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RESEARCH**

*APPLICATION NUMBER:*

**22-193**

**MICROBIOLOGY REVIEW(S)**

# Product Quality Microbiology Review

1 July 2008

**NDA:** 22-193

**Drug Product Name**

**Proprietary:** NGOIS

**Non-proprietary:** next generation ophthalmic irrigation solution.

**Drug Product Priority Classification:** S1

**Review Number:** 1

**Dates of Submission(s) Covered by this Review**

Letter	Stamp	Review Request	Assigned to Reviewer
September 21, 2007	September 24, 2007	October 09, 2007	October 11, 2007

**Submission History (for amendments only) – N/A**

**Applicant/Sponsor**

**Name:** Alcon Research. Ltd.

**Address:** 6201 South Freeway, Fortworth, Texas 76134

**Representative:** Sarah C. Cantrell, Asst. Director, Reg. Affairs

**Telephone:** 817-551-4517, FAX: 817-551-4630

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

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

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## Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA
  2. **SUBMISSION PROVIDES FOR:** A New Generation Ophthalmic Irrigation Solution [NGOIS].
  3. **MANUFACTURING SITE:**  
Both Products *NGOIS Part I & NGOIS Part II* will be manufactured at Alcon Manufacturing LTD., Fort Worth, Texas 76134.
  4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** NGOIS Part I (240 or 480 mL) and Part II (20 or 10 mL) are mixed aseptically prior to use for irrigation during surgical procedure.
  5. **METHOD(S) OF STERILIZATION:** NGOIS Part I - sterilized, NGOIS Part II - filled.
  6. **PHARMACOLOGICAL CATEGORY:** Ophthalmic irrigation solution used during surgical procedures.
- B. **SUPPORTING/RELATED DOCUMENTS:** None
- C. **REMARKS:** The consult requests review of a rolling NDA 22-193 for the Next Generation Ophthalmic Irrigation Solution (NGOIS). The application was submitted in nine volumes. Initial Quality Assessment was filed by Linda NG on December 26, 2007.

**filename:** C:\my documents\review\NDA\N022193R1

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## Executive Summary

### I. Recommendations

- A. **Recommendation on Approvability** – Based on the sterility assurance provided by the sponsor, the application is 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 product is manufactured in two parts. Part I is ~~\_\_\_\_\_~~ y sterilized product whereas Part II is \_\_\_\_\_ filled. b(4)
- B. **Brief Description of Microbiology Deficiencies** - None
- C. **Assessment of Risk Due to Microbiology Deficiencies** - Minimal

### III. Administrative

- A. **Reviewer's Signature** \_\_\_\_\_  
Vinayak B. Pawar, Ph.D.
- B. **Endorsement Block** \_\_\_\_\_  
James McVey
- C. **CC Block**  
N/A

10 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

Withheld Track Number: Microbiology-1

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/s/

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Vinayak Pawar  
7/2/2008 03:28:46 PM  
MICROBIOLOGIST

The NDA is recommended for approval from microbiology product  
quality standpoint.

James McVey  
7/2/2008 03:49:21 PM  
MICROBIOLOGIST