CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022555Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

19 OCTOBER 2009

NDA: 22-555

Drug Product Name
Proprietary: Hexvix
Non-proprietary: Hexaminolevulinate

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
30 June 2009	30 June 2009	17 August 2009	10 July 2009

Submission History (for amendments only): N/A

Applicant/Sponsor
Name: Photocure ASA
Address: Hoffsveien 48, NO-0377 Oslo, Norway
Representative: Linda Sutton, Chief Regulatory Officer, Cato Research
Telephone: 919-361-2286

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

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: New Drug Application 505(b)(1)

2. SUBMISSION PROVIDES FOR: A parenteral drug product

3. MANUFACTURING SITES:

(b) (4)

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Sterile lyophilized powder for injection in a glass vial (85 mg hexyl aminolevulinate/vial) and sterile solvent (50 mL/vial) in a glass vial or polypropylene (b) (4) vial.

5. METHOD(S) OF STERILIZATION: (b) (4)

(b) (4)

6. PHARMACOLOGICAL CATEGORY: Imaging Agent

B. SUPPORTING/RELATED DOCUMENTS: Product Quality Microbiology reviews (b) (4)

C. REMARKS: This was an eCTD submission. The drug product was previously reviewed (b) (4) for a different indication. The manufacturing processes for the drug product and solvent have not changed from a product quality microbiology standpoint.

filename: N022555R1.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 – The drug product is sterile

(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

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/s/

BRYAN S RILEY
10/19/2009

JAMES L MCVEY
10/21/2009
I concur.

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 22-555 **Applicant:** Photocure ASA **Letter Date:** 30 June 2009

Drug Name: Hexvix **NDA Type:** 505(b)(1) **Stamp Date:** 30 June 2009

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		eCTD submission
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	X		
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 studies?	X		
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		
7	Has the applicant submitted the results of analytical method verification studies?	X		
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?	X		
9	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: The submission references the submissions for [redacted] (b) (4) (a different indication for the same drug product). The drug product and manufacturing process for [redacted] (b) (4) and 22-555 are identical. [redacted] (b) (4) .

15 July 2009

Bryan S. Riley, Ph.D. Date
Senior Review Microbiologist

James L. McVey Date
OPS/NDMS Team Leader

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/s/

Bryan Riley
7/20/2009 10:59:46 AM
MICROBIOLOGIST

James McVey
7/20/2009 11:45:09 AM
MICROBIOLOGIST
I concur.