

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

NDA 21-872

CHEMISTRY REVIEW(S)



NDA 21-872

Keppra® (levetiracetam) Injection

UCB Pharma, Inc.

David J. Claffey, PhD

Office of New Drug Quality Assessment



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Chemistry Review Data Sheet

1. NDA 21-872
2. REVIEW #:2
3. REVIEW DATE: 28 July 2006
4. REVIEWER: David J. Claffey, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Documents

CMC Review #1

Document Date

28 NOV 2005

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

Amendment (AZ)

Amendment (BL)

Amendment (BL)

Amendment (BC)

Document Date

31 JAN 2006

31 MAR 2006

3 MAY 2006

13 JUN 2006

7. NAME & ADDRESS OF APPLICANT:

Name:

UCB Pharma, Inc.



CHEMISTRY REVIEW



Chemistry Review Data Sheet

Address: 1950 Lake Park Drive, Building 2100, Smyrna,
GA 30080

Representative: Linda F. Noa, M.S., RAC

Telephone: 777-970-8582

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: Keppra® Injection
- b) Non-Proprietary Name (USAN): Levetiracetam Injection
- c) Code Name/# (ONDC only):
- d) Chem. Type/Submission Priority (ONDC only):
 - Chem. Type: 3
 - Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: 505 (b) (1)

10. PHARMACOL. CATEGORY: Adjunctive Therapy in the treatment of partial onset seizures in adults with epilepsy

11. DOSAGE FORM: Solution for Injection

12. STRENGTH/POTENCY: 100 mg/ml (5 ml/vial)

13. ROUTE OF ADMINISTRATION: Intravenous

14. Rx/OTC DISPENSED: Rx OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

SPOTS product – Form Completed

Not a SPOTS product



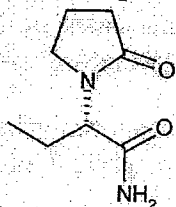
CHEMISTRY REVIEW



Chemistry Review Data Sheet

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT

(S)-(-)-alpha-ethyl-2-oxo-1-pyrrolidine acetamide



$C_8H_{14}N_2O_2$

MW = 170.21

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE ¹	STATUS ²	DATE REVIEW COMPLETED	COMMENTS

¹ Action codes for DMF Table:

1 – DMF Reviewed.

Other codes indicate why the DMF was not reviewed, as follows:

2 – Type 1 DMF

3 – Reviewed previously and no revision since last review

4 – Sufficient information in application

5 – Authority to reference not granted

6 – DMF not available

7 – Other (explain under "Comments")

² Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)



CHEMISTRY REVIEW



Chemistry Review Data Sheet

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
NDA	21-035	Keppra® Tablets
NDA	21-505	Keppra® Oral Solution
IND	68,187	Keppra Injection

18. STATUS:

ONDC:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics			
EES	Acceptable	28 FEB 2005	J. D'Ambrogio
Pharm/Tox			
Biopharm			
LNC			
Methods Validation			
OPDRA			
EA	FONSI (<i>cross reference requested</i>)	22-APR-2005	Florian Zielinski
Microbiology	Approval	8 JUN 2006	Vinayak Pawar

19. ORDER OF REVIEW (OGD Only) N/A

9 Page(s) Withheld

Trade Secret / Confidential

Draft Labeling

Deliberative Process

Withheld Track Number: Chemistry-1

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

/s/

David Claffey
7/28/2006 03:59:53 PM
CHEMIST

Ramesh Sood
7/28/2006 04:53:25 PM
CHEMIST

(First Round)



CHEMISTRY REVIEW



NDA 21-872

Keppra® (levetiracetam) Injection

UCB Pharma, Inc.

David J. Claffey, PhD

Office of New Drug Quality Assessment



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2. REVIEW #:1
3. REVIEW DATE: 28 NOV 2005
4. REVIEWER: David J. Claffey, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Documents

Document Date

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

Document Date

Original

20 DEC 2004

Amendment (BC) (response to IR of 15 AUG 2005)

15 SEP 2005

Amendment (BL) (updated labeling in response to IR of 15 AUG 2005)

15 SEP 2005

Amendment (BC) (response to IR of 30 NOV 2005)

14 DEC 2005

Email response to 15 DEC 2005 IR (accompanying BC not received at time of review completion)

20 DEC 2005

7. NAME & ADDRESS OF APPLICANT:



CHEMISTRY REVIEW



Chemistry Review Data Sheet

Name: UCB Pharma, Inc.
Address: 1950 Lake Park Drive, Building 2100, Smyrna,
GA 30080
Representative: Linda F. Noa, M.S., RAC
Telephone: 777-970-8582

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_____ SPOTS product – Form Completed



CHEMISTRY REVIEW

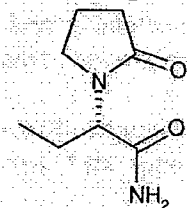


Chemistry Review Data Sheet

Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT

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39 Page(s) Withheld

Trade Secret / Confidential

Draft Labeling

Deliberative Process

Withheld Track Number: Chemistry-2

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

/s/

David Claffey
12/21/2005 10:05:20 AM
CHEMIST

Ramesh Sood
12/21/2005 10:56:04 AM
CHEMIST