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RESEARCH**

APPLICATION NUMBER:
200582Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

23 APRIL 2010

NDA: 200582

Drug Product Name

Proprietary: N/A

Non-proprietary: Topotecan Injection

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
29 October 2009	29 October 2009	9 December 2009	15 December 2009
22 March 2010	22 March 2010	N/A	N/A

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Hospira, Inc.

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

Representative: Wendy Tian

Telephone: 224-212-6163

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA 505(b)(2)
 2. **SUBMISSION PROVIDES FOR:** A sterile parenteral drug product
 3. **MANUFACTURING SITE:**

Zybus Hospira Oncology Private Ltd. (ZHOPL)
Pharmez
Special Economic Zone Plot No. 3
Matoda
Sarkhej Bavla Highway
Taluka Sanand
District Ahmedabad-382 210
Gujarat, India
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile aqueous solution in a 5 mL glass vial for intravenous injection, 4 mg/4 mL
 5. **METHOD(S) OF STERILIZATION:** (b) (4)
 6. **PHARMACOLOGICAL CATEGORY:** Cytotoxic drug
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** This was an electronic submission in the CTD format but was not an eCTD submission. An information request was sent to the applicant on 17 March 2010. The applicant was asked to provide the bacterial retention validation studies for the (b) (4). The applicant amended their application on 22 March 2010 with the requested information.

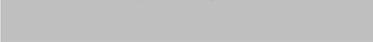
filename: N200582R1.doc

Executive Summary

I. Recommendations

- A. Recommendation on Approvability** – This submission is recommended for approval on the basis of product quality microbiology.
- 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** –  ^{(b) (4)}

- B. Brief Description of Microbiology Deficiencies** – N/A
- C. Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. Reviewer's Signature** _____
Bryan S. Riley, Ph.D.
- B. Endorsement Block** _____
James L. McVey, NDMS Team Leader
- C. CC Block**
N/A

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200582	ORIG-1	HOSPIRA INC	TOPOTECAN INJ

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BRYAN S RILEY
04/29/2010

JAMES L MCVEY
04/29/2010
I concur.