

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
201367Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

November 4, 2010

NDA: 201367

Drug Product Name

Proprietary:

(b) (4)

Non-proprietary: rufinamide oral suspension

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
April 30, 2010	April 30, 2010	May 18, 2010	May 25, 2010
September 1, 2010	September 2, 2010	September 30, 2010	September 30, 2010

Submission History (for amendments only) - N/A

Applicant/Sponsor

Name:

Eisai Inc

Address:

300 Tice Blvd., Woodcliff Lake, NJ 07677

Representative:

Ira Do, Pharm D, Senior Manager, RA,

Telephone:

Tel: 201-949-

Name of Reviewer:

Vinayak B. Pawar, Ph.D.

Conclusion:

The application is recommended for approval from product quality microbiology standpoint.

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original New Drug Application
 2. **SUBMISSION PROVIDES FOR:** A new Oral Suspension, (b) (4)
 3. **MANUFACTURING SITE:** (b) (4)
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** A non-sterile oral suspension designed to deliver 200 mg of rufinamide as a 5 mL dose (or increments thereof) either using an oral dosing syringe (b) (4)
 5. **METHOD(S) OF STERILIZATION:** Non-sterile suspension.
 6. **PHARMACOLOGICAL CATEGORY:** Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome.
- B. **SUPPORTING/RELATED DOCUMENTS:**
- C. **REMARKS:**
With regard to the new drug application, NDA 201367 which provides for rufinamide oral suspension, a memo was sent to the sponsor on June 23, 2010 which asked the sponsor to provide test methods and acceptance criteria to demonstrate the absence of *Burkholderia cepacia* species in the product. *Burkholderia cepacia* is a potential source of contaminant in non-sterile drug and cosmetic products. The sponsor provided a response on September 1, 2010. Initial Quality Assessment was provided by Martha Heimann, Ph.D. on May 20, 2010.

filename: N201367R1

Executive Summary

I. Recommendations

- A. Recommendation on Approvability** – Recommended for approval.
- 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** –

(b) (4)


- B. Brief Description of Microbiology Deficiencies** - none
- C. Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. Reviewer's Signature** _____
Vinayak B. Pawar, Ph.D., NDMS, OPS, CDER
- B. Endorsement Block** _____
Bryan S. Riley, Ph.D., NDMS, OPS, CDER
- C. CC Block**
N/A

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/s/

VINAYAK B PAWAR
11/09/2010

BRYAN S RILEY
11/09/2010
I concur.

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 201367

Applicant: Eisai Inc.

Letter Date: April 30, 2010

Drug Name:

NDA Type: Original

Stamp Date: April 30, 2010

(b) (4) **Oral Suspension**

The following are necessary to initiate a review of the NDA application:

	Content Parameter	Yes	No	Comments
1	Is the product quality microbiology information described in the NDA and organized in a manner to allow substantive review to begin? Is it legible, indexed, and/or paginated adequately?	X		
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		Section 3.2.P.3.3
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	X		Microbial Limits Test Section 3.2.P.5.3.3
4	Are any study reports or published articles in a foreign language? If yes, has the translated version been included in the submission for review?		X	
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?	X		Assay – Section 3.2.P.5.6.7. Efficacy –Section 3.2.P.2.5.2
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		Specifications – Section 3.2.P.5.1
7	Has the applicant submitted the results of analytical method verification studies?	X		Process Validation Batch results: conformed
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?		X	
9	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: The validation for the microbial limit tests as per the harmonized methods (USP<61>/Ph. Eur. 2.6.12 and USP<62>/Ph. Eur. 2.6.13) was conducted to confirm the applicability of the methods to Rufinamide Oral Suspension.

Reviewing Microbiologist

Date

Microbiology Secondary Reviewer/Team Leader

Date

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-201367	ORIG-1	EISAI INC	RUFINAMIDE ORAL SUSPENSION

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/s/

VINAYAK B PAWAR
06/18/2010

STEPHEN E LANGILLE
06/21/2010