CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206439Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

M E M O R A N D U M

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

DATE: 13 May 2014

TO: NDA 206439

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

THROUGH: John W. Metcalfe, Ph.D.
Senior Review Microbiologist
OPS/New Drug Microbiology Staff

cc: Teresa A. Wheelous, R.Ph.
Senior Regulatory Project Manager
OND/DNP

SUBJECT: Product Quality Microbiology assessment of Microbial Limits for NAMZARIC (memantine HCl extended release/donepezil HCl capsules) [Submission Date: 26 February 2014]

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

NAMZARIC 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).

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Table 1 – Microbial Limits Specifications

Test	Acceptance Criteria
Total Aerobic Microbial Count (USP <61>)	NMT (b) (4)
Total Yeast and Mold Count (USP <61>)	NMT (b) (4)
E. coli (USP <62>)	Absent in

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
05/16/2014

JOHN W METCALFE
05/16/2014
I concur.