CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206439Orig1s000

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: 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

Teresa A. Wheelous, R.Ph. cc:

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).



MEMORANDUM

Table 1 - Microbial Limits Specifications

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

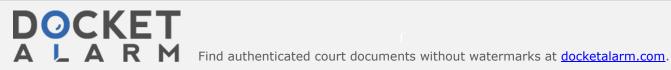
ADEQUATE

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.