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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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/s/

James McVey
5/28/03 11:10:31 AM
MICROBIOLOGIST

Peter Cooney
5/29/03 09:05:23 AM
MICROBIOLOGIST