

# **CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***  
**ANDA 61212**

**Name:** Bacitracin Ointment

**Sponsor:** Perrigo Company of Tennessee, Inc.  
(Formerly Kasco-Efco Laboratories, Inc.)

**Approval Date:** November 9, 1971

# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***  
**ANDA 61212**

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# **CENTER FOR DRUG EVALUATION AND RESEARCH**

***APPLICATION NUMBER:***

**ANDA 61212**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
ROCKVILLE, MARYLAND 20852

November 9, 1971

Our reference:

61-213 (146e.402)

Bacitracin Ointment Topical

61-212 (146e.402)

Bacitracin Ointment Ophthalmic

Stanley Shaffer  
President  
Kasco-Efco Laboratories, Inc.  
Post Office Box 73  
Cantiague Rock Road  
Hicksville, New York, 11802

Dear Mr. Shaffer:

Our laboratories have completed their assays on the samples from three batches of Bacitracin Ointment received by this office on September 7, 1971.

We have completed our review of your Form 6 application and have completed the evaluation of our laboratory assay results.

Your Form 6 application to manufacture Bacitracin Ointment, Topical and Ophthalmic, is approved.

The expiration date to be used on both of the aforementioned dosage forms is thirty-six (36) months. At such time that you feel that sufficient data have been accumulated to support a longer expiration date, you may submit such data, together with aged samples from at least three production batches (both topical and ophthalmic), to this office with a request to extend the expiration date for these products.

Your Form 6 for these products should be updated, when appropriate, to provide for changes in manufacturing and/or laboratory facilities, manufacturing and/or laboratory procedures, scientific and/or supervisory personnel, labeling, formulations, etc.

A signed copy of your December 30, 1970 submission, together with copies of all subsequent correspondence through September 13, 1971, is enclosed.

In addition to the aforementioned, we have the following suggestion and comments:

1. We feel that whenever possible, an identity test in addition to any other test should be performed on every raw material received and used by your firm in the manufacture of finished dosage forms, whether or not you receive a protocol from the firm manufacturing the raw material.

2. We think it would be wise, particularly on your ophthalmic ointment, to test the finished product for pathogenic organisms. It is very likely that, in the near future, antibiotic containing ophthalmic ointments will be required to be sterile.

3.

(b) (4)

(b) (4)

Sincerely yours,

Milton Eisler  
Certifiable Drug Review Staff (BD-145)  
Division of Anti-Infective Drug Products

Enclosure

cc: NYK-DO  
BD-145  
BD-145/OD  
BD-430/lab.  
MEisler:hb

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*  
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**CHEMISTRY REVIEWS**


CHEMISTRY REVIEW NOTES  
September 23, 1971

RE: Addenda to Form 6's for  
Bacitracin topical and  
ophthalmic ointments,  
Kasco-Efco, submitted  
August 2, 1971

The additional information on raw ingredient testing is  
satisfactory.

Chemical testing on the finished product is limited to Karl  
Fischer moisture and our results are satisfactory. The company  
did not submit moisture data.

(b) (4)

  
Lola G. Wayland  
Lola G. Wayland  
Chemist, ACB

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*  
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**MICROBIOLOGY REVIEWS**



MICROBIOLOGICAL ASSAY REVIEW NOTES

Re: Kasco-Efco Form 6  
#61212 Bac. ophthalmic ointment  
#61-213 Bac. topical ointment

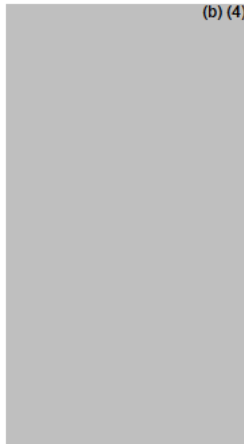
Label claim = 500 u/gm.

Subject ointments were submitted in support of Form 6  
were assayed according to directions in 21 CFR 141e.402(a).  
(b) (4)

Batch no.

9992  
(M-5006)

Tube 1

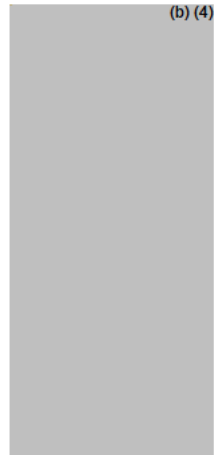


Day 1

Day 2

Day 3

Day 4



Average = 456 u/gm.

509 u/gm.

Batch no.

0232  
(M-5007)

Tube 1



Day 1

Day 2

Day 3

Day 4



Average = 474 u/gm.

509 u/gm.

Microbiological Assay Review Notes

Re: Kasco-Efco Form 6

#61-212 Bac. ophthalmic ointment

#61-213 Bac. topical ointment

Label claim = 500 u/gm.

Batch no.

8321  
(M-5008)

Tube 1  
2  
3  
4

(b) (4)

Day 1

(b) (4)

Tube 1  
2  
3  
4

Day 2

Tube 1  
2  
3  
4

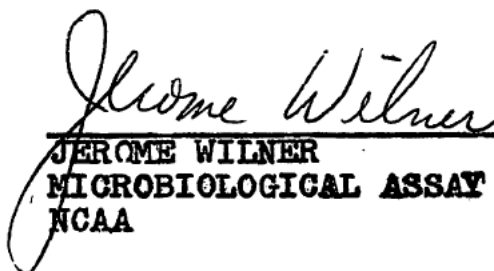
Day 3

Tube 1  
2  
3  
4

Day 4

Average = 458 u/gm.

494 u/gm.

  
JEROME WILNER  
MICROBIOLOGICAL ASSAY BRANCH  
NCAA

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*  
**ANDA 61212**

**ADMINISTRATIVE and CORRESPONDENCE**  
**DOCUMENTS**

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

*Date:* Oct. 18, 1971  
*Reply to*  
*Attn of:* B. Arret, Acting Deputy Director, NCAA - BD-431  
*Subject:* FORM 6  
*To:* Mr. Milton Eisler

Re: Bacitracin Ophthalmic Ointment  
Form 6 - #61-212  
and Bacitracin topical ointment  
Form 6 - #61-213  
Submitted by Kasco-Efco Labs  
Sept. 2, 1971

The information on raw ingredient testing is satisfactory. Moisture determinations by Karl Fisher for the two products are satisfactory as noted in the attached memorandum from Mrs. Wayland.

(b) (4)

*As he to  
file on this  
disagree  
MA*

Results of the three batches examined as noted in the attached memorandum from Mr. Wilner indicates that they are essentially 100 percent of label.

*Bernard Arret*  
B. Arret

cc:  
Dr. Banes - BD-400  
Dr. Weiss  
Mr. Arret  
Mr. Wilner  
Mrs. Wayland  
Mr. Selzer  
DA Lab

Att.-

July 16, 1971

Our reference:

61-213 (146e.402) ✓

Bacitracin Ointment Topical

61-212 (146e.402)

Bacitracin Ointment Ophthalmic

Pending Form 6's

Mr. Stanley Shaffer  
Kasco-Efco Laboratories, Inc.  
Post Office Box 730  
Cantiague Rock Road  
Hicksville, New York 11802

Dear Mr. Shaffer:

The review of your Form 6 application submitted December 30, 1970 and updated March 19, 1971, for the aforementioned reference products has been completed and we have the following comments:

1. When raw materials are characterized as compendia ingredients, unless you specify which tests your control laboratories perform, we must assume that they do all the tests indicated in the particular compendia.
2. Please provide us with an updated package insert for your Bacitracin Ophthalmic Ointment.
3. Before we can assign an equitable expiration date to both the Topical and Ophthalmic Bacitracin Ointments, our laboratories require aged samples to assay along with Kasco-Efco test results for each sample submitted. Expiration dates which have been authorized in the past on the basis of company data only for a product, must now also have FDA laboratories test samples from three ~~production~~\* batches of the aged product, to determine if FDA laboratories can corroborate company data for each batch. I would suggest that you provide us with samples\*\* from two lots that are 2 to 3 years old and from two lots that are 3 to 4 years old, for our laboratories to assay. There will be no charge for these test.

Page 2-- Mr. Stanley Shaffer

When we have received your response to our comments, and the samples requested, we will give further consideration to the approval of your Form 6 application for Bacitracin Topical and Bacitracin Ophthalmic Ointments.

Sincerely yours,

Milton Eisler  
Certifiable Drug Review Staff (BD-145)  
Division of Anti-Infective Drug Products

\* If available or possible  
\*\* One tube from each topical batch-  
as many from ophthalmic batches as  
are available.

cc:

BD-145

BD-145/OD

BD-430/lab. R/D init. RDH 7/16/71

MEisler:hb

April 19, 1971

Our references:

61-213 (146a.402)

Bacitracin Ointment Topical

61-212 (146a.402)

Bacitracin Ointment Ophthalmic

Mr. Stanley Shaffer, President  
Kasco-Efco Laboratories, Inc.  
P. O. Box 730  
Gentle Rock Road  
Richsville, New York 11802

81582  
81583  
81584

Dear Mr. Shaffer:

Our laboratories have completed their assays on the samples from the batches of Bacitracin Topical and Bacitracin Ophthalmic Ointment that we received from you on March 25, 1971.

We have evaluated all of the available data and conclude that they do not substantiate your September 25, 1970, request to extend the expiration date for the aforementioned products.

We performed twelve assays, four assays on each of three of the batches, without a single assay result exceeding the minimum potency required. Batch 6869 averaged 373 units/gram (74.6% of label), batch 7127 averaged 364 units/gram (72.8% of label), and batch 7576 averaged 372 units/gram (74.4% of label).

Our laboratories performed twelve (12) microbiological plate assays at \$16.00\* per assay and six (6) Karl Fischer moisture determinations at \$8.40\* per test for a total cost of \$252.00, and your account will be billed for this amount.

Sincerely yours,

cc:

NYK-DO

BD-145 (2) ✓

BB-145/OD

Fee Clerk (2)

BD-430/Lab

\* includes the 20% surcharge.

cc: TEHerman

DAPP:HEBislor:r

Milton Eisler

Certifiable Drug Review Unit (BD-145)

Division of Anti-Infective Drug Products

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION


Date: April 14, 1971

Reply to  
Attn of: BD-430

Subject: Kasco-Efco Bacitracin Ointment

To: Milton Eisler  
Certifiable Drug Review Staff  
Division of Anti-infective Drug Products  
BD-145

We have completed testing batches of subject product submitted with your memorandum of March 26, 1971. Results are reported on attached DA cards. Please note that in all instances the potency is less than 80% of label claim. We did not do the tests for metal particles since 10 to 30 tubes are required for each test. However, in view of low potencies, it would not be necessary to perform the test for metal particles.

  
Amiel Kirshbaum, Director  
National Center for Antibiotic Analysis  
Office of Pharmaceutical Research & Testing  
Bureau of Drugs

Attachments:  
Incoming corres.  
DA cards S1582/84



## MEMO RECORD

AVOID ERRORS  
PUT IT IN WRITING

DATE

MARCH 26, 1

FROM:

MILTON EISLER BD-145

OFFICE

D.S.E.

TO:

DR. PETER WEISS BD-431

DIVISION

D.A.D.P./C.D.

SUBJECT:

KASCO-EFCO - BACITRACIN OINTMENT

SUMMARY

TOPICAL AND OPHTHALMIC - NEW FORM - 6

These samples will serve both as exhibit samples and samples in support of a request to extend the expiration date for this product from [REDACTED] to [REDACTED].  
Some data as well as the samples have been submitted.

#481 Batch

Container size

Potency

defined

7276-Top

1 tube + 4oz

500u/g

7876-Top

2 tubes + 1/2oz

500u/g

7127-OPHTH.

8 tubes + 1/8oz

500u/g

6869-Top

2 tubes + 1oz

500u/g

Please run an appropriate number

1. of potency assays and at least 3 batches included  
Ophthalmic
2. moisture assays on at least 3 batches included  
Ophthalmic
3. Please consider whether it might not be appropriate to run metal particles on several of the ophthalmics.

SIGNATURE

Milton Eisler

DOCUMENT NUMBER

146c