

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
NDA 22-103

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

11 APRIL 2007

NDA: 22-103

Drug Product Name

Proprietary: Sanctura XR

Non-proprietary: trospium chloride extended release

Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
10/12/2006	10/13/2006		3/28/2007

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Indevus Pharmaceuticals, Inc.

Address: 33 Hayden Avenue

Representative: John Berryman

Telephone: 781-402-3451

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

Conclusion: Recommended for approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA
 2. **SUBMISSION PROVIDES FOR:** Extended release capsule
 3. **MANUFACTURING SITE:** / /
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** capsule for oral administration, — 60 mg
 5. **METHOD(S) OF STERILIZATION:** N/A
 6. **PHARMACOLOGICAL CATEGORY:** Overactive bladder
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** This submission was an electronic document in the format of the CTD. The consult was requested because the applicant was proposing to not have a microbial limit specification for the drug product despite reporting cultures with "atypical growth" on stability.

filename: N022103R1.doc

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 a non-sterile capsule.
- B. **Brief Description of Microbiology Deficiencies** – N/A
- C. **Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. **Reviewer's Signature** _____
Bryan S. Riley, Ph.D.
- B. **Endorsement Block** _____
James L. McVey
Microbiology Team Leader
- C. **CC Block**
N/A

1 Page(s) Withheld

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/s/

Bryan Riley
4/12/2007 10:36:07 AM
MICROBIOLOGIST

James McVey
4/13/2007 09:24:08 AM
MICROBIOLOGIST