

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-924

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

12 APR 2006

NDA: 21-924
21-924 BZ

Drug Product Name

Proprietary: Tirosint T4 soft capsule
Non-proprietary: Levothyroxine sodium
Drug Product Priority Classification: 3S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
30-NOV-2005	05-DEC-2005	01-FEB-2006	07-FEB-2006
30-MAR-2006	31-MAR-2006	N/A	15-MAR-2006

Submission History (for amendments only) – N/A

Applicant/Sponsor

Name: Institut Biochimique SA (IBSA)
Address: 8602 Mossford Drive
Huntington Beach, CA 92646

Representative: Clarence E. Jones, Ph.D.
US Agent
Telephone: (714) 963-0078

Name of Reviewer: Anastasia G. Lolas

Conclusion: Recommended for approval based on product quality microbiology

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** New Drug Application
 2. **SUBMISSION PROVIDES FOR:** New drug product
 3. **MANUFACTURING SITE:**
Drug product manufacturing, testing and packaging:
IBSA
Manno 1
Centro Insema
CH-6928 Manno, Switzerland

Microbiology testing:
IBSA and _____
Microbiological Laboratory
Via al Ponte 13
CH-6903 Lugano, Switzerland
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Soft capsule in blister packs of _____
 - Oral administration
 - 12.5, 25, 50, 75, 100, 125 and 150 µg
 5. **METHOD(S) OF STERILIZATION:** N/A
 6. **PHARMACOLOGICAL CATEGORY:** Thyroid drug
- B. **SUPPORTING/RELATED DOCUMENTS:** None
- C. **REMARKS:** A facsimile was sent to the applicant on March 2, 2006 to request the following:
1. *Please provide a summary of the microbial limits test method validation.*
 2. *Please provide the post-approval testing protocol for the microbial limits test. Will each lot of product be tested for microbial limits?*
 3. *Please provide the post-approval stability protocol for the microbial limits test.*

An electronic response was received on March 15, 2006. The amendment was submitted on March 30, 2006.

filename: N021924R1.doc

Executive Summary

I. Recommendations

- A. **Recommendation on Approvability** – Recommended for approval based on product quality microbiology
- 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** – The microbial limits specifications and test method are reviewed for this non-sterile product.
- B. **Brief Description of Microbiology Deficiencies** – None
- C. **Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. **Reviewer's Signature** _____
Anastasia G. Lolas
- B. **Endorsement Block**
Stephen E. Langille, Ph.D.
- C. **CC Block**
N/A

4 Page(s) Withheld

Trade Secret / Confidential

Draft Labeling

Deliberative Process

Withheld Track Number: Microbiology-1

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

/s/

Anastasia Lolas
4/12/2006 03:18:59 PM
MICROBIOLOGIST

Stephen Langille
4/12/2006 03:24:58 PM
MICROBIOLOGIST