

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

201657Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

Product Quality Microbiology Review

19 January 2012

NDA: 201-657/N-000

Drug Product Name

Proprietary: (not applicable)

Non-proprietary: Paricalcitol Injection

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
07 April 2011	07 April 2011	11 April 2011	14 April 2011
22 July 2011	22 July 2011	-	-

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Hospira, Inc.

Address: 275 North Field Drive
Dept. 0389, Bldg H2-2
Lake Forest, IL 60045

Representative: Laurie Wojtko,
Sr. Associate, Global Regulatory Affairs

Telephone: 224-212-6158

Name of Reviewer: Robert J. Mello, Ph.D.

Conclusion: The application is recommended for approval from microbiology product quality standpoint.

Product Quality Microbiology Data Sheet

- A.**
- 1. TYPE OF SUBMISSION:** New Drug Application - 505(b)(2)
 - 2. SUBMISSION PROVIDES FOR:** Marketing authorization
 - 3. MANUFACTURING SITE:** Hospira Inc., Rocky Mount, NC.
 - 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile solution; intravenous; 2 mcg/1mL, 5 mcg/1mL, 10 mcg/2mL, packaged in 2ml Type I glass vials with 13mm (b)(4) stoppers and 13mm colored Flip-off aluminum overseals.
 - 5. METHOD(S) OF STERILIZATION:** (b)(4)
 - 6. PHARMACOLOGICAL CATEGORY:** Treatment of secondary hyperparathyroidism associated with chronic kidney disease Stage 5.
- B. SUPPORTING/RELATED DOCUMENTS:**
- (b)(4)
 - (b)(4)
- C. REMARKS:**
- An ONDQA initial quality assessment was filed in DARRTS on 06 June 2011. The reviewer noted that the assessment of sterility assurance and adequacy of the data supporting a (b)(4) claim would be consulted to the OPS microbiology staff (OPS-IO/NDMS).
 - The submission is in electronic eCTD format.

Filename: N201657R1.doc

Executive Summary

I. Recommendations

- A. Recommendation on Approvability – Recommend Approval**
- 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 drug substance is** (b) (4)



- B. Brief Description of Microbiology Deficiencies - None**
- C. Assessment of Risk Due to Microbiology Deficiencies – N/A**

III. Administrative

- A. Reviewer's Signature:** _____
Robert J. Mello, Ph.D.
Senior Microbiology Reviewer
- B. Endorsement Block:** _____
Stephen E. Langille, Ph.D.
Senior Microbiology Reviewer
- C. CC Block**
NDA 201-657

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/s/

ROBERT J MELLO
01/20/2012

STEPHEN E LANGILLE
01/20/2012

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 201-657

Applicant: Hospira, Inc.

Letter Date: 07 April 2011

**Drug Name: Paricalcitol
Injection , 2µg/ml & 5µg/ml**

NDA Type: 505(b)(2)

Stamp Date: 07 April 2011

The following are necessary to initiate a review of the NDA application:

	Content Parameter	Yes	No	Comments
1	Is the product quality microbiology information described in the NDA and organized in a manner to allow substantive review to begin? Is it legible, indexed, and/or paginated adequately?	X		Section 3.2.A.1(Facilities & Equipment);
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		Sections 3.2.P.3.3 & 3.2.P.3.4
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	X		Section 3.2.P.3.5
4	Are any study reports or published articles in a foreign language? If yes, has the translated version been included in the submission for review?		X	
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity (CCI) studies?	X		Non-preserved product. CCI data in Section 3.2.P.2.5
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		Section 3.2.P.5.1 and -5.2 (Sterility and Endotoxin tests)
7	Has the applicant submitted the results of analytical method verification studies?	X		Section 3.2.P.5.3 (Sterility and Endotoxin tests)
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?	-	-	Not Applicable
9	Is this NDA fileable? If not, then describe why.	X		The submission is fileable.

Additional Comments: The manufacturing site is the Hospira facility in Rocky Mount, NC. There are two dosages (2µg/ml and 5µg/ml) filled in (b) (4)

Robert J. Mello, Ph.D., Senior Microbiology Reviewer

Date

John W. Metcalfe, Ph.D., Senior Microbiology Reviewer

Date

[End]

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/s/

ROBERT J MELLO
04/28/2011

JOHN W METCALFE
04/28/2011
I concur.