

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-626

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

Review for HFD-160

May 16, 2003

NDA: 21-626

Drug Product Name
Proprietary: Radiogardase®
Non-proprietary: Prussian Blue (Insoluble)
Drug Product Classification: Radioprotectant

Review Number: 1

Subject of this Review
Submission Date: March 10, 2003
Receipt Date: March 14, 2003
Consult Date: March 24, 2003
Date Assigned for Review: March 25, 2003

Submission History (for amendments only)
Date(s) of Previous Submission(s): NA
Date(s) of Previous Micro Review(s): NA

Applicant/Sponsor
Name: Heyl Chemisch-pharmazeutische Fabrik GmbH & Co. KG
Address: Goerzallee 253
D-14167 Berlin (Germany)
Representative: Dr. Brigitte Simons-Horvath
Telephone: 00 49 30 816-96 29

Name of Reviewer: John W. Metcalfe

Conclusion: Recommended for Approval

Executive Summary

- I. Recommendations**
 - A. Recommendation on Approvability – Recommended for approval from the standpoint of microbiological product quality.**
 - B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable - NA**
- II. Summary of Microbiology Assessments**
 - A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology –
See comments below on microbial limits.**
 - B. Brief Description of Microbiology Deficiencies - NA**
 - C. Assessment of Risk Due to Microbiology Deficiencies - NA**
- III. Administrative**
 - A. Reviewer's Signature _____**
 - B. Endorsement Block**
John W. Metcalfe, Ph.D.
Peter Cooney, Ph.D.
 - C. CC Block**
In DFS

Product Quality Microbiology Assessment**MAINTENANCE OF MICROBIOLOGICAL CONTROL AND
QUALITY: STABILITY CONSIDERATIONS**

- **Container Closure Integrity: NA**
- **Pyrogen/Endotoxin Testing: NA**
- **Microbial Limits Testing**

Testing for microbial limits is performed according to specification in the European Pharmacopeia. The European Pharmacopeia provides the following microbial limits for preparations for oral administration. Not more than 10^3 aerobic bacteria or 10^2 yeasts and molds per gram, and an absence in 10 grams of E. coli, Salmonella, Pseudomonas aeruginosa and Staphylococcus aureus. Data provided by the sponsor for Radiogardase CS-Heyl, batch 911035 (May 11, 1995) indicate recovery of <10 CFU/g of aerobic bacteria, <10 CFU/g of anaerobic bacteria, <10 CFU/g of yeast and molds, and a complete absence of the specific bacteria cited above.

Satisfactory

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/s/

John Metcalfe
5/29/03 01:58:19 PM
MICROBIOLOGIST

Peter Cooney
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