

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number **20-803**

CHEMISTRY REVIEW(S)

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

NDA #: 20-803

REVIEW # 01

DATE REVIEWED: 13-NOV-97

| <u>SUBMISSION TYPE</u> | <u>DOCUMENT DATE</u> | <u>CDER DATE</u> | <u>ASSIGNED DATE</u> |
|------------------------|----------------------|------------------|----------------------|
| Original | 03-FEB-97 | 04-FEB-97 | 07-FEB-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, 0.2%

Code Name/##: 82034-46-6

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

ANDA Suitability Petition/DESI/Patent Status:

PHARMACOL. CATEGORY: Treatment of signs and symptoms of seasonal allergic conjunctivitis

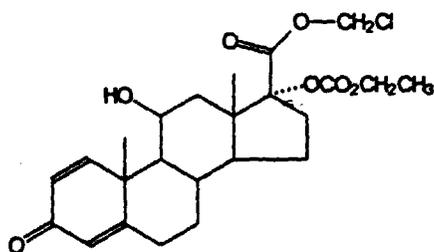
DOSAGE FORM: Ophthalmic suspension

STRENGTHS: 0.2%

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**

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LOTEPREDNOL ETABONATE 0.2%

Bausch & Lomb/Pharmos

INVESTIGATIONAL FORMULATIONS:

See Volume 2, pp. 02-010 to 02-015 of the original submission and p. 12 of this review.

ENVIRONMENTAL ASSESSMENT:

The review of the Environmental Assessment completed by Nancy Sager on 24-APR-97 recommended approval.

EVALUATION:

ACCEPTABLE

ESTABLISHMENT INSPECTIONS:

The following establishments have all been inspected and found to be in compliance:

EVALUATION:

ACCEPTABLE

METHODS VALIDATION:

An evaluation of the sponsor's "Methods Validation" is pending at this time.