CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206276Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

Product Quality Microbiology Review

31 December 2014

NDA: **206276**

Drug Product Name
Proprietary: PAZEO
Non-proprietary: Olopatadine Hydrochloride Ophthalmic Solution, 0.77%

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
30 July 2014	30 July 2014	12 August 2014	21 August 2014
5 December 2014	5 December 2014	N/A	N/A
17 December 2014	17 December 2014	N/A	N/A

Submission History (for 2nd Reviews or higher): Not applicable

Applicant/Sponsor
Name: Alcon
Address: 601 South Freeway
Fort Worth, TX 76134-2099
Representative: Naj Sharif, Ph.D.
Telephone: 817-568-6494

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

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original Submission – Priority Review

2. SUBMISSION PROVIDES FOR: (b) (4) processing information for two manufacturing sites and multiple contract manufacturing sterilization sites for container closure components.

3. MANUFACTURING SITES:

Alcon Research, Ltd.
6201 South Freeway
Fort Worth, Texas 76134
Drug Establishment Registration No. 1610287

and

sa Alcon-Couvreur nv
Rijksweg 14
B-2870 Puurs
Belgium
Drug Establishment Registration No. 3002037047

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

- Sterile Ophthalmic Solution
- Topical
- 0.77%

5. METHOD(S) OF STERILIZATION: (b) (4) processing

6. PHARMACOLOGICAL CATEGORY: Treatment of itching associated with allergic conjunctivitis

B. SUPPORTING/RELATED DOCUMENTS: Not applicable

C. REMARKS: The application was provided in eCTD format.

filename: N206276r1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability - Recommended for Approval

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 will be (b) (4) filled into 4 ml LDPE dropper bottles. The HPMC solution will be (b) (4) olopatadine solution. (b) (4)

B. Brief Description of Microbiology Deficiencies -
No deficiencies were identified based upon the information provided.

C. Contains Potential Precedent Decision(s)- ☐ Yes ☒ No

III. Product Quality Microbiology Risk Assessment

A. Initial Product Quality Microbiology Risk Assessment

CQA	Risk Factor	Prob. of Occ. (O)	Modifier for O[3, 4, 5]	Severity of Effect (S)	Detect. (D)	Risk Priority Number[6] (RPN)	Additional Review Emphasis based on Risk (in addition to normal review process)
Ster.	(b) (4)	10	-1	5	5	225	Simulations and interventions conducted during media fills, Environmental monitoring

(b) (4)

(b) (4)

RPN <50 = Low Risk; RPN 50-120 = Moderate Risk; RPN >120 = High Risk

B. Final Risk Assessment - The applicant has presented adequate information to mitigate risks outlined in the initial product quality microbiology risk assessment.

IV. Administrative

A. Reviewer's Signature _____

Stephen E. Langille, Ph.D.
Senior Microbiology Reviewer

B. Endorsement Block

Bryan Riley, Ph.D. – Acting NDMS Team Leader

C. CC Block

N/A

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