

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

207917Orig1s000

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: 27 October 2014

TO: NDA 207917

FROM: Erika Pfeiler, Ph.D.
Microbiologist
CDER/OPS/NDMS

THROUGH: Stephen Langille
Senior Review Microbiologist
CDER/OPS/NDMS

cc: Belainesh Robnett
Consumer Safety Officer
CDER/OND/ODEIII/DDDP

SUBJECT: Product Quality Microbiology assessment of Microbial Limits for
Adapalene and Benzoyl Peroxide Gel, 0.3%/2.5% [Submission Date:
17 SEP 2014]

The microbial limits specification for Adapalene and Benzoyl Peroxide Gel, 0.3%/2.5% is acceptable from a Product Quality Microbiology perspective. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.

Adapalene and Benzoyl Peroxide Gel, 0.3%/2.5% is a gel for cutaneous use. This is a multi-use product.

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). These limits include a total aerobic microbial count of NMT (b) (4) CFU/g, total yeast and mold count of NMT (b) (4) CFU/g, and the absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa* per gram. The specification also states that bile tolerant gram-negative bacteria should be absent per gram.

The product was tested for antimicrobial effectiveness on registration batches using methods

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described in USP <51> (Antimicrobial Effectiveness Testing), and results were found to be in agreement with those listed for Category 2 products.

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 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/

ERIKA A PFEILER
10/27/2014

STEPHEN E LANGILLE
10/27/2014