# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

**22-204**

# MICROBIOLOGY REVIEW(S)

# Product Quality Microbiology Review

**26-NOVEMBER-2008**

**NDA:** 22-204
22-204-BZ

**Drug Product Name**
**Proprietary:** Oxybutynin chloride topical gel
**Non-proprietary:** 4-(Diethylamine)-2-butynyl-a-phenylcylohexaneglycolate hydrochloride
**Drug Product Priority Classification:** Standard

**Review Number:** 1

**Dates of Submission(s) Covered by this Review**

| Letter | Stamp | Review Request | Assigned to Reviewer |
|---|---|---|---|
| 3/26/08 | 3/27/08 | 5/9/08 | 5/12/08 |
| 10/31/08 | 11/3/08 | N/A | N/A |

**Submission History:** Not applicable

**Applicant/Sponsor**
**Name:** Watson Laboratories, Inc.
**Address:** 577 Chipeta Way
Salt Lake City, Utah

**Representative:** Kevin Barber
**Telephone:** 801-588-6324

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

**Conclusion:** Recommended for approval

# Product Quality Microbiology Data Sheet

**A.** **1.** **TYPE OF SUBMISSION:** Original NDA

**2.** **SUBMISSION PROVIDES FOR:** Microbial limits and preservative effectiveness testing on a topical gel.

**3.** **MANUFACTURING SITE:** Watson Laboratories, Inc.
575 Chipeta Way
Salt Lake City, UT

**4.** **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**

- Topical gel
- Trans-dermal
- 100 mg/g

**5.** **METHOD(S) OF STERILIZATION:** Non-sterile drug product

**6.** **PHARMACOLOGICAL CATEGORY:** Treatment for overactive bladder syndrome

**B.** **SUPPORTING/RELATED DOCUMENTS:** None

**C.** **REMARKS:** The NDA was submitted in eCTD format. There was no initial quality assessment in DFS. A product quality microbiology information request was sent to the applicant on August 28, 2008. The applicant responded to this request with amendment BZ submitted on October 31, 2008.

**filename:** N022204R1.doc

# Executive Summary

## I. Recommendations

### A. Recommendation on Approvability -

NDA 22-204 is recommended for approval from the standpoint of product quality microbiology.

### B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -

Not applicable

## II. Summary of Microbiology Assessments

### A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -

The drug product contains (b) (4) and had been demonstrated to be hostile to microbial survival and growth.

### 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 _____

Stephen E. Langille, Ph.D.

### B. Endorsement Block

James McVey – Team Leader

### C. CC Block

N/A

4 pp withheld following this page as (b)(4) CCI/ TS.

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

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/s/
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Stephen Langille
12/2/2008 03:10:44 PM
MICROBIOLOGIST

James McVey
12/2/2008 03:28:58 PM
MICROBIOLOGIST
The request to lower the limit is appropriate.  I concur.