CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-272

CHEMISTRY REVIEW(S)

NDA 21-456

Aciphex® (rabeprazole sodium) 20 mg delayed release tablets

Eisai Inc.

Gene W. Holbert, Ph.D.

Division of Special Pathogen and Immunologic Drug Products

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Chemistry Review Data Sheet

1. NDA 21-456

2. REVIEW #: 1

3. REVIEW DATE: July 10, 2001

4. REVIEWER: Gene W. Holbert, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Original	09-JAN-2002
Amendment	26-MAR-2002

7. NAME & ADDRESS OF APPLICANT:

Name:	Eisai, Inc.
Address:	Glenpointe Centre West 500 Frank W. Burr Blvd. Teaneck, NJ 07666
Representative:	Matthew Biondi, RPh Associate Director, Regulatory Affairs
Telephone:	(201) 287-2239

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: Aciphex ®
b) Non-Proprietary Name (USAN): Rabeprazole Sodium
c) Code Name/# (ONDC only): E3810
d) Chem. Type/Submission Priority (ONDC only):

- Chem. Type: 6
- Submission Priority: S

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

10. PHARMACOL. CATEGORY: Antiulcerative (*H. Pylori* eradication)

11. DOSAGE FORM: Tablets

12. STRENGTH/POTENCY: 20 mg

13. ROUTE OF ADMINISTRATION: Oral

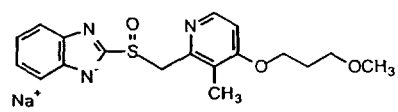
14. Rx/OTC DISPENSED: ✓ Rx ___ OTC

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

_____ SPOTS product – Form Completed ✓ Not a SPOTS product

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

(±)-2-[[[4-(3-methoxypropoxy)-3-methyl-2-pyridinyl]methyl]sulfinyl]-^{1}H-benzimidazole, sodium salt



Molecular Formula: $C_{18}H_{20}N_3O_3SNa$ Molecular Weight: 381.43 CAS: 117976-90-6

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)

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION

18. STATUS:

ONDC:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics			
EES	N/A		
Pharm/Tox	N/A		
Biopharm	Pending		J. Meyer
LNC	N/A		
Methods Validation	N/A		
OPDRA	N/A		
EA	N/A		
Microbiology			

Chemistry Review Data Sheet

OGD:

CONSULTS/CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Microbiology			
EES			
Methods Validation			
Labeling			
Bioequivalence			
EA			
Radiopharmaceutical			

19. ORDER OF REVIEW (OGD Only)

The application submission(s) covered by this review was taken in the date order of receipt. ____ Yes ____ No If no, explain reason(s) below:

2 page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Gene Holbert
9/4/02 11:11:11 AM
CHEMIST

Norman Schmuff
9/4/02 12:41:59 PM
CHEMIST