# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

# ANDA 65-024

# BIOEQUIVALENCE REVIEW(S)

Gentamicin Sulfate
Ophthalmic Ointment, 0.3%, USP
ANDA # 65-024
Reviewer: Chandra S. Chaurasia

Altana, Inc.
Melville, NY 11747
Submission Date:
August 04, 1998

# REVIEW OF A WAIVER REQUEST

## BACKGROUND

1. The firm has requested a waiver of *in vivo* bioequivalence study requirements for its drug product, Gentamicin Sulfate Ophthalmic Ointment, 0.3%, USP in accordance with the provisions established in 21 CFR §320.22(b). The reference listed drug (RLD) is Garamycin® 0.3% Ophthalmic Ointment (Schering, NDA # 50-425).

2. The drug is indicated for the topical treatment of ocular bacterial infections.

## FORMULATION COMPARISON

Components and composition of the test and the reference products are as follows:

| Comparison of Formulations | | |
|---|---|---|
| Ingredient | Test Product (mg/g) | RLD (mg/g) |
| Gentamicin sulfate as base | 3.0 | 3.0 |
| Methylparaben NF | N/A | [redacted] |
| Propylparaben NF | N/A | [redacted] |
| Mineral Oil | [redacted] | N/A |
| White Petrolatum | [redacted] | N/A |
| Petrolatum | N/A | [redacted] |

**COMMENTS**

1. The drug is classified "AT" in the list of the "Approved Drug Products with Therapeutic Equivalence Evaluation".

2. The test drug product contains the same active ingredient and in the same concentration as the currently approved RLD, and is intended for topical ophthalmic administration.

3. Although Mineral Oil is not included in the formulation of the RLD, this excipient [redacted] has been used in the same concentration as in the test drug (i.e., [redacted]%) in CIBA Vision's Gentamicin 0.3% Ophthalmic Ointment (approved 7/26/84, NDA 62-501).

4. The test drug formulation does not contain any preservative. However, in their Antimicrobial Effectiveness test done sequentially on days 0, 7, 14, 21 and 28, the firm has shown the test drug to be adequately preserved as formulated. Additionally, the earlier approved CIBA Vision's Gentamicin Sulfate Ophthalmic Ointment (approved 7/26/84, NDA 62-501) also does not contain any preservative in its formulation.

5. The ointment base in the reference drug is petrolatum, and that in the test drug is white petrolatum. It is to be noted that white petrolatum is a wholly or partially decolorized petrolatum and has identical compendial requirements as that of petrolatum (USP 23 NF 18, 1995).

6. The waiver of *in vivo* bioequivalence study requirements may be granted based on 21 CFR § 320.22(b) of the Bioavailability/Bioequivalence Regulations.

Note: *Information cited in items 3 and 4 above are not to be released through FOI.*

**RECOMMENDATION**

The Division of Bioequivalence agrees that the information submitted by Altana, Inc. demonstrates that its Gentamicin Sulfate Ophthalmic Ointment, 0.3%, USP, falls under 21 CFR § 320.22(b) of Bioavailability/Bioequivalence Regulations. The Division of Bioequivalence recommends that the waiver of *in vivo* bioequivalence study be granted. From the bioequivalence point of view, the Division of Bioequivalence deems Altana's Gentamicin Sulfate Ophthalmic Ointment, 0.3%, USP to be bioequivalent to the reference listed product, Schering's Garamycin®, Ophthalmic Ointment, 0.3%, USP.

CS Chaurasia

Chandra S. Chaurasia
Division of Bioequivalence
Review Branch I

RD INITIALLED YHUANG
FT INITIALLED YHUANG _____ Date: 10/21/98

Concur _____ Date: 10/27/98

Dale P. Conner, Pharm. D.
Director, Division of Bioequivalence

BIOEQUIVALENCY COMMENTS

ANDA: # 65-024 APPLICANT: Altana, Inc.

DRUG PRODUCT: Gentamicin Sulfate Ointment, 0.3%, USP

The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,

Dale P. Conner

Dale P. Conner, Pharm. D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

CC: ANDA # 65-024
ANDA DUPLICATE
DIVISION FILE
HFD-650/Bio Secretary-Bio Drug File
HFD-652/C. Chaurasia

Endorsements:
HFD-652/C. Chaurasia CC 10/21/98
HFD-652/YC Huang WH 10/21/98
HFD-650/D. Conner DB 10/27/98

X: \NEW\FIRMSAM\ALTANA\LTRS&REV\65024W.898
PRINTED IN FINAL ON 10/21/98

BIOEQUIVALENCY - ACCEPTABLE

**WAIVER (WAI)**

Strength: 0.3%
**Outcome: AC**

**Outcome Decisions: Acceptable**
**AC - Acceptable**

WINBIO COMMENTS: The waiver is granted

# OFFICE OF GENERIC DRUGS

# DIVISION OF BIOEQUIVALENCE

**ANDA # 65-024** **SPONSOR:** Altana, Inc.

**DRUG & DOSAGE FORM:** Gentamicin Sulfate Ophthalmic Ointment

**STRENGTH:** 0.3%, 3.5 g

**TYPE OF STUDY:** SD SDF MULT OTHER Waiver Request

**STUDY SITE:** NA **CLINICAL:** NA **ANALYTICAL:** NA

---

**STUDY SUMMARY:**
The Division of Bioequivalence agrees that the information submitted by Altana, Inc. demonstrates that its Gentamicin Sulfate Ophthalmic Ointment, 0.3%, USP, falls under 21 CFR § 320.22(b)of Bioavailability/Bioequivalence Regulations. The Division of Bioequivalence recommends that the waiver of *in vivo* bioequivalence study be granted.

---

**PRIMARY REVIEWER:** Chandra S. Chaurasia, Ph.D. **BRANCH:** I
**INITIAL:** CS Chaurasia **DATE:** 10/21/98

Team Leader
**~~BRANCH CHIEF~~:** Yih Chain Huang, Ph.D. **BRANCH:** I
**INITIAL:** YCH **DATE:** 10/21/98

**DIRECTOR, DIVISION OF BIOEQUIVALENCE:** Dale P. Conner, Pharm.D.
**INITIAL:** DPC **DATE:** 10/27/98

**DIRECTOR, OFFICE OF GENERIC DRUGS:**
**INITIAL:** _____ **DATE:** _____