

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
22-066

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

05 Apr 2007

NDA: 22-066/N-000
22-066/N-000 (BI)
22-066/N-000 (BC)

Drug Product Name

Proprietary: OMNISCAN™ Pharmacy Bulk Package
Non-proprietary: gadodiamide injection

Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
06 JULY 2006	07 JULY 2006	02 AUG 2006	07 AUG 2006
12 OCT 2006(BI)	13 OCT 2006	N/A	N/A
14 NOV 2006(BC)	15 Nov 2006	N/A	N/A

Submission History (for amendments only) – N/A

Applicant/Sponsor

Name: GE Healthcare
Address: 101 Carnegie Center
Princeton, NJ 08540-6231
Representative: Michael Barbush
Senior Regulatory Manager
Telephone: 609-514-6427

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:** Original NDA submission
 2. **SUBMISSION PROVIDES FOR:** Request to market a new pharmacy drug package of an existing, approved drug product.
 3. **MANUFACTURING SITE:** GE Healthcare Ireland
IDA Business Park
Carrigtohill
Co. Cork,
IRELAND
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile solution for injection: Intravenous; 0.5mmol/ml (287 mg/mL); packaged as 50ml/50ml and 100 ml/100 ml _____ bottles.
 5. **METHOD(S) OF STERILIZATION:** _____
 6. **PHARMACOLOGICAL CATEGORY:** Contrast agent for magnetic resonance imaging procedures.

B. **SUPPORTING/RELATED DOCUMENTS:**

- The Applicant provided a Letter of Authorization to reference _____ DMF # _____ for the _____ Black rubber closure.
- The applicant has cross referenced IND 32,218 and NDA 20-123; both for Omniscan (gadodiamide) injection.
- The applicant has also cross referenced NDA 18-956 Omnipaque™ (iohexol) Injection, for container closure information.
- Microbiology review #1; J. L. McVey, March 4, 2003 for NDA 18-956/S-055 & 20-608/S-006 (Omnipaque™ (iohexol) Injection, Pharmacy Bulk Package).
- Microbiology review #1; S. Langille, 16 March 2004 for NDA 18-956/SCP-060.
- Microbiology review #1; J. Barletta, 23 NOV 2005 for NDA 18-956/SCM-067 & SCM-068, and NDA 20-608/SCM-014 & SCM-015.

C. **REMARKS:**

- An ONDQA PAL Initial Quality Assessment was filed in DFS on 25 AUG 2006.
- The following paper submissions, in CTD format, were received for review:
 - Module 1, Volume 1 of 1 – Paper Desk Copy dated 06 JULY 2006
 - Module 2, Volume 1 of 1 – Paper Desk Copy dated 06 JULY 2006
 - Module 3, Volume 1 of 1 – Paper Desk Copy dated 06 JULY 2006

- White (microbiology) bound copy, N-000 (BI); 12 OCT 2006, Response to 18 SEPT 2006 Filing communication requesting additional microbiology information.
- Blue (archival) bound copy, N-000 (BC); 14 NOV 2006, Response to 18 SEPT 2006 Filing communication requesting additional stability data.

Filename: N022066R1.doc

APPEARS THIS WAY ON ORIGINAL

Executive Summary**I. Recommendations**

- A. **Recommendation on Approvability** - The application is recommended for approval from microbiology product quality standpoint.
- 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. **Brief Description of Microbiology Deficiencies** – No deficiencies noted. One comment concerning sample preparation for bacterial endotoxin testing should be communicated to the applicant. No response is required or requested.

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

III. Administrative

- A. **Reviewer's Signature** _____
Robert J. Mello, Ph.D.

- B. **Endorsement Block** _____
Stephen E. Langille, Ph.D.

- C. **CC Block**
In DFS

14 Page(s) Withheld

✓ Trade Secret / Confidential

 Draft Labeling

 Deliberative Process

Withheld Track Number: Microbiology- 1

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

/s/

Robert Mello
4/10/2007 10:09:08 AM
MICROBIOLOGIST

Recommend Approval

Stephen Langille
4/10/2007 10:17:03 AM
MICROBIOLOGIST