

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

**75-412**

***APPLICATION NUMBER:***

**CHEMISTRY REVIEW(S)**

1. CHEMISTRY REVIEW NO. 4
2. ANDA # 75-412
3. NAME AND ADDRESS OF APPLICANT

Novex Pharma  
380 Elgin Mills Road East  
Richmond Hill, Ontario  
Canada L4C 5H2

4. LEGAL BASIS FOR SUBMISSION

In the opinion and to the best knowledge of the firm, there are no patents that claim the listed drug referred to in this application or that claim a use of the listed drug, and the drug product Timoptic is not entitled to a period of marketing exclusivity

5. SUPPLEMENT(s)
6. PROPRIETARY NAME

Original 7/2/98

7. NONPROPRIETARY NAME
8. SUPPLEMENT(s) PROVIDE(s) FOR:

Timolol Maleate, USP

9. AMENDMENTS AND OTHER DATES:

Amendment 7/22/99  
Amendment 3/16/00 – Microbiology  
Amendment 3/31/00 – Labeling  
Amendment 4/14/00 – Labeling  
Amendment 8/3/00

10. PHARMACOLOGICAL CATEGORY

Treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

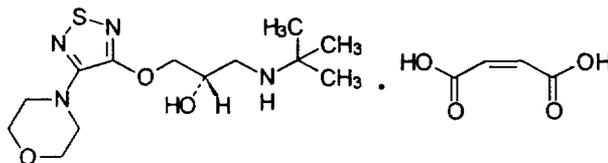
13. DOSAGE FORM                      14. POTENCY

Sterile Ophthalmic Solution              0.5%

15. CHEMICAL NAME AND STRUCTURE

Timolol Maleate. 2-Propanol, 1-[(1,1-dimethylethyl)amino]-3-[[4-(4-morpholinyl)-1,2,5-thiadiazol-3-yl]oxy]-, (S)-, (Z)-2-butendioate (1:1) (salt).

$C_{13}H_{24}N_4O_3S \cdot C_4H_4O_4$ . M.Wt. 432.5. 26921-17-5. Anti-adrenergic (Beta-receptor). USP 23, page 1553.



16. RECORDS AND REPORTS

17. COMMENTS

Microbiology is satisfactory 5/15/00

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER:

*N. Nashed*  
Nashed E. Nashed, Ph.D.

DATE COMPLETED:

*8/15/00*  
8/15/00

Supervisor: Paul Schwartz, Ph.D.

*PS 8/30/00*

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Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

Chem. Rev 4.

8/15/00