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APPLICATION NUMBER:

74511

BIOEQUIVALENCY REVIEW(S)

JAN 18 1995

Sulfacetamide Sodium and
Prednisolone Sodium Phosphate 10%/0.25%
Ophthalmic Solution, USP.
ANDA #74-511
Reviewer: Sikta Pradhan, Ph.D.
WP#74511W.694

Akorn, Inc.
Decatur, IL
Submission Date:
June 24, 1994

Review of a Waiver Request

Sulfacetamide Sodium and Prednisolone Sodium Phosphate (USP, 10%/0.25%) is a topical ophthalmic solution intended for local therapeutic effects. The firm has requested a waiver of in vivo bioequivalence study requirements for its drug product, Sulfacetamide Sodium and Prednisolone Sodium Phosphate Ophthalmic Solution, USP, 10%/0.25%

Table 1

<u>Formulations</u>	<u>Test</u> <u>(Sulster™)</u> <u>(mg/mL)</u>	<u>Reference (Iolab)</u> <u>Vasocidin[®]</u> <u>(mg/mL)</u>	<u>Steris Lab</u> <u>(First Generic)</u> <u>(mg/mL)</u>
✓ Sulfacetamide Sodium, Monohydrate, USP	100.0	100.0	100.0
✓ Prednisolone			
✓ Sodium Phosphate, USP			
✓ Thimerosal, USP			
✓ Edetate Disodium, USP			
✓ Boric Acid, USP			
✓ Poloxamer 407, NF			
✓ Hydrochloric Acid, NF			
✓ Sodium hydroxide			
✓ Purified Water			

Comments

1. The compositions of the test, reference and first approved generic products are presented in table 1. Both test and reference products contain same amount of active and inactive drug ingredients except Poloxamer 407, and the amount of this inactive ingredient present in the test is same as that present in the first approved generic product.
2. The route of administration, dosage form, and strength of the proposed Akorn product are identical with that of the reference listed drug Vasocidin^R marketed by IOLAB.

Recommendation:

1. The proposed formulation of the test product, Sulfacetamide Sodium and Prednisolone Sodium Phosphate (USP, 10%/0.25%) Ophthalmic Solution manufactured by Akorn, Inc., met the FDA regulations set forth for an in vivo bioavailability/bioequivalence study waiver of a topical ophthalmic product. The test product is therefore deemed bioequivalent to the reference product, Vasocidin^R manufactured by Iolab.
2. From the bioavailability/bioequivalence point of view the proposed Akorn formulation is acceptable and the waiver of in-vivo bioequivalence study on the test product has been granted.
3. Application is acceptable.

/S/

Sikta Pradhan, Ph. D.
Division of Bioequivalence
Review Branch I

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/S/

Date: 1/18/95

cc: ANDA # 74-511 (original, duplicate), HFD-600 (Hare), HFD-630, HFD-652 (Mhatre, Pradhan), HFC-130 (JAllen), Drug File

SP/011795/ntp/WP#74511W.694