

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-545

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

Review for HFD-550

10 September 2002

NDA: 21-545

Drug Product Name

Proprietary: —

Non-proprietary: olopatadine HCl ophthalmic solution 0.2%

Drug Product Classification: Ophthalmic

Review Number: 1

Subject of this Review

Submission Date: 14 August 2002

Receipt Date: 16 August 2002

Consult Date: 21 August 2002

Date Assigned for Review: 29 August 2002

Applicant/Sponsor

Name: Alcon Research, Ltd.

Address: 6201 South Freeway, Fort Worth, TX 76134-2099

Representative: Angela C. Kothe, Ph.D.

Telephone: (817)551-4933

Name of Reviewer: Paul Stinavage

Conclusion: The application is recommended for approval on the basis of sterility assurance.

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUPPLEMENT:** N/A
 2. **SUPPLEMENT PROVIDES FOR:** N/A
 3. **MANUFACTURING SITES:** Fort Worth, TX and Kaysersberg, France
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Ophthalmic
 5. **METHOD(S) OF STERILIZATION:** —
 6. **PHARMACOLOGICAL CATEGORY:** The product is intended for treatment of allergic conjunctivitis.
- B. **SUPPORTING/RELATED DOCUMENTS:**
- C. **REMARKS:** The trade product sizes will be manufactured by:
Alcon Manufacturing, Ltd.
ASPEX (Alcon Sterile Products) Manufacturing Facility
6201 South Freeway
Fort Worth, TX 76134-2099

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Executive Summary**I. Recommendations**

- A. Recommendation on Approvability** – The application is recommended for approval on the basis of sterility assurance.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -**

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

III. Administrative

- A. Reviewer's Signature** _____
- B. Endorsement Block**
 - P. Stinavage
 - P.H. Cooney
- C. CC Block**
 - cc:
 - Original NDA 21-545
 - HFD-550/Division File/NDA 21-545/M. Puglisi/L. Gorski/R. Rodriguez

14 Page(s) Withheld

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

§ 552(b)(4) Draft Labeling

§ 552(b)(5) Deliberative Process

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

/s/

Paul Stinavage
9/19/02 11:09:31 AM
MICROBIOLOGIST

Trade packages manufactured at _____
size manufactured at Kayzersberg, France.

Sample

Peter Cooney
9/19/02 02:49:33 PM
MICROBIOLOGIST