

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

203985Orig1s000

MICROBIOLOGY REVIEW(S)

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 203985

Applicant: Novartis
Pharmaceuticals Corp.

Letter Date: 2/29/2012

Drug Name: Afinitor
zDISPERZ

NDA Type: 505(b)(1)

Stamp Date: 2/29/2012

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		3.2.P.3.3
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	X		(b) (4)
4	Are any study reports or published articles in a foreign language? If yes, has the translated version been included in the submission for review?		X	
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?			N/A
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		3.2.P.3.4: control-critical-steps.pdf
7	Has the applicant submitted the results of analytical method verification studies?	X		(b) (4)
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?			N/A
9	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: None

Steven P. Donald, M.S.

3/22/2012

Reviewing Microbiologist

Date

Stephen E. Langille, Ph.D.

3/22/2012

Microbiology Secondary Reviewer/Team Leader

Date

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/s/

STEVEN P DONALD
03/23/2012

STEPHEN E LANGILLE
03/23/2012

Product Quality Microbiology Review

3/20/2012

NDA: 203985

Drug Product Name

Proprietary: Afinitor zDISPERZ

Non-proprietary: everolimus

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
2/29/2012	2/29/2012	3/12/2012	3/14/2012

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Novartis Pharmaceuticals Corporation

Address: One Health Plaza, East Hanover, New Jersey 07936-1080

Representative: Yanina Gutman, Drug Regulatory Affairs

Telephone: 862 778 1767

Name of Reviewer: Steven P. Donald, M.S.

Conclusion: Recommended for approval

Product Quality Microbiology Data Sheet

- A.**
- 1. TYPE OF SUBMISSION:** Original NDA
 - 2. SUBMISSION PROVIDES FOR:** The manufacture of an oral drug product
 - 3. MANUFACTURING SITE:**
Novartis Pharma AG, Lichtstrasse 35, CH-4056 Basel, Switzerland, and
Novartis Pharma Stein AG, Schaffhauserstrasse, CH-4332 Stein,
Switzerland
 - 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Tablet, oral, 2 mg, 3 mg and 5 mg dispersible tablets in ^{(b) (4)} blister packs.
 - 5. METHOD(S) OF STERILIZATION:** Non sterile product
 - 6. PHARMACOLOGICAL CATEGORY:** Antineoplastic
- B. SUPPORTING/RELATED DOCUMENTS:** None
- C. REMARKS:** eCTD format; new age appropriate formulation for pediatric patients; pediatric exclusivity determination request.

filename: ^{(b) (4)}

Executive Summary

I. Recommendations

- A. Recommendation on Approvability -**
NDA 203985 is recommended for approval from the standpoint of product quality microbiology.
- 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 substance will be (b) (4)
- B. Brief Description of Microbiology Deficiencies –** No product quality microbiology deficiencies were identified based upon the information provided.
- C. Assessment of Risk Due to Microbiology Deficiencies – N/A**

III. Administrative

- A. Reviewer's Signature** _____
Steven P. Donald, M.S.
- B. Endorsement Block** _____
Stephen E. Langille, Ph.D.
Senior Microbiology Reviewer
- C. CC Block**
N/A

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/s/

STEVEN P DONALD
03/21/2012

STEPHEN E LANGILLE
03/22/2012