# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

**22-210**

# MICROBIOLOGY REVIEW(S)

# Product Quality Microbiology Review

**19-MAY-2008**

**NDA:** 22-210

**Drug Product Name**
**Proprietary:** Zentase
**Non-proprietary:** Pancreatic enzyme product delayed-release capsules
**Drug Product Priority Classification:** Priority

**Review Number:** 1

**Dates of Submission(s) Covered by this Review**

| Letter | Stamp | Review Request | Assigned to Reviewer |
|---|---|---|---|
| 12/14/07 | 12/14/07 | 12/31/07 | 1/3/08 |
| 3/27/08 | 3/27/08 | N/A | N/A |

**Submission History (for amendments only):** Not applicable

**Applicant/Sponsor**
**Name:** Eurand Pharmaceuticals Ltd.
**Address:** 790 Township Line Road
Suite 250
Yardley, PA 19067

**Representative:** John N. Caminis MD
**Telephone:** 267-759-9338

**Name of Reviewer:** Stephen E. Langille, Ph.D.

**Conclusion:** Recommended for approval

# Product Quality Microbiology Data Sheet

**A. 1. TYPE OF SUBMISSION:** Priority NDA

**2. SUBMISSION PROVIDES FOR:** New drug product

**3. MANUFACTURING SITE:** Eurand SpA
Via Martin Luther King, 13
20060 Pessano con Borgano
Italy

**4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**

- Delayed release capsule
- Oral
- 5,000, 10,000, 15,000 and 20,000 units of lipase

**5. METHOD(S) OF STERILIZATION:** Not applicable

**6. PHARMACOLOGICAL CATEGORY:** Treatment for exocrine pancreatic insufficiency.

**B. SUPPORTING/RELATED DOCUMENTS:** None

**C. REMARKS:** The application was arranged in CTD format. A paper copy of the submission was provided for review. An initial quality assessment for this drug product was not entered into DFS. A request for additional product quality microbiology information was sent to the applicant on 2/5/08.

**filename:** N022210R1.doc

# Executive Summary

**I. Recommendations**

**A. Recommendation on Approvability -**
NDA 22-210 is recommended for approval on the basis of a satisfactory product quality microbiology review.

**B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -**
Not applicable

**II. Summary of Microbiology Assessments**

**A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology –**
The drug product is a solid oral dosage form with microbial limit specifications.

**B. Brief Description of Microbiology Deficiencies -**
No deficiencies were identified based upon the information provided.

**C. Assessment of Risk Due to Microbiology Deficiencies -**
Not applicable

**III. Administrative**

**A. Reviewer's Signature _____**
Stephen E. Langille, Ph.D.

**B. Endorsement Block**
James McVey – Team Leader

**C. CC Block**
N/A

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/s/
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Stephen Langille
5/20/2008 08:15:06 AM
MICROBIOLOGIST

Solid oral dosage form with adequate microbial limits.

James McVey
5/22/2008 03:22:36 PM
MICROBIOLOGIST

## Deliverables by Mid-Cycle for Product Quality Microbiology

(1) Team participation requested, submission received and assigned to Microbiology reviewer (by day 21).

(2) Microbiology reviewer performs filing review and a preliminary review of draft labeling (by day 45).

(3) Microbiology reviewer completes the filing checklist and identifies filing issues and/or other major deficiencies. Checklist is signed off in DFS by secondary reviewer/Team Leader (by day 45).

(4) When potential fileability issues or serious deficiencies are identified, the Microbiology reviewer attends the filing meeting and presents the filing issues and/or deficiencies to be communicated to the applicant.

(5) First review completed prior to mid-cycle meeting with secondary reviewer's concurrence. Information request sent soon after completion of the first review (by month 5).

(6) Microbiology reviewer attends appropriate team meetings and the mid-cycle meeting and presents findings accordingly.

(7) Reviewer and secondary reviewer/Team Leader communicate frequently regarding the review status, submission data and deficiencies.

# PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

**NDA Number:** 22-210 **Applicant:** Eurand Pharmaceuticals Limited **Letter Date**: 12/14/07

**Drug Name:** Zentase **NDA Type:** Priority **Stamp Date:** 12/17/07

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 | | |
| 3 | Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product? | X | | |
| 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 | |
| 6 | Has the applicant submitted microbiological specifications for the drug product and a description of the test methods? | X | | |
| 7 | Has the applicant submitted the results of analytical method verification studies? | X | | |
| 8 | Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions? | | X | No such studies were requested for product quality microbiology |
| 9 | Is this NDA fileable? If not, then describe why. | X | | |

**Additional Comments:** The applicant has provided sufficient information for a product quality microbiology review.

Stephen E. Langille - Reviewing Microbiologist Date

James McVey - Secondary Reviewer/Team Leader Date

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/s/
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Stephen Langille
2/4/2008 01:24:34 PM
MICROBIOLOGIST

James McVey
2/4/2008 01:27:19 PM
MICROBIOLOGIST