CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202872Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

06 August 2012

NDA: 202-872/N000

Drug Product Name
Proprietary: To be determined
Non-proprietary: loteprednol etabonate ophthalmic gel, 0.5%

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
29 November 2011	29 November 2011	27December 2011	28 December 2011
27 March 2012 (SD9)	27 March 2012	NA	NA
28 June 2012 (SD 15)	28 June 2012	NA	NA

Submission History (for amendments only): NA

Applicant/Sponsor
Name: Bausch & Lomb Incorporated
Address: 7 Giralda Farms Suite 1001
Madison, New Jersey 07940
Representative: Mary Harrell
Manager Global Pharma Regulatory Affairs
Telephone: (973) 360-6462

Name of Reviewer: Denise A. Miller

Conclusion: Approve

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: New Drug Application

2. SUBMISSION PROVIDES FOR: The manufacturing and marketing of a sterile ophthalmic topical gel.

3. MANUFACTURING SITE:
Bausch & Lomb, Inc.
8500 Hidden River Parkway
Tampa, FL 33637
CFN: 1052807

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

- Dosage form: Sterile ophthalmic gel 0.5g/4 mL and 5g/10 mL dropper bottles
- Route of Administration: topical ophthalmic
- Strength/Potency: 5%

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

(b) (4)

6. PHARMACOLOGICAL CATEGORY: anti-inflammatory and pain reduction following ocular surgery.

B. SUPPORTING/RELATED DOCUMENTS: NA

C. REMARKS:
Application was in the e-CTD format

filename: N202872N000R1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability - Recommend to approve from a quality microbiology standpoint.

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

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – The manufacturing process involves (b) (4) [redacted]

B. Brief Description of Microbiology Deficiencies - None

C. Assessment of Risk Due to Microbiology Deficiencies - NA

III. Administrative

A. Reviewer's Signature _____

Denise A. Miller
Microbiologist, OPS/NDMS

B. Endorsement Block _____

Steven E. Langille, Ph.D.
Senior Microbiologist, OPS/NDMS

C. CC Block

N/A

20 pages has been withheld in full as B(4) CCI/TS immediately following this page

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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.

/s/

DENISE A MILLER
08/08/2012

STEPHEN E LANGILLE
08/09/2012

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 202-872 **Applicant:** Bausch and Lomb **Letter Date:** 29 November 2011

Drug Name: Loteprednol Etabonate ophthalmic gel 0.5% **NDA Type:** 505(b)(1) **Stamp Date:** 29 November 2011

The following are necessary to initiate a review of the NDA application:

	Content Parameter	Yes	No	Comments
1	Is the product quality microbiology information described in the NDA and organized in a manner to allow substantive review to begin? Is it legible, indexed, and/or paginated adequately?	√		e-CTD format
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	√		
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	√		
4	Are any study reports or published articles in a foreign language? If yes, has the translated version been included in the submission for review?		√	
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?	√		
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	√		
7	Has the applicant submitted the results of analytical method verification studies?	√		
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?	NA		
9	Is this NDA fileable? If not, then describe why.	√		

Additional Comments: Facility floor plans were not located in the submission. The submission also did not list any hold times or provide supportive studies.

Denise A. Miller, Microbiologist Date

Stephen E. Langille, Ph.D. Date

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

/s/

DENISE A MILLER
01/12/2012

STEPHEN E LANGILLE
01/12/2012