

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

202611Orig1s000

MICROBIOLOGY REVIEW(S)



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

DATE: 9 March 2012
TO: NDA 202611 (in DARRTS)
FROM: Bryan S. Riley, Ph.D., Acting Team Leader (OPS/NDMS)
THROUGH: John W. Metcalfe, Ph.D., Senior Review Microbiologist (OPS/NDMS)
CC: Nenita Crisostomo, RN, Regulatory Health Project Manager (OND/DRUP)
SUBJECT: NDA 202611 amendment dated 6 March 2012 (Review #2 of NDA)

The following product quality microbiology deficiency (identified in the Product Quality Microbiology review dated 1 February 2012) was provided to the applicant on 29 February 2012:

The proposal to [REDACTED] ^{(b) (4)} for Microbial Limits is unacceptable because it does not comply with 21 CFR 211.165(a) and (b). As an alternative [REDACTED] ^{(b) (4)}, you may propose to omit finished product microbial limits testing for batch release. In addition, microbial limits testing should be performed at the initial time point (at a minimum) on stability samples.

The applicant responded in the subject amendment by stating that they would remove microbial limits testing from the drug product release specification and would perform microbial limits testing on stability samples at the initial and final time points.

Microbiology Reviewer Comment: The applicant's response to the deficiency is acceptable and the NDA is now recommended for approval on the basis of product quality microbiology.

END

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/s/

BRYAN S RILEY
03/09/2012

JOHN W METCALFE
03/09/2012
I concur.

Product Quality Microbiology Review

1 FEBRUARY 2012

NDA: 202611/N-000

Drug Product Name

Proprietary: N/A

Non-proprietary: Mirabegron Tablet

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
26 August 2011	29 August 2011	2 December 2011	7 December 2011

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Astellas Pharma US, Inc

Address: Three Parkway North Deerfield, IL 60015-2548

Representative: Judy Kannenberg, Associate Director, Regulatory Affairs

Telephone: (847) 317-1277

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Approvable pending resolution of Product Quality Microbiology Deficiencies. (Please see List of Microbiology Deficiencies on page 7 of this review)

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** 505(b)(1) NDA
 2. **SUBMISSION PROVIDES FOR:** A new drug product
 3. **MANUFACTURING SITE:** Astellas Pharma Technologies Inc.
3300 Marshall Avenue
Norman, OK 73072
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Coated Tablet, 25 or 50 mg
 5. **METHOD(S) OF STERILIZATION:** N/A
 6. **PHARMACOLOGICAL CATEGORY:** Treatment of Overactive Bladder
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** This was an eCTD submission.

filename: N202611R1.doc

Executive Summary

I. Recommendations

- A. Recommendation on Approvability** – This submission is approvable pending resolution of Product Quality Microbiology Deficiencies. (Please see List of Microbiology Deficiencies on page 7 of this review).
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – N/A

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – The drug product is a non-sterile tablet.
- B. Brief Description of Microbiology Deficiencies** – The applicant is proposing to test for Microbial Limits (b) (4) is unacceptable because it does not comply with 21 CFR 211.165(a) and (b).
- C. Assessment of Risk Due to Microbiology Deficiencies** – There is minimal risk due to the Microbiology Deficiency.

III. Administrative

- A. Reviewer's Signature** _____
Bryan S. Riley, Ph.D.
Senior Review Microbiologist, OPS/NDMS
- B. Endorsement Block** _____
John W. Metcalfe, Ph.D.
Senior Review Microbiologist, OPS/NDMS
- C. CC Block**
N/A

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/s/

BRYAN S RILEY
02/02/2012

JOHN W METCALFE
02/02/2012
I concur.