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 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 ^{(b) (4)}
<i>Salmonella</i> sp. (USP <62>)	Absent in ^{(b) (4)}

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.

END

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/s/

BRYAN S RILEY
12/04/2013

STEPHEN E LANGILLE
12/04/2013