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RESEARCH**

*APPLICATION NUMBER:*  
**21-132**

**MICROBIOLOGY REVIEW(S)**

# Product Quality Microbiology Review

2 JULY 2009

**NDA:** 22-427 and amendments

**Drug Product Name**

**Proprietary:** ACUVAIL 0.45% Preservative-Free

**Non-proprietary:** ketorolac tromethamine ophthalmic solution

**Review Number:** 1

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

Letter	Stamp	Review Request	Assigned to Reviewer
29 September 2008	30 September 2008	3 October 2008	7 October 2008
21 November 2008	21 November 2008	N/A	N/A
30 April 2009	1 May 2009	N/A	N/A
17 June 2009	17 June 2009	N/A	N/A

**Submission History (for amendments only):** N/A

**Applicant/Sponsor**

**Name:** Allergan

**Address:** 2525 Dupont Drive, Irvine, CA 92612

**Representative:** Elizabeth Bancroft

**Telephone:** 714-246-4391

**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 SUBMISSION:** Original NDA [505(b)(1)]
  2. **SUBMISSION PROVIDES FOR:** A sterile drug product
  3. **MANUFACTURING SITE:** Allergan, Inc.  
8301 Mars Drive  
Waco, TX
  4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile ophthalmic solution in unit dose (LDPE) (b) (4) vials, 0.4 mL/vial, 0.45%
  5. **METHOD(S) OF STERILIZATION:** (b) (4)
  6. **PHARMACOLOGICAL CATEGORY:** Non-Steroidal Anti-Inflammatory
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** This was an eCTD submission. An information request was sent to the applicant (5 November 2008) requesting validation data for the filling equipment and an endotoxin specification for the drug product. The equipment sterilization validation information and endotoxin specification were provided in amendment 0003 (dated 21 November 2008). Two endotoxin testing facilities were added in amendment 0007 (dated 30 April 2009). An additional endotoxin testing facility was added in amendment 0008 (dated 17 June 2009).

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**Executive Summary****I. Recommendations**

- A. **Recommendation on Approvability** – This submission 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** - (b) (4)  
[Redacted]
- B. **Brief Description of Microbiology Deficiencies** – N/A
- C. **Assessment of Risk Due to Microbiology Deficiencies** – N/A

**III. Administrative**

- A. **Reviewer's Signature** \_\_\_\_\_  
Bryan S. Riley, Ph.D.  
Senior Review Microbiologist OPS/NDMS
- B. **Endorsement Block** \_\_\_\_\_  
James L. McVey  
Team Leader OPS/NDMS
- C. **CC Block**  
N/A

6 Pages Withheld as b(4) Trade Secret/Confidential

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/s/

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Bryan Riley  
7/8/2009 07:58:38 AM  
MICROBIOLOGIST

James McVey  
7/8/2009 01:30:54 PM  
MICROBIOLOGIST  
I concur.