CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205718Orig1s000

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: October 2, 2013

TO: NDA 205718

FROM: John W. Metcalfe, Ph.D.
Senior Microbiology Reviewer
CDER/OPS/NDMS

THROUGH: Stephen E. Langille, Ph.D.
Senior Microbiology Reviewer
CDER/OPS/NDMS

cc: Mary Chung, PharmD.
Regulatory Health Project Manager
CDER/OND/ODEIII/DGIEP

SUBJECT: Product Quality Microbiology assessment of Microbial Limits for NDA 205718 [Submission Date: 26 September 2013]

The Microbial Limits specification for Netupitant and Palonosetron (Fixed Dose Combination Capsule) is acceptable from a Product Quality Microbiology perspective. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.

Netupitant and Palonosetron (Fixed Dose Combination Capsule) is a Tablet/Capsule combination 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). The Microbial Limits acceptance criteria are provided in table 1.

M E M O R A N D U M

Table 1. Microbial Limits Tests and Acceptance Criteria

Test	Method	Acceptance Criteria
Total Aerobic Microbial Count	USP<61>	(b) (4)
Total Combined Yeasts/Molds Count	USP<61>	
Escherichia coli	USP<62>	

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

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

/s/

JOHN W METCALFE
10/02/2013

STEPHEN E LANGILLE
10/02/2013