

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

NDA 22-206

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

21 AUGUST 2008

NDA: 22-206/N-000

Drug Product Name

Proprietary: RAPAFLO™

Non-proprietary: Silodosin

Drug Product Priority Classification: P

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
12 DEC 2007	13 DEC 2007	23 JAN 2008	30 JAN 2008
10 JULY 2008	11 JULY 2008	n/a	n/a
18 AUG 2008	19 AUG 2008	n/a	n/a

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Watson Laboratories, Inc.

Address: 577 Chipeta Way
Salt Lake City, UT 84108

Representative: Kevin Barber, Exec. Dir. Regulatory

Telephone: 801-588-6324

Name of Reviewer: Robert J. Mello, Ph.D.

Conclusion: The submission is recommended for approval from a microbiology product quality standpoint.

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original Application
 2. **SUBMISSION PROVIDES FOR:** Marketing Authorization
 3. **MANUFACTURING SITE:** Watson Laboratories, Inc., 1033 Stoneleigh, Carmel, NY 10512
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Hard gelatin capsule, Immediate release; Oral administration, 4mg and 8mg strengths
 5. **METHOD(S) OF STERILIZATION:** Not Applicable
 6. **PHARMACOLOGICAL CATEGORY:** Treatment for the signs and symptoms of Benign Prostatic Hyperplasia (BPH)

B. **SUPPORTING/RELATED DOCUMENTS:**

C. **REMARKS:**

- The ONDQA PAL Initial Quality Assessment was performed and is on file in DFS (29 JAN 2008). Reference was made to agency correspondence with the sponsor (20 JULY 2007) in which the sponsor was advised that deletion of _____ would be a review issue. The sponsor agreed to provide additional data in the NDA to support the limits and justification for _____
/ / / / /
- The application was submitted electronically in eCTD format.
- The drug product was initially developed by Kissei Pharmaceutical Co. Ltd. and was subsequently transferred to the sponsor Watson Laboratories.
- In the July 10, 2008 (BZ) amendment, the sponsor responded to a June 03, 2008, request to provide _____ testing. Additional information was needed and the sponsor received that additional request on July 31, 2008. On August 11, 2008 the applicant provided information on the previously executed and currently planned production of the drug product in response to a request for information on the production history for the site. The information was submitted as an amendment (18 AUG 2008) in support of the study proposal _____
_____. These _____ issues are described in Sections P.2.5 and P.5.1 below.

b(4)

b(4)

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Executive Summary

I. Recommendations

- A. Recommendation on Approvability – Recommend Approval
- 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 an oral capsule. As such, there should be suitable controls of the finished dosage form. b(4)
- B. Brief Description of Microbiology Deficiencies – None.
- C. Assessment of Risk Due to Microbiology Deficiencies – N/A

III. Administrative

- A. Reviewer's Signature _____
Robert J. Mello, Ph.D.
- B. Endorsement Block _____
James L. McVey
- C. CC Block
NDA 22-206/N-000

**APPEARS THIS WAY
ON ORIGINAL**

6 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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/s/

Robert Mello
8/21/2008 07:46:40 AM
MICROBIOLOGIST

Recommend Approval

James McVey
8/21/2008 08:26:46 AM
MICROBIOLOGIST
I concur.