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RESEARCH**

APPLICATION NUMBER:

204592Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

Product Quality Microbiology Review

4/04/2013

NDA: 204592

Drug Product Name

Proprietary: Zorvolex Capsules

Non-proprietary: diclofenac acid

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
12/20/2012	12/20/2013	3/19/2013	3/21/2013

Submission History (for 2nd Reviews or higher)

None

Applicant/Sponsor

Name: Iroko Pharmaceuticals, LLC

Address: 150 Rouse Blvd., Philadelphia, PA 19112

Representative: Michelle Wilson, 100 Springhouse Dr. Suite 205,
Collegeville, PA 19426

Telephone: 513 829-1108

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:** Manufacture and marketing of an oral drug product
3. **MANUFACTURING SITE:** [REDACTED] (b) (4)
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Capsules, Oral, 18 mg and 35 mg
5. **METHOD(S) OF STERILIZATION:** N/A
6. **PHARMACOLOGICAL CATEGORY:** Analgesic
- B. **SUPPORTING/RELATED DOCUMENTS:** None
- C. **REMARKS:** The sponsor is requesting the elimination of bioburden and specified microorganism testing for product release and approval of the stability protocol.

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Executive Summary**I. Recommendations**

- A. **Recommendation on Approvability** - Recommended for 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** - The drug product is manufactured using [REDACTED] (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
- D. **Contains Potential Precedent Decision(s)**- Yes No

III. Administrative

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

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

STEVEN P DONALD
04/05/2013

STEPHEN E LANGILLE
04/08/2013