

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205677Orig1s000

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: 6 June 2013

TO: NDA 205677

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

THROUGH: Stephen E. Langille, Ph.D.
Senior Review Microbiologist
OPS/New Drug Microbiology Staff

cc: Cathleen Michaloski, BSN, MPH
Sr. Regulatory Project Manager
OND/DNP

SUBJECT: Product Quality Microbiology assessment of Microbial Limits for
Tasimelteon 20-mg capsules [Submission Date: 31 May 2013]

The Microbial Limits specification for Tasimelteon 20-mg capsules 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 hard gelatin 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 Specification

Test	Method	Acceptance Criteria
Total Aerobic Microbial Count	USP <61>	NMT (b) (4)
Total Combined Yeast and Mold Count	USP <61>	NMT (b) (4)
<i>Escherichia coli</i>	USP <62>	Not detected in (b) (4)
<i>Salmonella</i> species	USP <62>	Not detected in (b) (4)
<i>Pseudomonas aeruginosa</i>	USP <62>	Not detected in (b) (4)
<i>Staphylococcus aureus</i>	USP <62>	Not detected 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
06/06/2013

STEPHEN E LANGILLE
06/06/2013