

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-711

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

Review for HFD-160

3 JUNE 2004

NDA: 21-711

Drug Product Name

Proprietary: VASOVIST

Non-proprietary: Gadofosveset Trisodium

Drug Product Priority Classification: S

Review Number: 1

Subject of this Review

Submission Date: 12 December 2003

Receipt Date: 15 December 2003

Consult Date: 24 December 2003

Date Assigned for Review: 12 January 2004

Submission History (for amendments only)

Date(s) of Previous Submission(s): N/A

Date(s) of Previous Micro Review(s): N/A

Applicant/Sponsor

Name: EPIX Medical

Address: 71 Rogers Street; Cambridge, MA 02142

Representative: Robert Morgan, Esq.

Telephone: 617-250-6050

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

Conclusion: Recommend for Approval

Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUPPLEMENT:** N/A
2. **SUPPLEMENT PROVIDES FOR:** N/A
3. **MANUFACTURING SITE:** Mallinckrodt Medical Inc
8800 Durant Rd
Raleigh, NC 27616
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile liquid for IV administration, 0.25 mmol/mL
5. **METHOD(S) OF STERILIZATION:** Terminal Moist Heat
6. **PHARMACOLOGICAL CATEGORY:** Magnetic Resonance Angiography
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** N/A

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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 terminally sterilized using moist heat.
- B. **Brief Description of Microbiology Deficiencies** – N/A
- C. **Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. **Reviewer's Signature** _____
- B. **Endorsement Block**
Bryan S. Riley, Ph.D. (Microbiology Reviewer)
Peter H. Cooney, Ph.D. (Microbiology Supervisor)
- C. **CC Block**
N/A

5 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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/s/

Bryan Riley
6/30/04 10:11:50 AM
MICROBIOLOGIST

Peter Cooney
6/30/04 11:13:11 AM
MICROBIOLOGIST