

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number **20-583**

CHEMISTRY REVIEW(S)

**Division of Anti-inflammatory, Analgesic
and Ophthalmic Drugs**
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-583

REVIEW # 02: Amendment #1

DATE REVIEWED: 22-AUG-97

SUBMISSION TYPE

Original

DOCUMENT DATE

10-MAR-97

CDER DATE

13-MAR-97

ASSIGNED DATE

NAME & ADDRESS OF APPLICANT:

Bausch & Lomb
Pharmaceutical Division
8500 Hidden River Parkway
Tampa, FL 33637

Contact: Christine Simmons, Pharm.D.

DRUG PRODUCT NAME

Proprietary: Lotemax™

Established: Loteprednol Etabonate Ophthalmic Suspension, 0.5%

Code Name/#: 82034-46-6

Chem.Type/Ther.Class: 1S/4041410

ANDA Suitability Petition/DESI/Patent Status:

PHARMACOL. CATEGORY: Ocular inflammation

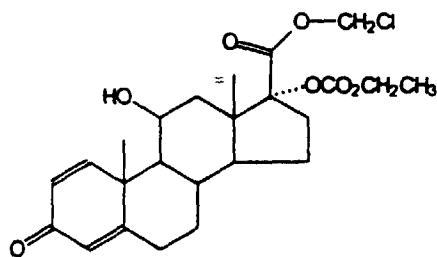
DOSAGE FORM: Ophthalmic suspension

STRENGTHS: 0.5%

ROUTE OF ADMINISTRATION: Topical (eye)

DISPENSED: ☒ Rx ☐ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA AND WEIGHT:



$C_{24}H_{31}ClO_7$

Mol. Wt.: 466.96

LOTEPREDNOL ETABONATE

Chloromethyl 17 α -[(ethoxycarbonyl)oxy]-
11 β -hydroxy-3-oxoandrosta-1,4-diene-17 β -carboxylate

NDA # 20-583

LOTEPREDNOL ETABONATE 0.5%

Bausch & Lomb/Pharmos

9/22/97
Allan Fenselau, Ph.D.
Review Chemist
Date
HFD-550

8-25-97
Hasmukh B. Patel
Chemistry Team Leader
Date
HFD-550

cc: Original NDA #20-583

Home District Office

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