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SUPERSEDING
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MILITARY SPECIFICATION

ZINC BACITRACIN, HYDROCORTISONE, NEOMYCIN SULFATE, AND POLYMYXIN B SULFATE OINTMENT

This specification is mandatory for use by all Departments and Agencies of the Department of Defense.

1. SCOPE

1.1 This specification covers Zinc Bacitracin, Hydrocortisone, Neomycin Sulfate, and Polymyxin B Sulfate Ointment in 1/8 ounce (3.5 Grams) in tubes. Potency: 60 Months. (See 6.2).

2. APPLICABLE DOCUMENT

2.1 The following documents, of the issue in effect on date of invitation for bids or request for proposal, form a part of this specification to the extent specified herein:

SPECIFICATIONS

Federal

PPP-C-00186a Containers, Packaging and Packing for Drugs, Chemicals, and Pharmaceuticals.

STANDARDS

Military

MIL-STD-105 Sampling Procedures and Tables for Inspection by Attributes.
MIL-STD-129 Marking for Shipment and Storage.

(Copies of specification and standards required by contractors in connection with specific procurement functions should be obtained from the procuring activity or as directed by the contracting officer.)

2.2 Other publications. The following documents form a part of this specification to the extent specified herein. Unless otherwise indicated, the issue in effect on date of invitation for bids or request for proposal shall apply.

AMERICAN PHARMACEUTICAL ASSOCIATION PUBLICATION

National Formulary.

(Application for copies should be addressed to the Mack Publishing Company, Easton, Pa. 18042.)

U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION

Federal Food, Drug, and Cosmetic Act and
Regulations Promulgated Thereunder.

(Application for copies should be addressed to the Food and Drug Administration, Washington, D. C. 20204.)

U. S. PHARMACOPEIAL CONVENTION, INC.

Pharmacopeia of the United States.

(Application for copies should be addressed to the Mack Publishing Company, Easton, Pa. 18042.)

3. REQUIREMENTS

3.1 Material. Shall be a topical and ophthalmic ointment containing in each gram of ointment, within the designated assay limits for the ointment, the following:

Polymyxin B (as Polymyxin B Sulfate)- - -	5000 units
Bacitracin (as Zinc Bacitracin) - - - - -	400 units
Neomycin (as Neomycin Sulfate)- - - - - -	3.5 mg
Hydrocortisone- - - - - - - - - - - - - -	10 mg
White Petrolatum (low melting) q.s.- - -	1 gram

Shall be suitable for topical and ophthalmic use.

3.1.1 The Polymyxin B Sulfate, Zinc Bacitracin, Neomycin Sulfate, and Hydrocortisone shall be thoroughly mixed and suspended as finely divided particles in a base consisting of White Petrolatum.

3.1.2 Each lot of each antibiotic shall be certified by the Food and Drug Administration (F.D.A.).

3.2 Certification. The finished ointment shall conform to pertinent provisions of the General Regulations for the Certification of Antibiotics and Antibiotic-Containing Drugs, Title 21, paragraph 146e.422, except that the ointment shall assay to contain not less than 90.0 percent and not more than 125.0 percent of the specified amount of each antibiotic. The assay limit for the Hydrocortisone shall be not less than 90.0 percent and not more than 110.0 percent of the specified amount, when determined by an appropriate, accurate, and reproducible method.

3.3 Ingredients.

3.3.1 Zinc Bacitracin, Hydrocortisone, Neomycin Sulfate, and Polymyxin B Sulfate. The Zinc Bacitracin, Hydrocortisone, Neomycin Sulfate, and Polymyxin B Sulfate, entering into the preparation of the ointment shall be in accordance with the tests, standards, and requirements of the U.S.P., including any supplements or revisions thereto, except that the Neomycin Sulfate shall assay to contain not less than 70.0 percent of Neomycin base, calculated on the anhydrous basis.

3.3.2 Other ingredients. The white petrolatum, entering into the preparation of the ointment, shall be in accordance with the tests, standards, and requirements of the U.S.P., including any supplements or revisions thereto, and in addition shall comply with the following:

3.3.2.1 Melting point. Shall have a melting point of not more than 44° C., when determined as specified in 4.5.1.

3.3.2.2 Moisture. Shall have a moisture content of not more than 0.3 percent when determined as specified in 4.5.2.

3.4 Appearance. The ointment shall be a soft, homogeneous, faintly yellow, unctuous mass, smooth and free of grittiness, lumps, or other unincorporated material. Shall be free of foreign matter.

3.5 The ointment shall be nonirritating to the eye and shall permit diffusion of the active ingredients throughout the secretions of the eye.

3.6 Particle size. Particle size of the ointment, when determined as specified in 4.5.3, shall comply with the following ranges:

90 percent of the particles shall not exceed 20 microns in any maximum dimension.

99 percent of the particles shall not exceed 35 microns in any maximum dimension.

No particle shall exceed 80 microns in any maximum dimension.

3.7 Bacterial count. The ointment shall contain no viable microorganisms per gram, when determined in accordance with the F.D.A. method for ophthalmic ointments.

3.8 Melting range. Melting range for the finished ointment shall be 42° C. ± 2° C., when determined as specified in 4.5.1.

3.9 Compatibility of containers. The immediate container (tube) shall not interact physically or chemically with the contents. The strength, quality, purity, and appearance of the contents shall not be affected by the immediate container, nor shall the immediate container be altered in any manner by the contents.

3.10 Contents. Filled immediate containers shall contain an average weight of not less than 3.5 grams, and no one immediate container shall contain less than 3.3 grams.

3.11 Delivery. Not less than 56 months of the expiration dating period (potency period) shall remain at the time of delivery of the product to the Government.

3.12 Metal particles. Shall comply with the metal particles test as specified in 4.5.4.

3.13 Workmanship. The material and its containers shall be free from defects which detract from their appearance or may impair their serviceability.

4. QUALITY ASSURANCE PROVISIONS

4.1 Supplier responsibility for inspection. Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies and services conform to prescribed requirements.

4.1.1 Records of examinations and tests performed by or for the contractor shall be maintained by the contractor and made available to the Government, upon the Government's request, at any time, or from time to time, during the performance of the contract and for a period of 5 years after delivery of the supplies to which such records relate.

4.1.2 No company supplying any ingredient(s) to the contractor will be considered an acceptable facility for the performance of any inspection requirements specified herein.

4.2 Lot. For purposes of this specification, a lot, batch, or control is that single, uniform, and homogeneous quantity of ointment, produced from one formulation, subjected to the same compounding and manufacturing operation, and filled into final containers.

4.3 Sampling. Sampling shall be conducted in accordance with MIL-STD-105.

For visual examination	Inspection level	AQL (percent defective)	Unit of product
Major	S-2	1.0	Filled tube
Minor	II	2.5	Unit package

4.3.1 For raw material and end item testing. Noncompliance with any of the following is cause for rejection.

Characteristic	Requirement paragraph	Inspection level*	Minimum sample
End item:			
Assay	3.2	S-2 (Composite of final filled tubes)	5
Particle size	3.6		
Bacterial count	3.7		
Melting range	3.8		
Contents	3.10		
Metal particles	3.12	---	10
Label adhesion	---	PPP-C-00186a	10
Leakage	---	PPP-C-00186a	10
Raw material:		**	
Zinc Bacitracin	3.3.1		
Hydrocortisone			
Neomycin Sulfate			
Polymyxin B Sulfate			
White Petrolatum	3.3.2		

*Where possible, the same sample shall be used for two (2) or more tests.

**Sufficient quantities shall be selected from each lot of raw material to perform tests indicated in applicable test methods. Failure of any sample to comply with test requirements shall be cause for rejection of the lot represented.

4.4 Examination. The Zinc Bacitracin, Hydrocortisone, Neomycin Sulfate, and Polymyxin B Sulfate ointment shall be examined to determine compliance with all requirements of this specification. Nonconformance will be permitted to the extent indicated in 4.3 and 4.3.1

4.4.1 Classification of defects. Examination will be conducted in accordance with the following classification of defects:

Categories and defects*

Major

101. Ointment not homogeneous, not free from separation.

102. Ointment not smooth.

103. Ointment not free from grit.

104. Ointment not free from foreign matter.

105. Ointment not compatible with the container.

106. Labeling not legible, not free from defacing marks and tears.

107. Labeling not complete.

108. Tube not flexible.

Minor

201. Exterior of tube not free from contents or foreign matter.

202. Unit package not free from stains.

203. Tube not free from pitting, cracking, flaking, or peeling.

*Inspection is not restricted to the classified possible defects listed above.

4.5 Tests.

4.5.1 Melting range. The melting range of the white petrolatum used in the manufacture of the ointment, and the melting range of the ointment shall meet the requirements specified in 3.3.2 and 3.8, respectively, when determined by the U.S.P. class II procedure.

4.5.2 Moisture content. The moisture content of the white petrolatum used in the manufacture of the ointment shall meet the requirements specified in 3.3.2.2 when determined by the U.S.P. Titrimetric Method for moisture determination.

4.5.3 Particle size. The particle size of the ointment shall be determined microscopically.

4.5.4 Metal particles test. Select ten tubes of the finished ointment. Extrude the contents of each tube, as completely as possible, into a separate glass, Petri dish, 60 by 15 mm, and heat at 80° to 85° C. for at least 2 hours (a higher temperature may be used, if necessary to allow adequate settling of metal particles). Allow the ointment to cool to room temperature without agitation. Invert each Petri dish on the stage of a suitable microscope, adjusted to furnish about 30X magnification, and equipped with an eyepiece micrometer disc which has been calibrated at the magnification being used. In addition to the normal illuminator, use a Nicholas illuminator, mounted in such a way as to illuminate the inverted Petri dish from above as well as from below. Examine the entire bottom of the Petri dish for metal particles, recording the total number exceeding 50 microns in any single dimension.

The lot is acceptable if (1) a total of not more than 50 particles exceeding 50 microns in any single dimension are found in the ten tubes; and (2) not more than one tube is found to contain more than 8 particles.

If the lot fails the above test, repeat the test on twenty additional tubes of ointment from the same lot. The total number of metal particles exceeding 50 microns is any single dimension, from the thirty tubes tested, shall not exceed 150, with not more than three tubes containing more than 8 particles.

5. PREPARATION FOR DELIVERY

5.1 Preparation for delivery shall be as specified herein and shall be in accordance with all applicable paragraphs of Interim Federal Specification PPP-C-00186a, dated 15 May 1969, and Amendment-1, dated 27 October 1969:

5.1.1 Immediate containers. Shall comply with the following classification:

GROUP B CLASS 1 TYPE b CLOSURE B

5.2 Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below.

5.2.1 Immediate containers. Each immediate container label shall bear the following information. However, the information is not required to appear in the sequence indicated, except where specifically indicated:

(a) the item name designated as "ZINC BACITRACIN, HYDROCORTISONE, NEOMYCIN SULFATE, AND POLYMYXIN B SULFATE OINTMENT"

The phrase "TOPICAL AND OPHTHALMIC" shall appear immediately below the item name

As an alternate, the F.D.A. approved and certified name may be used.

(b) the quantity of contents designated as "1/8 oz (3.5 Grams)"

Note: The official abbreviation "g." may be used in lieu of the word "grams."

(c) the lot or control number

(d) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

(e) the expiration date

(f) a list of the active ingredients and their concentrations

Note: Shall be listed as shown in 3.1 or as approved and certified by the F.D.A.

(g) the statement "Store at controlled room temperature (59° - 86° F.)."

5.2.2 Unit packages. Each unit package label shall bear the following information. However, the information is not required to appear in the sequence indicated, except where specifically indicated:

(a) the item name designated as "ZINC BACITRACIN, HYDROCORTISONE, NEOMYCIN SULFATE, AND POLYMYXIN B SULFATE OINTMENT

The phrase "TOPICAL AND OPHTHALMIC" shall appear immediately below the item name

As an alternate, the F.D.A. approved and certified name may be used.

(b) the quantity of contents designated as "1/8 oz (3.5 Grams)"

Note: The official abbreviation "g." may be used in lieu of the word "grams."

(c) the Federal Stock No.

(d) the lot or control number

(e) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

(f) the expiration date

(g) a list of the active ingredients and their concentrations

Note: Shall be listed as shown in 3.1 or as approved and certified by the F.D.A.

(See additional labeling information on page 10)

(h) the statement "Caution: Federal law prohibits dispensing without prescription."

(i) the statement "Store at controlled room temperature (59° - 86° F.)."

5.2.2.1 Extended potency lines. Paragraph 3.9.8 of PPP-C-00186a shall apply to the unit package labels.

5.3 Packaging and packing.

5.3.1 Unit of issue. One tube, as specified, constitutes one unit of issue.

5.3.2 Unit package. Each unit shall be packaged as specified in 5.2.5 of PPP-C-00186a.

5.3.3 Procedure code. Procedure code No. 15 of PPP-C-00186a applies.

5.4 Marking.

5.4.1 Intermediate package. In paragraph 5.5.3 of PPP-C-00186a, add: "Type II Shelf-Life markings shall be shown as specified in MIL-STD-129. Marking shall include the expiration date and the following legend:

"STORE AT CONTROLLED ROOM TEMPERATURE (59° - 86° F.)."

5.4.2 Exterior container. In paragraph 5.5.4 of PPP-C-00186a, add: Type II Shelf-Life markings shall be shown as specified in MIL-STD-129. Marking shall include the expiration date and the following legend:

"STORE AT CONTROLLED ROOM TEMPERATURE (59° - 86° F.)."

6. NOTES

6.1 Ordering data. Procurement documents should specify the following:

(a) Number and date of this specification
(b) the Federal Stock No.
(c) applicable levels of packaging and packing (see PPP-C-00186a).

6.2 This specification covers the following item:

FSN 6505-890-1568 ZINC BACITRACIN, HYDROCORTISONE, NEOMYCIN SULFATE, AND POLYMYXIN B SULFATE OINTMENT, 1/8 oz (3.5 Grams).

6.3 This specification does not cover all types, classes grades, or sizes of the commodity indicated by the title of this specification, or those which are commercially available, but is intended to cover the type which is normally procured to meet Military requirements.

Custodians:
Army - MD
Navy - MS
Air Force - 03

Preparing activity:
Defense Supply Agency - DM

Project No. 6505-1281

Review activities:
Army - MD
Navy - MS
Air Force - 03

Review information is current as of the date of this document. For future coordination of changes to this document, draft circulation should be based on the information in the current DODISS.

STANDARDIZATION DOCUMENT IMPROVEMENT PROPOSAL

OMB Approval
No. 22-R255

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DOCUMENT IDENTIFIER AND TITLE

MIL-Z-36818

NAME OF ORGANIZATION AND ADDRESS

CONTRACT NUMBER

MATERIAL PROCURED UNDER A

☐ DIRECT GOVERNMENT CONTRACT ☐ SUBCONTRACT

1. HAS ANY PART OF THE DOCUMENT CREATED PROBLEMS OR REQUIRED INTERPRETATION IN PROCUREMENT USE?

A. GIVE PARAGRAPH NUMBER AND WORDING.

B. RECOMMENDATIONS FOR CORRECTING THE DEFICIENCIES

2. COMMENTS ON ANY DOCUMENT REQUIREMENT CONSIDERED TOO RIGID

3. IS THE DOCUMENT RESTRICTIVE?

☐ YES ☐ NO *(If "Yes", in what way?)*

4. REMARKS

SUBMITTED BY *(Printed or typed name and address - Optional)*

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DATE

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REPLACES EDITION OF 1 JAN 66 WHICH MAY BE USED

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