

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 20-816

MICROBIOLOGY REVIEW(S)

JUN 5 1997

REVIEW FOR HFD-550

**OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review #1 of NDA 20-816
June 3, 1997**

- A. 1. APPLICATION NUMBER:** 20-816
- APPLICANT:** Alcon Laboratories, Inc.
P.O. Box 6600
Fort Worth, Texas
- 2. PRODUCT NAME:** AZOPT™ (brinzolamide, 1%)
- 3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:** Sterile, multi-dose, brinzolamide ophthalmic suspension 1% for topical (ocular) administration. The drug product will be supplied in DROP-TAINER® LDPE bottles.
- 4. METHOD OF STERILIZATION:**
- 5. PHARMALOGICAL CATAGORY and/or PRINCIPLE INDICATION:** Carbonic anhydrase inhibitor indicated for treatment of intraocular pressure in patients with ocular hypertension or open-angle glaucoma.
- 6. DRUG PRIORITY CLASSIFICATION:** not provided
- B. 1. DATE OF INITIAL SUBMISSION:** Jan. 26, 1997
- 2. RELATED DOCUMENTS:**
- 3. DATE OF CONSULT:** Feb. 3, 1997
- 4. ASSIGNED FOR REVIEW:** Feb. 7, 1997
- C. REMARKS:** The entire Part 7 (Microbiology) dossier was provided on CD-ROM using Word Perfect 5.1 format. Hard copies of volumes 1.1 (summary) and 1.50 (sterilization validation) also provided.

D. CONCLUSIONS:

The submission is recommended for approval for microbiology issues concerning sterility assurance. Specific comments are provided in "E. Review Notes".



6/3/97

Neal Sweeney, Ph.D.

cc: NDA 20-816
HFD-550/Division File
HFD-550/Chemist/H. Patel
HFD-550/CSO/L. Lobianco
HFD-805/Consult File/N. Sweeney

Drafted by: N. Sweeney, June 3, 1997
R/D initialed by P. Cooney, June 3, 1997



for PH Cooney 6-5-97

**APPEARS THIS WAY
ON ORIGINAL**