

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-764

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

Review for HFD-550

19 AUGUST 2004

NDA: 21-764

Drug Product Name

Proprietary: N/A

Non-proprietary: Brimonidine Tartrate Ophthalmic Solution

Drug Product Priority Classification: S

Review Number: 1

Subject of this Review

Submission Date: 27 April 2004

Receipt Date: 28 April 2004

Consult Date: 6 May 2004

Date Assigned for Review: 7 May 2004

Submission History (for amendments only)

Date(s) of Previous Submission(s): N/A

Date(s) of Previous Micro Review(s): N/A

Applicant/Sponsor

Name: Alcon Research, Ltd.

Address: 6201 South Freeway, Ft. Worth, TX 76134

Representative: Michael Pfleger

Telephone: 817-551-4877

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommend Approval

Product Quality Microbiology Data Sheet

- A.
1. TYPE OF SUPPLEMENT: N/A
 2. SUPPLEMENT PROVIDES FOR: N/A
 3. MANUFACTURING SITE: _____

 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Sterile Ophthalmic Solution, 0.15% in 8 mL (5mL fill), 10 mL (10 mL fill) or 15 mL (15 mL fill) _____ bottles.
 5. METHOD(S) OF STERILIZATION: _____
 6. PHARMACOLOGICAL CATEGORY: Alpha Adrenergic Agonist
- B. SUPPORTING/RELATED DOCUMENTS: N/A
- C. REMARKS: N/A

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Executive Summary

I. Recommendations

- A. Recommendation on Approvability** – This submission is recommended for approval on the basis of product quality microbiology (please see comment for the applicant on page 9).
- 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 ~~_____~~ and _____
- B. Brief Description of Microbiology Deficiencies** – N/A
- C. Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. Reviewer's Signature** _____
- B. Endorsement Block**
Bryan S. Riley, Ph.D. (Microbiology Reviewer)
Microbiology Supervisor
- C. CC Block**
N/A

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/s/

Bryan Riley
8/26/04 10:53:34 AM
MICROBIOLOGIST

Peter Cooney
8/26/04 11:14:05 AM
MICROBIOLOGIST

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