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RESEARCH**

APPLICATION NUMBER:

21-764

CHEMISTRY REVIEW(S)



NDA 21-764

Brimonidine Tartrate Ophthalmic Solution, 0.15%

Alcon, Inc.

Linda Ng, Ph.D.

**Division of Anti-inflammatory, Analgesic, and Ophthalmic
Drug Products**

HFD-550



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Chemistry Review Data Sheet

1. NDA 21-764
2. REVIEW #: 2
3. REVIEW DATE: 23-Feb-2005
4. REVIEWER: Linda Ng, Ph.D.
5. PREVIOUS DOCUMENTS:

Previous Documents

Original IND 64,330
Original NDA
Amendment
Amendment
Amendment

Document Date

27-Nov-2002
27-Apr-2004
11-May-2004
03-Jan-2005
20-Jan-2005

6. SUBMISSION(S) BEING REVIEWED:

Previous Documents

Amendment
Amendment
Amendment
Amendment
Amendment
Amendment

Document Date

15-Oct-2004
01-Feb-2005
03-Feb-2005
08-Feb-2005
22-Feb-2005
23-Feb-2005



CHEMISTRY REVIEW



Chemistry Review Data Sheet

7. NAME & ADDRESS OF APPLICANT:

Name: Alcon, Inc.
Address: P.O. Box 62
Bosch 69
CH-6331, Hunenberg
Switzerland
Alcon Research, Ltd.
Representative: 6201 South Freeway
Fort worth, Texas 76134-2099
Telephone: 817-551-4877
Facsimile: 817-551-4630

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: None
- b) Non-Proprietary Name (USAN): Brimonidine Tartrate
- c) Code Name/# (ONDC only):
- d) Chem. Type/Submission Priority (ONDC only):
 - Chem. Type: 3
 - Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: Filed under 505 (b)(2) of the Federal Food, Drug and Cosmetic Act: Allergan's ALPHAGAN P (brimonidine tartrate ophthalmic solution) 0.15%

10. PHARMACOL. CATEGORY: Alpha-2 adrenergic agonist

11. DOSAGE FORM: Solution

12. STRENGTH/POTENCY: 0.15% (one drop in the affected eye(s) three-times-daily, approximately 8 hours apart)

13. ROUTE OF ADMINISTRATION: Ophthalmic

14. Rx/OTC DISPENSED: Rx OTC

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