

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
75411

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS, HFD-620
Microbiology Review #2
May 12, 2000

A. 1. ANDA 75-411

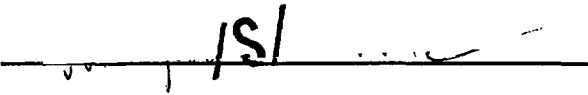
APPLICANT Novex Pharma
c/o Apotex Corporation
50 Lakeview Parkway Suite 127
Vernon Hills, IL 60061

2. PRODUCT NAME: Timolol Maleate Ophthalmic solution USP
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 0.25% solution
ophthalmic drops
4. METHOD(S) OF STERILIZATION:
5. PHARMACOLOGICAL CATEGORY: Beta-Adrenergic Receptor
Blocking Agent

- B. 1. DATE OF INITIAL SUBMISSION: July 2, 1998
(Received July 6, 1998)
2. DATE OF AMENDMENT: March 16, 2000
Subject of this review (Received March 20, 2000)
3. RELATED DOCUMENTS: None
4. ASSIGNED FOR REVIEW: May 12, 2000

C. REMARKS: The subject amendment provides for the response to microbiology deficiencies in the letter dated February 8, 2000.

D. CONCLUSIONS: The submission is recommended for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes".


Nrapendra Nath, Ph.D.

CC: Original ANDA
Duplicate ANDA
Division Copy
Field Copy
Drafted by N. Nath, HFD 600, V:\microrev\75-411a2.doc
Initialed by A. High

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Microbiology Comments to be Provided to the Applicant

ANDA: 75-411

APPLICANT: Novex Pharma

DRUG PRODUCT: Timolol Maleate Ophthalmic Solution USP 0.25%

Microbiology Deficiencies:

1. A specification for _____ must be set.

Please clearly identify your amendment to this facsimile as "RESPONSE TO MICROBIOLOGY DEFICIENCIES" in your cover letter.

Sincerely yours,

A handwritten signature in black ink, appearing to read "M. Fanning" with a stylized flourish.

Mary Fanning, M.D., Ph.D.
Associate Director of Medical Affairs
Office of Generic Drugs
Center for Drug Evaluation and Research

REVIEW FOR HFD-600
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF ANDA

December 15, 1999

A. 1. ANDA 75-411

SPONSOR Novex Pharma
c/o Apotex Corporation
50 Lakeview Parkway Suite 127
Vernon Hills, IL 60061

2. PRODUCT NAMES: Timolol Maleate

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 0.25% Solution,
Ophthalmic

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Beta-Adrenergic Receptor Blocking Agent

6. DRUG PRIORITY CLASSIFICATION: NA

B. 1. DATE OF INITIAL SUBMISSION: ~~July 6, 1998~~ ^{7/26/99}

2. DATE OF AMENDMENT: NA

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: September 24, 1999

C. REMARKS: The drug product is preserved, and into multi-use bottles.

D. CONCLUSIONS: This submission is **not approvable** on the basis of product quality microbiology. Please see "Microbiology Comments to be Provided to the Applicant" at the end of this review.

/S/

12-15-99

Bryan Riley, Ph.D.

PRC 12/20/99

cc:

- HFD 600/Consult File
- HFD 600/J. Buccine
- HFD 600/Rev Chemist
- HFD 805/Consult File
- HFD 805/B. Riley

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