

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

40374

BIOEQUIVALENCY REVIEW(S)

Triamcinolone Acetonide Ointment USP, 025%
ANDA #40-374
Reviewer S. P. Shrivastava

Thames Pharmacal Co., Inc.
Ronkonkoma, NY
Submission Date:

~~June 1, 1999~~
May 22, 2001

AMENDMENT TO THE REVIEW DATED 7-23-1999

Background information:

1. There are two ANDAs from Thames Pharmacal on triamcinolone acetonide (TA) ointment.
2. The ANDA 40-374 is for strength 0.025% strength (submission date 6-1-1999) that was reviewed by Dr. Shrivastava and was found acceptable by the Division of Bioequivalence (DBE) on 7-23-1999.
3. The ANDA 40-386 is for 0.5% strength(submission date 8-31-2000) that was reviewed by Dr. Pradhan and was found acceptable by the DBE on 9-18-2000.
4. At the time of the above mentioned reviews, the RLDs for 0.5% and 0.025% ointments were from two different firms (Aristocort^R for 0.5% ointment from Fujisawa and KenologR for 0.025% from Apothecan/Westwood-Squibb).
5. Currently, Clay Park's ointments (0.025% - ANDA 87356, 0.1% - ANDA 87357, and 0.5% - ANDA 87385) are the RLDs for triamcinolone acetonide (TA) ointments.
6. BECAUSE OF THE CHANGE IN THE RLD, THIS AMENDMENT IS NECESSARY
7. TA ointment is a pre-62 drug product (coded AT in the Orange Book) does not need a biostudy and does not need to be formulated Q₁ and Q₂ same as the RLD. It is acceptable under 21CFR 320.24(b)(6) and deemed bioequivalent to the RLD.

The formulations of the ointments are shown below.

Ingredient	Thames Pharmacal	Clay-Park
✓ 1. Triamcinolone Acetonide, USP	✓ 0.025%	0.025%
✓ 2. Light mineral oil		
✓ 3. White petrolatum		

RECOMMENDATION

The Division of Bioequivalence agrees that the information submitted by Thames Pharmacal Co., Inc. demonstrates that its triamcinolone acetonide ointment, 0.025% falls under CFR 320.24(b)(6) of the Bioavailability/Bioequivalence Regulations. The 0.025% topical ointment of the test product is deemed bioequivalent to Triamcinolone Acetonide Ointment, 0.025% manufactured by Clay-Park.

The firm should be informed of the recommendation.

ISI

S. P. Shrivastava, Ph.D.
Review Branch II
Division of Bioequivalence

RD INITIALED S.NERURKAR
FT INITIALED S.NERURKAR

ISI
Date 5/23/2001

ISI

Concur: _____ Date 5/23/2001

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

cc: ANDA #'S 40-374 , Amendment to review dated 7-23-1999, HFD-655 (SShrivastava, SNerurkar), Drug File

SPS/072099/WD#40374wr.699

* Please make a US document

**OFFICE OF GENERIC DRUGS
DIVISION OF BIOEQUIVALENCE**

ANDA # : 40-374

SPONSOR : Thames Pharmacal Co., Inc

DRUG AND DOSAGE FORM :

Triamcinolone Acetonide Ointment

STRENGTH(S) :

0.025%

TYPES OF STUDIES :

Waiver, Pre-62 Drug

CLINICAL STUDY SITE(S) :

N/A

ANALYTICAL SITE(S) :

N/A

STUDY SUMMARY : Waiver; Pre-62 Drug; AT Rated

DISSOLUTION : N/A

DSI INSPECTION STATUS

Inspection needed: No	Inspection status:	Inspection results:
First Generic <u> No </u>	Inspection requested: (date)	
New facility <u> </u>	Inspection completed: (date)	
For cause <u> </u>		
Other <u> </u>		

PRIMARY REVIEWER : S. P. Shrivastava BRANCH : II

INITIAL SP

DATE : 7/20/99

TEAM LEADER : S Nerurkar BRANCH : II

INITIAL : SN

DATE : 7/22/1999

DIRECTOR, DIVISION OF BIOEQUIVALENCE : DALE P. CONNER, Pharm. D.

INITIAL : DC

DATE : 7/23/99

BIOEQUIVALENCY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 40-374

APPLICANT: Thames Pharmacal Co., Inc.

DRUG PRODUCT:

Triamcinolone Acetonide Ointment, 0.025%

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,

(
-
/ST
-
)
.

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

CC: ANDA
ANDA DUPLICATE
DIVISION FILE
HFD-651/ Bio Drug File
HFD-655/ Reviewer

Endorsements: (Final with Dates)
HFD-655/ SShrivastava
HFD-655/ Bio team Leader
HFD-650/ D. Conner

563 7/21/99 *AW* 7/22/99
DM 7/26/99

BIOEQUIVALENCY - ACCEPTABLE

submission date: 6/1/99

1. WAIVER (WAI)

Strengths: 0.025%

✓ Outcome: AC

Outcome Decisions: AC - Acceptable

Triamcinolone Acetonide Ointment USP, 0.025%
ANDA #40-374
Reviewer: S. P. Shrivastava
WD #40374w.699

Thames Pharmacal Co., Inc.
Ronkonkoma, NY
Submission Date:
June 1, 1999

REVIEW OF ONE WAIVER REQUEST

The firm has requested a waiver of *in-vivo* bioequivalence study requirements for its 0.025 triamcinolone acetonide ointment. The product is indicated for skin rashes and itches. The listed reference product is 0.025% Kenalog® Ointment manufactured by Westwood-Squibb Pharmaceuticals.

COMMENTS

1. The product is a pre-1962 drug, and is coded AT in the Therapeutic Equivalence List, suggesting no known or suspected bioequivalence problems.
2. The reference and test products are intended for identical indications.
3. The test product contains the same active ingredient in identical strength to the corresponding reference product. The composition of the test and reference formulations are as follows:

[Not for Release Under F.O.I.]

<u>Ingredient</u>	<u>Test, 0.025%</u> <u>(mg/g)</u>	<u>Ref., 0.025%</u> <u>(mg/g)</u>
✓ Triamcinolone Acetonide, USP	0.25	0.25
✓ Light Mineral Oil		
✓ White Petrolatum, USP		

These adequately establish bioequivalence of the product under CFR 320.24(b)(6).

RECOMMENDATION

The Division of Bioequivalence agrees that the information submitted by Thames Pharmacal Co., Inc. demonstrates that its triamcinolone acetonide ointment, 0.025% falls under CFR 320.24(b)(6) of the Bioavailability/Bioequivalence Regulations. The 0.025% topical ointment of the test product is deemed bioequivalent to Kenalog® Ointment, 0.025% manufactured by Westwood-Squibb Pharmaceuticals.

The firm should be informed of the recommendation.

ISI
S. P. Shrivastava, Ph.D.
Review Branch II
Division of Bioequivalence

RD INITIALED S.NERURKAR
FT INITIALED S.NERURKAR

ISI
Date 7/22/1999

Concur:

ISI

Date 7/23/99

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

cc: ANDA #S 40-374 Original, HFD-655 (SShrivastava, SNerurkar), Drug File