

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

**NDA #: 20-841**

**REVIEW # 01**

**DATE REVIEWED: 19-FEB-98**

| <b><u>SUBMISSION TYPE</u></b> | <b><u>DOCUMENT DATE</u></b> | <b><u>CDER DATE</u></b> | <b><u>ASSIGNED DATE</u></b> |
|-------------------------------|-----------------------------|-------------------------|-----------------------------|
| Original                      | 07-MAR-97                   | 10-MAR-97               | 17-MAR-97                   |

**NAME & ADDRESS OF APPLICANT:**

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

Contact: Christine Simmons, Pharm.D.

**DRUG PRODUCT NAME**

Proprietary:

Established: Loteprednol Etabonate Ophthalmic Suspension, 0.5%

Code Name/#: CAS-82034-46-6

Chem.Type/Ther.Class: 1S / 404

ANDA Suitability Petition/DESI/Patent Status:

PHARMACOL. CATEGORY: Treatment of post-operative inflammation following ocular surgery

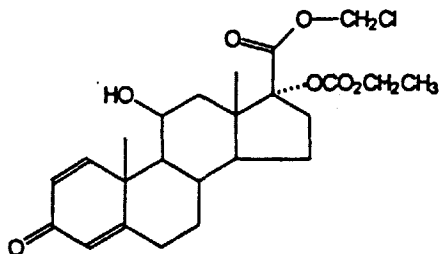
DOSAGE FORM: Ophthalmic suspension

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**

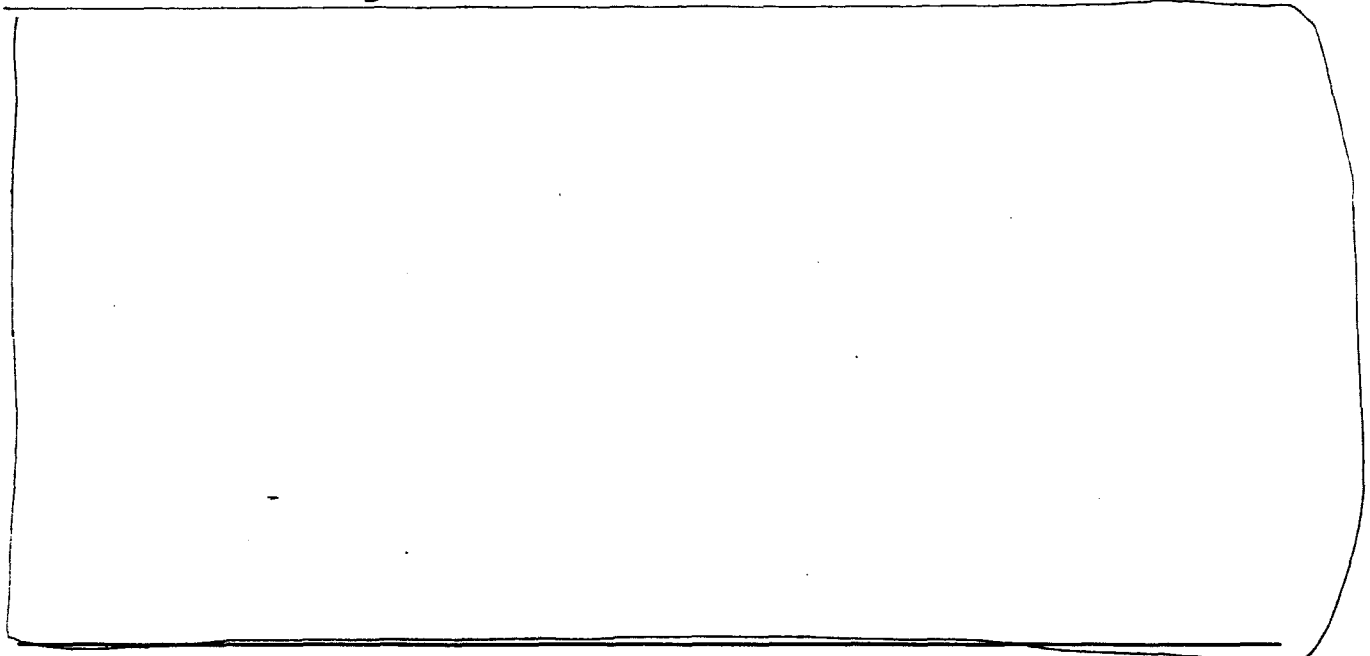
Chloromethyl 17 $\alpha$ -[(ethoxycarbonyl)oxy]-  
11 $\beta$ -hydroxy-3-oxoandrosta-1,4-diene-17 $\beta$ -carboxylate

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Bausch & Lomb/Pharmos

LOTEPREDNOL ETABONATE 0.5%

Ophthalmic Suspension



/S/

2/19/98

Allan Fenselau, Ph.D.  
Review Chemist

Date  
HFD-550

/S/

2-20-98

Hasmukh B. Patel  
Chemistry Team Leader

Date  
HFD-550

cc: Original NDA #20-841

Home District Office

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filename: n20841dp.rev

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APPEARS TO BE  
ORIGINAL