

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205613Orig1s000

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: December 2, 2013

TO: NDA 205613

FROM: Vinayak B. Pawar, Ph.D., Senior Review Microbiologist, NDMS, OPS.

THROUGH: John W. Metcalfe, Ph.D., Senior Review Microbiologist, NDMS, OPS.

cc: Kevin B. Bugin, Regulatory Project Manager, CDER/ODEIII/DGIEP

SUBJECT: Product Quality Microbiology assessment of Microbial Limits for
“Budesonide 2 mg Rectal Foam”- Submission Date: November 15, 2013.

The Microbial Limits specification for “Budesonide 2 mg Rectal Foam” is acceptable from a Product Quality Microbiology perspective. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.

Budesonide 2 mg Rectal Foam is a Foam formulation in a Metered-Dose Canister for rectal administration. The NDA was submitted by Salix Pharmaceuticals, Raleigh, NC.

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). 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 test methods were verified [Report METH-VALRPT-32] to be appropriate for use with the drug product following procedures consistent with those in USP Chapter <61> i.e. Total Aerobic Microbial Count at NMT (b) (4) CFU/g & Total Combined Yeasts and Molds Count NMT (b) (4) CFU/g. Since the drug product is for rectal use, the product will not be tested for specified organisms per USP <62>.

As described in Section 2.3.P.2.5, the original drug product developed and commercialized in Europe contained (b) (4) (b) (4)

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(b) (4)

Therefore the proposed final commercial formulation to be commercialized in United States will contain all ingredients except (b) (4).

The drug product will also be tested for Microbial Limits per USP <61> 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. All of the NDA registration batches of Budesonide 2 mg Rectal Foam met USP requirements for microbial limits at all time points tested under both storage conditions and orientations (Section 3.2.P.8.3).*

END

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/s/

VINAYAK B PAWAR
12/03/2013

JOHN W METCALFE
12/03/2013
I concur.