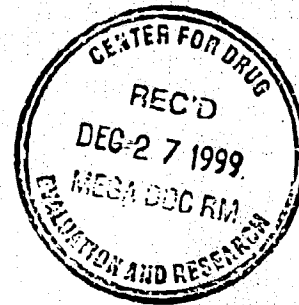


MICRO

REVIEW FOR HFD-550
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA

DEC 23 1999

December 22, 1999



A. 1. NDA 21-114

SPONSOR

Alcon Laboratories
6201 South Freeway
Fort Worth, Texas
76134-2099

2. PRODUCT NAMES: BETAXON (Levobetaxolol Hydrochloride Ophthalmic Suspension, 0.5%)
 3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Three sizes of plastic dropper container are available for this ophthalmic suspension: 5 mL, 10 mL and 15 mL.
 4. METHOD(S) OF STERILIZATION:
 5. PHARMACOLOGICAL CATEGORY: Beta-adrenergic blocking agent (with calcium channel blocking activity) for reducing intraocular pressure
 6. DRUG PRIORITY CLASSIFICATION: 2P
- B.
1. DATE OF INITIAL SUBMISSION: May 25, 1999
 2. DATE OF AMENDMENT: n/a
 3. RELATED DOCUMENTS: The application refers to ALCON's NDA for BETOPTIC® S Ophthalmic Suspension (NDA 19-845) for manufacturing processes.
 4. ASSIGNED FOR REVIEW: June 7, 1999

C. REMARKS: The application describes an ophthalmic suspension manufactured at the Alcon facility in Fort Worth, Texas, using the ASPEX area for [redacted] manufacturing.

D. CONCLUSIONS: The application is recommended for an APPROVABLE action from the perspective of product quality microbiology. Comments are provided at the end of this review, advising the applicant that documentation of the validation of an in-process control should be included in the submission.

APPEARS THIS WAY
ON ORIGINAL

[redacted] /S/

12-22-97

David Hussong, PhD.

[redacted] /S/

12/23/99

cc:

- HFD 160/Consult File
- HFD 550/CSO/Gorski and Zeccola
- HFD 830/Chemist/A. Fenselau, S. Tso and L. Ng
- HFD 805/D. Hussong

Drafted by: D. Hussong, 12/21/99
R/D initialed by: P. Cooney

Filename, d:\nda\21-114r1.DOC

APPEARS THIS WAY
ON ORIGINAL

REVIEW FOR HFD-550
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2 OF NDA

January 31, 2000


A. 1. NDA 21-114

SPONSOR

Alcon Laboratories
6201 South Freeway
Fort Worth, Texas
76134-2099

2. PRODUCT NAMES: BETAXON (Levobetaxolol Hydrochloride Ophthalmic Suspension, 0.5%)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Three sizes of plastic dropper container are available for this ophthalmic suspension: 5 mL, 10 mL and 15 mL.

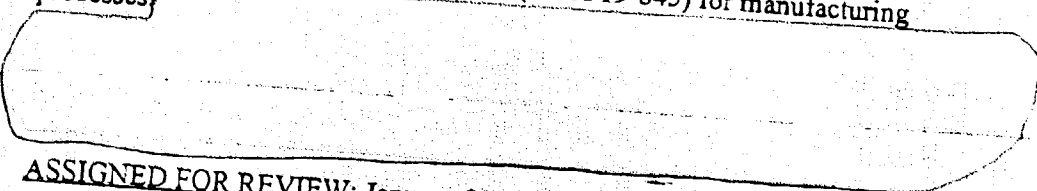
4. METHOD(S) OF STERILIZATION: 

5. PHARMACOLOGICAL CATEGORY: Beta-adrenergic blocking agent (with calcium channel blocking activity) for reducing intraocular pressure

6. DRUG PRIORITY CLASSIFICATION: 2P

B. 1. DATE OF INITIAL SUBMISSION: May 25, 1999

2. DATE OF AMENDMENT: January 24, 2000 (subject of this review)

3. RELATED DOCUMENTS: The application refers to ALCON's NDA for BETOPTIC® S Ophthalmic Suspension (NDA 19-845) for manufacturing processes; 

4. ASSIGNED FOR REVIEW: January 31, 2000

- C. REMARKS: The submission responds to a comment from Microbiologist's Review #1 and to chemistry deficiencies.

- D. CONCLUSIONS: The application is recommended for APPROVAL from the perspective of product quality microbiology.

APPEARS THIS WAY
ON ORIGINAL

1 - 31 - 2000

/S/

David Hussong, Ph.D.

/S/ 1/31/00

cc:

- HFD 160/Consult File
- HFD 550/CSO/Gorski and ~~Cooney~~
- HFD 830/Chemist/A. Fenselau, S. Tso and L. Ng
- HFD 805/D. Hussong

Drafted by: D. Hussong, 01/31/2000
R/D initialed by: P. Cooney

Filename, d:\nda\21-114\2.DOC

APPEARS THIS WAY
ON ORIGINAL