

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

206255Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

Product Quality Microbiology Review

March 06, 2014

NDA: 206255

Drug Product Name

Proprietary: Ivermectin 1% Cream

Non-proprietary: N/A

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
December 20, 2013	December 20, 2013	January 22, 2014	January 23, 2014

Submission History (for 2nd Reviews or higher) - N/A

Applicant/Sponsor

Name: Galderma Research & Development

Address: 5 Cedar Brook Drive, Cranbury, New Jersey
08512

Representative: Elaine Clark, Sr. Director, US Regulatory
Submissions

Telephone: 817-961-5492

Name of Reviewer: Vinayak B. Pawar, Ph.D.

Conclusion: Recommend Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA
 2. **SUBMISSION PROVIDES FOR:** An anti-inflammatory drug substance in a topical cream vehicle.
 3. **MANUFACTURING SITE:** G PRODUCTION Inc.
19400 Route Transcanadienne
Baie d'Urfé, Québec, Canada H9X 3S4
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Ivermectin 1% cream containing 1% w/w (10mg/g) of ivermectin packaged in laminated tube. Proposed tube sizes for registration are 30g, 45g and 60g.
 5. **METHOD(S) OF STERILIZATION:** Non Sterile Drug Product
 6. **PHARMACOLOGICAL CATEGORY:** Topical treatment of inflammatory lesions of rosacea.
- B. **SUPPORTING/RELATED DOCUMENTS:** None
- C. **REMARKS:** This is an original NDA for a non-sterile drug product for the topical treatment of inflammatory lesions of rosacea. This is an electronic submission.

filename: N206255R1

Executive Summary**I. Recommendations**

- A. **Recommendation on Approvability** - Recommend Approval.
- 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** – This non-sterile drug product contains (b) (4)
- B. **Brief Description of Microbiology Deficiencies** - None
- C. **Assessment of Risk Due to Microbiology Deficiencies** – N/A
- D. **Contains Potential Precedent Decision(s)** - Yes No

III. Administrative

- A. **Reviewer's Signature** _____
Vinayak B. Pawar, Ph.D., Sr. Review Microbiologist, OPS/CDER
- B. **Endorsement Block** _____
John W. Metcalfe, Ph.D., Sr. Review Microbiologist, OPS/CDER
- C. **CC Block**
N/A

7 Page(s) has been Withheld in Full as b4 (CCI/TS) immediately following this page

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/s/

VINAYAK B PAWAR
03/07/2014

JOHN W METCALFE
03/07/2014
I concur.

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 206255 **Applicant:** Galderma Research & Development **Letter Date:** 12/20/2013

Drug Name: Ivermectin 1% Cream **NDA Type:** Original **Stamp Date:** 12/20/2013

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		Non-sterile drug product, Section 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		Non-sterile drug product.
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	N/A
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?	X		(b) (4)
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		Microbial Limits [USP <61>,<62>], Method: 1BD.05.MET.8015, Section 3.2.P.5.1
7	Has the applicant submitted the results of analytical method verification studies?	X		Microbial Limits Test & APE Test, Section 3.2.P.8.3
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?		X	N/A
9	If sterile, are extended post-constitution and/or post-dilution hold times in the draft labeling supported by microbiological data?		X	N/A
10	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: The non-sterile drug product is (b) (4)

Vinayak B. Pawar, Ph.D., Sr. Review Microbiologist, Primary Reviewer

Date

John W. Metcalfe, Ph.D., Sr. Review Microbiologist, Secondary reviewer

Date

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/s/

VINAYAK B PAWAR
01/31/2014

JOHN W METCALFE
01/31/2014
I concur.