

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-505

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

Consult review for HFD-120

18 DECEMBER 2002

ANDA/NDA: NDA 21-505

Name of Drug: Keppra Oral Solution

Review Number: 1

Submission Date: June 19, 2002

Applicant: UCB Pharma

Name of Reviewer: Vinayak Pawar

Conclusion: The application is recommended for approval

Product Quality Microbiology Data Sheet

- A.
1. **NDA/ANDA/IND/:** NDA 21- 505
 2. **REVIEW NUMBER:** 1
 3. **REVIEW DATE:** 18 December 2002
 4. **TYPE OF SUPPLEMENT:** NA
 5. **SUPPLEMENT PROVIDES FOR:** NA
 6. **APPLICANT/SPONSOR:**
Name: UCB Pharma
Representative: Patricia A. Fritz
Telephone: (770)-437-5554
 7. **MANUFACTURING SITE:** Mallinckrodt Inc. of Hobart New York
 8. **DRUG PRODUCT NAME:**
Proprietary: Keppra®
Non-proprietary: Levetiracetam
Drug Priority Classification:
 9. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Oral Solution, 100 mcg/mL
 10. **METHOD(S) OF STERILIZATION:** NA
 11. **PHARMACOLOGICAL CATEGORY:** Anti-Convulsant
- B.
1. **DOCUMENT/LETTER DATE:** June 19, 2002
 2. **RECEIPT DATE:** June 20, 2002
 3. **CONSULT DATE:** October 29, 2002
 4. **DATE OF AMENDMENTS:** NA
 5. **ASSIGNED FOR REVIEW:** November 11, 2002
 6. **SUPPORTING/RELATED DOCUMENTS:** See remarks below.
- C. **REMARKS:** The consult requests review of a new drug application (NDA 21-505) for manufacture and marketing of Keppra® 100 mg/mL as adjunct therapy in the treatment of partial onset seizures, in adults with epilepsy. Selected pages (Vol. 3, section 3.5.2.8, p72; Vol. 4, section 4.5.2, pp 55 & 56; Vol. 8, section 4.9.38, p 648; Vol. 9, section 4.9.42, pp 42-44, pp 733-817; Vol 11, section 4.9.68, pp 1081-1084) were sent for review.
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Executive Summary**I. Recommendations**

- A. Recommendation on Approvability -**
As demonstrated by the _____ Testing and the
_____ testing results the application for
manufacture of the oral drug product is recommended for approval
from the microbiology 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**
Kepra oral solution is manufactured in 2 oz. _____ glass bottles,
16 oz. _____ glass bottles, 60 cc. White HDPE bottles, and 16 oz.
White HDPE bottles. Formula is preserved with Methylparaben
and propylparaben _____
_____ Product bioburden is monitored by
_____ Test.
- 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/18 December 2002
Pater H. Cooney/
- C. CC Block**
cc:
Original NDA 21-505
HFD-120/Division File/Melina Griffis

3 Page(s) Withheld

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this page is the manifestation of the electronic signature.**

/s/

Vinayak Pawar
1/17/03 02:11:26 PM
MICROBIOLOGIST

Peter Cooney
1/17/03 03:09:05 PM
MICROBIOLOGIST