

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-689

MICROBIOLOGY REVIEW

06/29/04

Product Quality Microbiology Review

Consult review for HFD-180

DD JUNE, 2004

NDA: NDA 21-689

Name of Drug: Nexium IV

Review Number: 1

Submission Date: September 10, 2003

Applicant: Astra-Zeneca LP

Name of Reviewer: Vinayak Pawar

Conclusion: The application is recommended for approval from microbiological standpoint.

Product Quality Microbiology Data Sheet

- A.
1. **NDA:** NDA 21-689
 2. **REVIEW NUMBER:** 1
 3. **REVIEW DATE:** xx June, 2004
 4. **TYPE OF SUPPLEMENT:** NA
 5. **APPLICATION FOR:** An alternative injectable form.
 6. **APPLICANT/SPONSOR:**

Name: Astra-Zeneca LP
Representative: Michael Angioli
Telephone: 302-885-1389
 7. **MANUFACTURING SITE:** Westborough, Massachusetts
 8. **DRUG PRODUCT NAME:**

Proprietary: NEXIUM I.V.
Non-proprietary: esomeprazole sodium
Drug Priority Classification: Standard
 9. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** 20 & 40 mg Intravenous
 10. **METHOD(S) OF STERILIZATION:** _____
 11. **PHARMACOLOGICAL CATEGORY:** Treatment of gastroesophageal reflux disease
- B.
1. **DOCUMENT/LETTER DATE:** September 10, 2003
 2. **RECEIPT DATE:** Electronic submission
 3. **CONSULT DATE:** November 26, 2003
 4. **DATE OF AMENDMENTS:** NA
 5. **ASSIGNED FOR REVIEW:** January 12, 2004
 6. **SUPPORTING/RELATED DOCUMENTS:**
- C. **REMARKS:** The consult requests review of NDA 21-689 for an alternative dosage form of NEXIUM I.V., previously marketed in a capsule form. The product will be manufactured in Westborough, MA based on manufacturing process developed in AstraZeneca Liquid Production, Sweden. The NDA was provided in an electronic form.

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Executive Summary**I. Recommendations**

- A. Recommendation on Approvability -**
Based on the data provided for _____ of the product, sterilization validation of equipment and containers and the simulated media fill data, the microbiological product safety issues have been adequately addressed. Therefore, the application is recommended for approval from microbiological standpoint.
- B. Recommendation on Phase 4 Commitments and/or Agreements, if Approvable**
NA

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology**
The manufacturing process for the drug product includes
- 
- B. Brief Description of Microbiology Deficiencies**
None
- C. Assessment of Risk Due to Microbiology Deficiencies-**
NA

III. Administrative

- A. Reviewer's Signature** _____
- B. Endorsement Block**
Vinayak Pawar/DD June 2004
Peter H. Cooney
- C. CC Block**
cc:
Original NDA 21-689
HFD-180/Division File/Melissa Hancock Furness

3 Page(s) Withheld

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

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

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/s/

Vinayak Pawar
6/22/04 03:05:06 PM
MICROBIOLOGIST

Peter Cooney
6/29/04 08:37:28 AM
MICROBIOLOGIST