

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-697

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

Review for HFD-590

21 May 2004

NDA: 21-697

Drug Product Name

Proprietary: VAPRISOL™

Non-proprietary: Conivaptan hydrochloride Injection

Drug Product Classification: Metabolic

Review Number: 1

Subject of this Review

Submission Date: 30 January 2004

Receipt Date: 3 February 2004

Consult Date: 15 March 2004

Date Assigned for Review: 24 March 2004

Applicant/Sponsor

Name: Yamanouchi Pharma America, Inc.

Address: Mack Centre IV, S. 61 Paramus Road, Paramus, NJ 07652

Representative: Jacquelyn Hartley

Telephone: (201) 708-2714

Name of Reviewer: Paul Stinavage, Ph.D.

Conclusion: The submission is recommended for approval on the basis of sterility assurance.

Product Quality Microbiology Data Sheet

- A.
1. TYPE OF SUPPLEMENT: N/A
 2. SUPPLEMENT PROVIDES FOR: N/A
 3. MANUFACTURING SITE: Yamanouchi Pharmaceutical Company,
Ltd., Yaizu Technology Center, 180
Ozumi, Yaizu-shi, Shizuoka-ken, Japan
 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND
STRENGTH/POTENCY: 5 mg/mL in 4 mL/ampoule, _____
 5. STERILIZATION METHOD(S): _____
 6. PHARMACOLOGICAL CATEGORY: Treatment of euvolemic or
hypervolemic hyponatremia in
hospitalized patients
- B. SUPPORTING/RELATED DOCUMENTS: DMF _____ IND's 56-813, _____
_____ 55-607, _____
- C. REMARKS: The product will be manufactured at the applicant's facility in
Japan. _____
_____ This is entirely an electronic
submission.

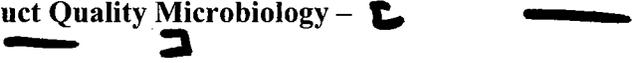
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Executive Summary

I. Recommendations

- A. Recommendation on Approvability** – The submission is recommended for approval on the basis of sterility assurance.
- 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** – N/A
- C. Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. Reviewer's Signature** _____
- B. Endorsement Block**
 - P. Stinavage
 - P. Cooney
- C. CC Block**
 - cc:
 - Original NDA 21-697
 - HFD-510/Division File/NDA 21-697

2 Page(s) Withheld

§ 552(b)(4) Trade Secret / Confidential

§ 552(b)(4) Draft Labeling

§ 552(b)(5) Deliberative Process

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

/s/

Paul Stinavage
6/2/04 11:07:39 AM
MICROBIOLOGIST



Peter Cooney
6/2/04 12:06:59 PM
MICROBIOLOGIST