

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-571**

**MICROBIOLOGY REVIEW**

**Product Quality Microbiology Review  
Review for HFD-550**

**23 SEPTEMBER 2003**

**NDA: 21-571**

**Drug Product Name**

**Proprietary:**

**Non-proprietary: 1.5% Levofloxacin Ophthalmic Solution**

**Drug Product Priority Classification: S**

**Review Number: 1**

**Subject of this Review**

**Submission Date: 30 April 2003**

**Receipt Date: 1 May 2003**

**Consult Date: 7 May 2003**

**Date Assigned for Review: 30 May 2003**

**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: Santen inc.**

**Address: 555 Gateway Drive, Napa, CA 94558**

**Representative: Jeff Wells, Pharm.D.**

**Telephone: 707-254-1750**

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

**Conclusion: Recommended for Approval**

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## Product Quality Microbiology Data Sheet

- A.
1. TYPE OF SUPPLEMENT: N/A
  2. SUPPLEMENT PROVIDES FOR: N/A
  3. MANUFACTURING SITE: Santen Oy  
Nittyhaankatu 20 PO Box 33  
33720 Tampere  
FINLAND
  4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Sterile Solution in a — plastic bottle with a dropper tip for ophthalmic administration, 1.5%
  5. METHOD(S) OF STERILIZATION: —
  6. PHARMACOLOGICAL CATEGORY: Antimicrobial
- B. SUPPORTING/RELATED DOCUMENTS: NDA 21-199 (QUIXIN, levofloxacin ophthalmic solution, 0.5%)
- C. REMARKS: Approved NDA 21-199 (QUIXIN) uses the same — and container closure as this application. The validation of the — process for this — was contained in NDA 21-199/SCP-003. See Product Quality Microbiology reviews of NDA 21-199/SCP-003 (dated 30 May 2002 and 2 July 2002).

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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.
- 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 \_\_\_\_\_
- B. **Brief Description of Microbiology Deficiencies** – N/A
- C. **Assessment of Risk Due to Microbiology Deficiencies** – The drug product is \_\_\_\_\_ using a validated manufacturing process. Therefore, the drug product presents minimal risk from the standpoint of product quality microbiology.

**III. Administrative**

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

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/s/  
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Bryan Riley  
9/23/03 03:10:44 PM  
MICROBIOLOGIST

Peter Cooney  
9/24/03 09:07:49 AM  
MICROBIOLOGIST

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