

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

**75-117**

***APPLICATION NUMBER:***

**MICROBIOLOGY REVIEW**

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

A. 1. ANDA 75-412

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: 0.5% solution  
as 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)

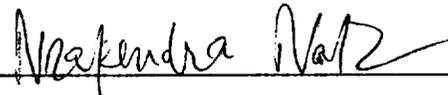
2. DATE OF AMENDMENT: March 16, 2000  
Subject of this review (received March 20, 2000)

3. RELATED DOCUMENTS: None

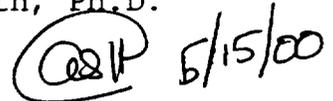
4. ASSIGNED FOR REVIEW: May 12, 2000

C. REMARKS: The subject amendment provides for the response to  
microbiology deficiencies in the letter dated February 10,  
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.

 @NH 5/15/00

cc:

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releasable.

Micro Rev. 2

5/12/00

OFFICE OF GENERIC DRUGS, HFD-620  
Microbiology Review #1  
January 5, 2000

A. 1. ANDA 75-412

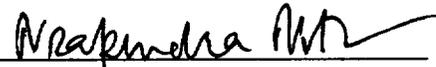
APPLICANT Novex Pharma  
c/o Apotex Corporation  
50 Lakeview Parkway Suite 127  
Vernon Hills, IL 60061

2. PRODUCT NAME: Timolol Maleate Ophthalmic solution USP  
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 0.5% solution as ophthalmic drops  
4. METHOD(S) OF STERILIZATION:  
5. PHARMACOLOGICAL CATEGORY: Beta-Adrenergic Receptor Blocking Agent

- B. 1. DATE OF INITIAL SUBMISSION: July 2, 1998  
Subject of this review (Received July 6, 1998)  
2. DATE OF AMENDMENT: ~~July 26, 1999~~  
3. RELATED DOCUMENTS:  
4. ASSIGNED FOR REVIEW: January 4, 2000

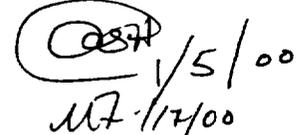
C. REMARKS:

- D. CONCLUSIONS: The submission is not recommended for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes" and "Microbiology Comments to be Provided to the Applicant" found at the end of this review.



Nrapendra Nath, Ph.D.

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h.

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Micro Review 10

1/25/00