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 euvoletic 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.
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

Withheld Track Number: Microbiology-
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