

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-770

CHEMISTRY REVIEW(S)



NDA 21-770

Brimonidine Purite® Ophthalmic Solution 0.1%

Allergan, Inc.

**Libaniel Rodriguez, Ph.D.
Division of Anti-infective and Ophthalmology
Products**

HFD-520



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P DRUG PRODUCT [Brimonidine Purite®, Ophthalmic Solution 0.1%]	10



Chemistry Review Data Sheet

1. NDA 21-770
2. REVIEW #: 2
3. REVIEW DATE: 29-JUL-2005
4. REVIEWER: Libaniel Rodriguez
5. PREVIOUS DOCUMENTS:

Previous Documents

IND 32-292
NDA 20-613
NDA 21-262
Original NDA 21-770
BC
BC
BC

Document Date

31-OCT-1988
31-AUG-1995
29-JUN-2000
27-MAY-2004
15-JUL-2004
17-SEP-2004
17-MAR-2005

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

AZ

Document Date

27-JUN-2005

7. NAME & ADDRESS OF APPLICANT:

Name: Allergan, Inc
2525 Dupont Drive
Address: P.O. Box 19534
Irvine, CA 92623-9534
Representative: Lewis Gryziewicz
Telephone: 714 246 4500



CHEMISTRY REVIEW



Chemistry Review Data Sheet

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: N/A
- b) Non-Proprietary Name (USAN): Brimonidine Tartrate Ophthalmic Solution 0.1%
- c) Code Name/# (ONDC only): AGN 190342
- d) Chem. Type/Submission Priority (ONDC only):
 - Chem. Type: 3
 - Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: 505(b)(1)

10. PHARMACOL. CATEGORY: Alpha 2 agonist

11. DOSAGE FORM: Ophthalmic Solution

12. STRENGTH/POTENCY: 0.1%

13. ROUTE OF ADMINISTRATION: Topical (one drop three times per day per eye)

14. Rx/OTC DISPENSED: Rx OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

SPOTS product – Form Completed

Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

Brimonidine tartrate, (1) 6-Quinoxaline, 5-bromo-*N*-(4,5-dihydro-1 *H*-imidazol-2-yl)-, [*S*-(*R*^{*}*R*^{*})]-2-3-dihydroxybutanedioate (1:1)

(2) 5-Bromo-6-(2-imidazolin-2-ylamino)quinoxaline D-tartrate (1: 1)
C₁₁H₁₀BrN₅•C₄H₆O₆. MW 442.22. CAS Registry Number 79570-19-7.

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