

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205858Orig1s000

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: 02 January 2014

TO: NDA 205858
NDA 206545 (references NDA 205858 for all CMC information)

FROM: Jessica G. Cole, PhD
Review Microbiologist
CDER/OPS/New Drug Microbiology Staff

THROUGH: Bryan Riley, PhD
Microbiology Team Leader
CDER/OPS/New Drug Microbiology Staff

cc: Mara Bauman Miller
Regulatory Health Project Manager
CDER/OND/OHOP/DHP

SUBJECT: Product Quality Microbiology assessment of Microbial Limits for
Idelalisib [Submission Date: 11 September 2013]

The Microbial Limits specification for Idelalisib is acceptable from a Product Quality Microbiology perspective. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.

Idelalisib is a coated tablet for oral administration. The tablets are provided in a 100 mg and 150 mg strength and are intended for treatment of refractory non-Hodgkin lymphoma.

The manufacturing process consists of a [REDACTED] (b) (4)

[REDACTED]

The applicant conducted microbial limits testing on all drug product lots during development. On-going stability studies include microbial limits testing at 6, 12, and 24 months. All stability and release results demonstrated [REDACTED] (b) (4)

[REDACTED]

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/s/

JESSICA COLE
01/02/2014

BRYAN S RILEY
01/02/2014
I concur.

PRODUCT QUALITY MICROBIOLOGY NON-STERILE DRUG PRODUCT FILING CHECKLIST

NDA Number: 205-858 **Applicant:** Gilead Sciences **Letter Date:** 11 September 2013
Drug Name: Idelalisib **NDA Type:** NME NDA **Stamp Date:** 11 September 2013
Dosage Form: Oral tablet **Reviewer:** Jessica Cole, PhD

The following are necessary to initiate a review of the NDA application:

	Content Parameter	Yes	No	Comments
1	Is the product quality microbiology information described in the NDA and organized in a manner to allow substantive review to begin? Is it legible, indexed, and/or paginated adequately?	X		
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		
3	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?		X	No microbiological specification is proposed but a justification was provided
4	Has the applicant submitted the results of analytical method verification studies?		X	No test methods are proposed
5	Has the applicant submitted preservative effectiveness studies (if applicable)?	X		USP<51> testing was conducted but this is a solid tablet, which are not included in the compendial test methods.
6	Is this NDA fileable? If not, then describe why.	X		This NDA is fileable but an information request is included below.

Product Quality Microbiology Information Request:

1. You propose

(b) (4)

(b) (4)



Jessica Cole, PhD
Reviewing Microbiologist

23 September 2013
Date

Bryan Riley, PhD
Microbiology Team Leader

Date

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/s/

JESSICA COLE
09/25/2013

BRYAN S RILEY
09/25/2013
I concur.