

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**205266Orig1s000**

**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:** 12 March 2015

**TO:** NDA 205266

**FROM:** Stephen E. Langille, Ph.D.  
Acting Branch Chief, DMA Branch 3  
CDER/OPS/NDMS

**THROUGH:** Bryan Riley, Ph.D.  
Acting Branch Chief, DMA Branch 2  
CDER/OPS/NDMS

**cc:** Anuja Patel  
Regulatory Project Manager  
OMPT/CDER/OND/OHOP/DOPII

**SUBJECT:** Product Quality Microbiology assessment of microbial limits for ODOMZO® (Sonidegib) capsules [Submission Date: 26 September 2014]

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**The microbial limits specification for ODOMZO® (Sonidegib) capsules is acceptable from a Product Quality Microbiology perspective. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.**

ODOMZO® is a 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).

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 microbial limits specification is provided in the table below:

## MEMORANDUM

Test	Limit	Test Methodology
Total Aerobic Microbial Count	NMT $10^3$ CFU/g	USP <61>
Total Yeasts and Molds Count	NMT $10^2$ CFU/g	USP <61>
<i>Escherichia coli</i>	Absence in 1g	USP <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/  
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STEPHEN E LANGILLE  
03/12/2015

BRYAN S RILEY  
03/12/2015  
I concur.