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RESEARCH**

*APPLICATION NUMBER:*  
**21-980**

**MICROBIOLOGY REVIEW**

# Product Quality Microbiology Review

## Review for HFD-520

27 February 2005

**NDA:** 21-980

**Drug Product Name**

**Proprietary:** Fluorescite

**Non-proprietary:** Fluorescein injection, USP

**Drug Product Classification:** S1

**Review Number:** 1

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

Letter	Stamp	Consult Sent	Assigned to Reviewer
September 28, 2005	September 29, 2005	October 27, 2005	October 31, 2005

**Submission History (for amendments only)**

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

**Applicant/Sponsor**

**Name:** Alcon Research, Ltd

**Address:** Fort Worth, Texas

**Representative:** Terry J. Dagnon

**Telephone:** 817-551-4325

**Name of Reviewer:** Vinayak B. Pawar

**Conclusion:** The application is recommended for approval from microbiological standpoint.



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**Executive Summary**

**I. Recommendations**

- A. **Recommendation on Approvability** – Based on the sterility assurance provided by the product quality information submitted for review the application is recommended for approval.
- B. **Recommendations on Phase 4 Commitments and/or Agreements, if Approvable - NA**

**II. Summary of Microbiology Assessments**

- A. **Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – The manufacturing process involves \_\_\_\_\_  

- B. **Brief Description of Microbiology Deficiencies - None**
- C. **Assessment of Risk Due to Microbiology Deficiencies - NA**

**III. Administrative**

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

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/s/  
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Vinayak Pawar  
2/28/2006 03:51:08 PM  
MICROBIOLOGIST

The application is recommended for approval from microbiology standpoint.

James McVey  
3/1/2006 08:16:35 AM  
MICROBIOLOGIST

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