

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-518

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

Review for HFD-580

14 April 2003

NDA: 21-518

Drug Product Name

Proprietary: Vesicare® Tablets
Non-proprietary: solifenacin succinate
Drug Product Classification: Treatment for overactive bladder

Review Number: 1

Subject of this Review

Submission Date: December 19, 2002
Receipt Date: Not Provided
Consult Date: February 3, 2003
Date Assigned for Review: March 14, 2003

Submission History (for amendments only)

Date(s) of Previous Submission(s):
Date(s) of Previous Micro Review(s):

Applicant/Sponsor

Name: Yamanouchi Pharma America, Inc.
Address: Mack Center IV
S. 61 Paramus Road,
Paramus, NJ 07652
Representative: Rudolph W. Lucek
Telephone: (201) 909-3041

Name of Reviewer: Stephen E. Langille, Ph.D.

Conclusion: Recommended for approval

Product Quality Microbiology Data Sheet

- A. 1. TYPE OF SUPPLEMENT: Not Applicable
2. SUPPLEMENT PROVIDES FOR: Not Applicable
3. MANUFACTURING SITE: Yamanouchi
Pharmaceutical Co., Ltd.
Norman Manufacturing
Center
Norman, OK 73072
4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND
STRENGTH/POTENCY:
- Oral
 - Tablet
 - 5 mg and 10 mg
5. METHOD(S) OF STERILIZATION: Non-sterile drug product
6. PHARMACOLOGICAL CATEGORY: Treatment for overactive
bladder
- B. SUPPORTING/RELATED DOCUMENTS: None
- C. REMARKS:

filename: c:/reviews/21-518r1.doc

Executive Summary**I. Recommendations**

- A. Recommendation on Approvability -**
The submission is recommended for approval from the standpoint of microbial product quality
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -**

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -**
The product is a non-sterile solid oral dosage form that —
- B. Brief Description of Microbiology Deficiencies -**
No deficiencies were identified based upon the information provided.
- C. Assessment of Risk Due to Microbiology Deficiencies -**
Not applicable

III. Administrative

- A. Reviewer's Signature** _____
- B. Endorsement Block**
Stephen E. Langille, Ph.D.
Peter Cooney, Ph.D.
- C. CC Block**
In DFS

3 Page(s) Withheld

**This is a representation of an electronic record that was signed electronically and
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/s/

Stephen Langille
5/1/03 09:19:35 AM
MICROBIOLOGIST

Peter Cooney
5/1/03 10:18:33 AM
MICROBIOLOGIST