

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-048/22-223

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

17 September 2007

NDA: 22-048

Drug Product Name

Proprietary:

Triesence

Non-proprietary:

triamcinolone acetonide injectable suspension.

Drug Product Priority Classification: Priority

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
24 MAY 2007	29 MAY 2007	01 OCT 2007	25 JUN 2007

Applicant/Sponsor

Name:

Alcon Hunenberg Switzerland

US Agent

Name:

Alcon Research, Ltd.

Address:

6201 South Freeway
Fort Worth, TX 76134-2099

Representative:

Terry J. Dagnon

Telephone:

817-551-4325

Name of Reviewer:

John W. Metcalfe, Ph.D.

Conclusion:

Recommended for approval.

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA.
 2. **SUBMISSION PROVIDES FOR:** A new drug product.
 3. **MANUFACTURING SITE:**
Alcon Manufacturing, Ltd.
6201 South Freeway
Fort Worth, TX. 76134
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Suspension for injection in - mL glass vial.
 - Intravitreal injection.
 - 40 mg/mL.
 5. **METHOD(S) OF STERILIZATION:** _____
 6. **PHARMACOLOGICAL CATEGORY:** Ophthalmic.
- B. **SUPPORTING/RELATED DOCUMENTS:** None.
- C. **REMARKS:**
The submission is provided in paper (6 white jacket microbiology copies of Module 3 and one green jacket of Module 2).

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Executive Summary**I. Recommendations**

- A. Recommendation on Approvability** – NDA 22-048 is recommended for approval from the standpoint of product quality microbiology.
- 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 bulk drug suspension is filled into glass vials which are closed with rubber stoppers and aluminum seals prior to being placed into blister packages and _____ sterilized _____.
- B. Brief Description of Microbiology Deficiencies** – There are no microbiology deficiencies identified.
- C. Assessment of Risk Due to Microbiology Deficiencies** – Not applicable.

III. Administrative

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

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

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

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/s/

John Metcalfe
9/19/2007 12:34:32 PM
MICROBIOLOGIST

Bryan Riley
9/19/2007 12:50:17 PM
MICROBIOLOGIST

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