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Microbiology Review(s)



Product Quality Microbiology Review Review for HFD-180

May 12, 2003

NDA: 21-372

Drug Product Name

Proprietary:

Non-proprietary: Palonosetron Hydrochloride Injection

Drug Product Classification: anti emetic

Review Number: 1

Subject of this Review

Submission Date: September 26, 2002

Receipt Date:

Consult Date: October 25, 2003

Date Assigned for Review: November 7, 2002

Submission History (for amendments only):

Applicant/Sponsor

Name:

Helsinn Healthcare SA

Address:

Via Plan Scairolo

6912 Pazzallo (Lugano) - Switzerland

Representative:

Telephone:

Authorized Agent:

Dr. Craig Lehmann

August Consulting Inc.

515 Capitol of Texas Highway, Suite 150

Austin, TX 78746 (512) 347-1755

Name of Reviewer:

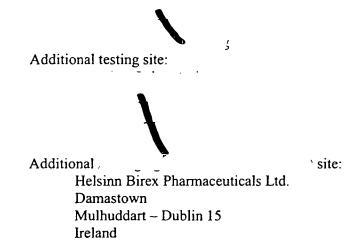
James L. McVey

Conclusion: This application is recommended for approval from a product quality microbiology perspective.



Product Quality Microbiology Data Sheet

- A. 1. TYPE OF SUPPLEMENT:
 - 2. SUPPLEMENT PROVIDES FOR:
 - 3. MANUFACTURING SITE: The drug product will be manufactured, tested for release and for stability and released for commercial use by:



- 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: 0.25 mg/ 5 mL vial for intravenous administration.
- 5. METHOD(S) OF STERILIZATION: The product is followed by sterilization..
- 6. PHARMACOLOGICAL CATEGORY: anti emetic
- B. SUPPORTING/RELATED DOCUMENTS:

 DMF (16063) for drug substance not reviewed for product quality microbiology.
- C. REMARKS: Well organized and assembled application.

filename: 21372r1

Executive Summary

- I. Recommendations
 - **A.** Recommendation on Approvability This application is recommended for approval from a product quality microbiology perspective.
 - B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -
- II. Summary of Microbiology Assessments
 - A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology The product is sterilized to sterilized with a validated

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- B. Brief Description of Microbiology Deficiencies None.
- C. Assessment of Risk Due to Microbiology Deficiencies Minimal risk is seen from a product quality microbiology perspective.
- III. Administrative
 - A. Reviewer's Signature
 - B. Endorsement Block
 Review Microbiologist. J.L. McVey
 Microbiology Supervisor. P.H. Cooney
 - C. CC Block

cc: DFS

HFD- 805/McVey/21372r1



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