

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Application Number 21-496**

**MICROBIOLOGY REVIEW(S)**

# **Product Quality Microbiology Review**

## **Review for HFD-550**

**22 AUGUST 2002**

**NDA: 21-496**

**Drug Product Name**

**Proprietary: Duocaine**

**Non-proprietary: \_\_\_\_\_**

**Drug Product Classification: S**

**Review Number: 1**

**Subject of this Review**

**Submission Date: 28 February 2002**

**Receipt Date: 6 March 2002**

**Consult Date: 13 March 2002**

**Date Assigned for Review: 20 March 2002**

**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: Amphastar Pharmaceuticals, Inc.**

**Address: 11570 Sixth Street, Rancho Cucamonga, CA, 91730**

**Representative: Diane Gerst, VP Reg. Affairs**

**Telephone: 626-459-5253**

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

**Conclusion: Recommended for Approval**

## Product Quality Microbiology Data Sheet

- A.
1. TYPE OF SUPPLEMENT: N/A
  2. SUPPLEMENT PROVIDES FOR: N/A
  3. MANUFACTURING SITE: Rancho Cucamonga, CA
  4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Sterile aqueous solution for parenteral administration, 10 mg/mL, 10mL/vial, 1% Lidocaine HCl & 0.375 Bupivacaine HCl
  5. METHOD(S) OF STERILIZATION: —
  6. PHARMACOLOGICAL CATEGORY: Anesthetic
- B. SUPPORTING/RELATED DOCUMENTS: N/A
- C. REMARKS: none

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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 \_\_\_\_\_, into sterile glass vials.
- B. **Brief Description of Microbiology Deficiencies** – N/A
- C. **Assessment of Risk Due to Microbiology Deficiencies** – The sterilizing \_\_\_\_\_ has been validated for use with the drug product and the \_\_\_\_\_ processes for the stoppers, vials and filling equipment have been appropriately validated. The \_\_\_\_\_ process has also been validated using media fills. Therefore, the drug product poses little risk to public health from a product quality microbiology standpoint.

### 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

**THIS SECTION  
WAS  
DETERMINED  
NOT  
TO BE  
RELEASABLE**

*6 pages*

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/s/

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Bryan Riley  
9/9/02 09:20:54 AM  
MICROBIOLOGIST

Peter Cooney  
9/10/02 10:59:41 AM  
MICROBIOLOGIST

**APPEARS THIS WAY  
ON ORIGINAL**