

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-862

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

Consult review for HFD-550

9 June, 2005

Drug Product Name

Proprietary: Nevanac 0.1% Suspension
Non-proprietary: nepafenac ophthalmic suspension
Drug Product Priority Classification: IP

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
February 25, 2005	March 2, 2005	March 4, 2005	March 8, 2005

Submission History (for amendments only)

Submission Date(s)	Microbiology Review #	Review Date(s)
NA	NA	NA

Applicant/Sponsor

Name: Alcon Research, Inc.
Address: 6201 S Freeway, Fort Worth, TX
Representative: Angela C. Kothe
Telephone: 817-551-4933

Name of Reviewer: Vinayak Pawar

Conclusion: The application is recommended for approval from microbiology product quality standpoint.

Product Quality Microbiology Data Sheet

- A.
1. TYPE OF SUBMISSION: NDA
 2. SUBMISSION PROVIDES FOR: New Ophthalmic Drug product
 3. MANUFACTURING SITE: Fort Worth, TX
 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Ophthalmic drops.
 5. METHOD(S) OF STERILIZATION: —
 6. PHARMACOLOGICAL CATEGORY: Ophthalmic non-steroid anti-inflammatory suspension.
- B. SUPPORTING/RELATED DOCUMENTS: None
- C. REMARKS: The consult requests review of NDA 21-862 for the drug product Nevanac an ophthalmic suspension for the — pain and inflammation — cataract surgery. Nine volumes of module 2 and five volumes of module 3 were submitted for review.

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Executive Summary

I. Recommendations

- A. **Recommendation on Approvability** – Based on product quality microbiology review the application is recommended for approval.
- B. **Recommendation on Phase 4 Commitments and/or Agreements, if Approvable** - None

II. Summary of Microbiology Assessments

- A. **Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** . _____
- B. **Brief Description of Microbiology Deficiencies** - None
- C. **Assessment of Risk Due to Microbiology Deficiencies**- None

III. Administrative

- A. **Reviewer's Signature** _____
Vinayak Pawar, Ph.D.
- B. **Endorsement Block** _____
Bryan S. Riley, Ph.D.
- C. **CC Block**
cc:
Original NDA 21-862
HFD-550/Division File/Raphael Rodriguez

7 Page(s) Withheld

§ 552(b)(4) Trade Secret / Confidential

§ 552(b)(5) Deliberative Process

§ 552(b)(5) Draft Labeling

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

/s/

Vinayak Pawar
6/20/05 11:29:45 AM
MICROBIOLOGIST

Recommended for approval from microbiology product quality standpoint

Bryan Riley
6/20/05 11:37:17 AM
MICROBIOLOGIST