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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-372

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:

Additional testing site:

Additional site:

Helsinn Birex Pharmaceuticals Ltd.
Damastown
Mulhuddart – Dublin 15
Ireland

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 _____

- 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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