

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**205382Orig1s000**

**MICROBIOLOGY / VIROLOGY REVIEW(S)**

MEMORANDUM



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

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**DATE:** 5 June 2013

**TO:** NDA 205382

**FROM:** Stephen E. Langille, Ph.D.  
Senior Microbiology Reviewer  
NDMS/OPS

**THROUGH:** John Metcalfe  
Senior Microbiology Reviewer  
NDMS/OPS

**cc:** Angela H. Ramsey  
Regulatory Project Manager  
CDER/ODEII/DPARP

**SUBJECT:** Product Quality Microbiology assessment of Microbial Limits for  
(b) (4) TM/Elipta™ (umeclidinium) [Submission Date: 30 April 2013]

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**The Microbial Limits specification for (b) (4) TM/Elipta™ (umeclidinium) is acceptable from a Product Quality Microbiology perspective. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.**

(b) (4) TM/Elipta™ (umeclidinium) is a dry powder for oral inhalation.

The drug product is tested for Microbial Limits 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 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 (b) (4) as part of the post-approval stability protocol.

# MEMORANDUM

## ADEQUATE

**Reviewer Comments – The microbiological quality of the drug product is controlled via a suitable testing protocol.**

### **Additional Information:**

The drug product is tested for Microbial Limits at release using a two tiered test method identical to that used for a similar product (NDA 203-975). The applicant proposes the use of in-process control testing, consistent with quality by design principles. (b) (4)

(b) (4)

(b) (4) testing is not conducted as part of the in-process test regimen. This is acceptable because the two excipients most likely to contribute to the (b) (4) of the finished product are subjected to (b) (4) testing as part of the in-process control test.

Alternatively, (b) (4) approach was provided in section P.2.5 of the application and has been reproduced in figures 1 and 2 below.

**MEMORANDUM**

(b) (4)



**MEMORANDUM**

(b) (4)



**END**

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/s/  
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STEPHEN E LANGILLE  
06/06/2013

JOHN W METCALFE  
06/06/2013  
I concur.