

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
200738Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

1 JULY 2010

NDA: 200738

Drug Product Name

Proprietary: LOTEMAX

Non-proprietary: loteprednol etabonate ophthalmic ointment, 0.5%

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
22 December 2009	23 December 2009	N/A	30 December 2009

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Bausch & Lomb Inc.

Address: 8500 Hidden River Parkway, Tampa, FL 33637

Representative: Julie Townsend

Telephone: 813-866-2299

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

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA 505(b)(1)
 2. **SUBMISSION PROVIDES FOR:** A new sterile ophthalmic drug product.
 3. **MANUFACTURING SITE:** Bausch & Lomb
8500 Hidden River Parkway
Tampa, FL 33637
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile Topical Ophthalmic Ointment in a multi-dose tin tube (3.5g fill in a 3.5g tube) and physician sample (1g in a 2g tube), 0.5%. [REDACTED] (b) (4) the drug product meets the acceptance criteria for USP <51> Anti-Microbial Effectiveness Testing.
 5. **METHOD(S) OF STERILIZATION:** [REDACTED] (b) (4)
 6. **PHARMACOLOGICAL CATEGORY:** Corticosteroid
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** This was an eCTD submission.

filename: N200738R1.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

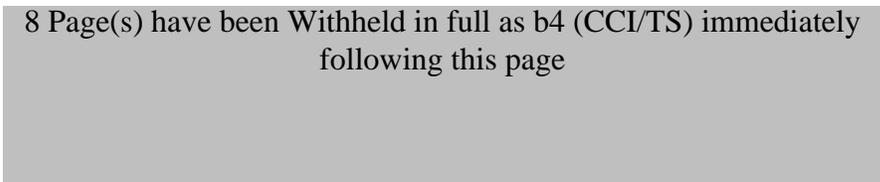
II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – The sterile drug substance
 (b) (4)
- 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.
Senior Review Microbiologist, OPS/NDMS
- B. Endorsement Block** _____
Stephen E. Langille, Ph.D.
Senior Review Microbiologist, OPS/NDMS
- C. CC Block**
N/A

8 Page(s) have been Withheld in full as b4 (CCI/TS) immediately following this page



Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200738	ORIG-1	BAUSCH AND LOMB INC	LOTEPREDNOL ETABONATE OINTMENT, 0.5%

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/s/

BRYAN S RILEY
07/01/2010

STEPHEN E LANGILLE
07/02/2010

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 200738

Applicant: Bausch & Lomb Inc. **Letter Date:** 22 December 2009

Drug Name: Lotemax
(Lotepredol Etabonate
Ophthalmic Ointment, 0.5%)

NDA Type: 505(b)(1)

Stamp Date: 23 December 2009

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?	X		eCTD submission
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	X		
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?		X	
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?	X		
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		
7	Has the applicant submitted the results of analytical method verification studies?	X		
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?	X		
9	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: The drug product is a non-aqueous ophthalmic ointment.

5 January 2010

Bryan S. Riley, Ph.D. Date
Senior Review Microbiologist

James L. McVey Date
OPS/NDMS Team Leader

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200738	ORIG-1	BAUSCH AND LOMB INC	LOTEPREDNOL ETABONATE OINTMENT, 0.5%

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/s/

BRYAN S RILEY
01/08/2010

JAMES L MCVEY
01/11/2010
I concur.