MILITARY SPECIFICATION

PETROLATUM, WHITE, USP

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

1. SCOPE

1.1 Scope. This specification covers Petrolatum, White, USP.

1.2 Classification. The white petrolatum covered by this specification shall be of the following sizes (see 6.2):

Size 1 - 1 lb
Size 2 - 5 lb

2. APPLICABLE DOCUMENTS

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

SPECIFICATIONS

FEDERAL

PPP-C-186 - Containers, Packaging and Packing for Drugs, Chemicals and Pharmaceuticals.

Beneficial comments (recommendations, additions, deletions) and any pertinent data which may be of use in improving this document should be addressed to: Hq, Defense Personnel Support Center, ATTN: Directorate of Medical Materiel, DPSC-ATT, 2800 South 20th Street, Phildelphia, PA 19101, by using the self-addressed Standardization Document Improvement Proposal (DD Form 1426) appearing at the end of this document or by letter.

MILITARY

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

(Copies of specifications 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 proposals shall apply.

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

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

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

U. S. PHARMACOPEIAL CONVENTION, INC.

The United States Pharmacopeia (USP).

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

The National Formulary (NF).

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

3. REQUIREMENTS

3.1 Material. Shall be Petrolatum, White, USP, and shall be in accordance with the tests, standards, and requirements of the USP, including any supplements or revisions thereto.

3.2 Delivery. Not more than 6 months shall have elapsed from the date of manufacture of the finished product to the date of delivery to the Government.

3.3 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, (i) as to any expiration dated item, for the expiration dating period specified by the contractor for such item, or such longer period as may be required by regulation of any federal agency; or (ii) as to non-dated items, for not less than 3 years after delivery of the item to the Government.

4.1.2 No company supplying any ingredient(s) to the contractor will be considered an acceptable facility for the performance of the 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 finished product 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.

TABLE I. Sampling.

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

4.4 Examination. The finished product shall be examined to determine compliance with all requirements of this specification. Nonconformance will be permitted to the extent indicated in 4.3.

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

TABLE II. Classification of defects.

Categories	Defects 1/
Major	
101	Finished product not free from foreign matter.
102	Finished product not homogeneous.
Minor	
201	Exterior of immediate container is not free from contents or foreign matter.
202	Label not free form defacing marks and tears.

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

4.5 Packaging inspection. The inspection of the intermediate package, packing and marking for shipment and storage shall be in accordance with quality assurance provisions of the applicable container specification and the marking requirements of MIL-STD-129.

4.6 Labeling inspection. Sampling shall be in accordance with MIL-STD-105 and the unit of product shall be the unit of issue. The inspection lot shall be the number of units of issue of each batch, lot, control number, etc., offered for inspection at one time. The inspection level for labeling shall be S-2 and the acceptance number shall be zero.

4.7 Tests. Tests shall be performed to determine compliance with all requirements of this document and all referenced documents.

5. PACKAGING

5.1 Packaging requirements. The requirements for packaging shall be in accordance with all applicable requirements of PPP-C-186, and as specified herein.

5.2 Packaging. Packaging shall be level A or C, as specified (see 6.1).

5.2.1 Unit of issue. One can containing 1 lb, size 1, or one can containing 5 lb, size 2, as specified, constitutes one unit of issue.

5.2.2 Level A.

5.2.2.1 Immediate container: size 1 and size 2. The immediate container for size 1 and size 2 shall be a commercially available immediate container considered acceptable by the Food and Drug Administration (FDA) for the product contained therein and shall be of such compatibility that neither the contents nor the container are altered in any way by each other.

5.2.2.2 Unit package. At the option of the contractor, a unit package may be furnished. If a unit package is furnished, each can shall be packaged as specified in 5.2.5 of PPP-C-186.

5.2.2.3 Intermediate packaging. Twelve (12) units of size 1 or six (6) units of size 2 shall be packaged as specified in 5.2.14.1 of PPP-C-186.

5.2.3 Level C. Units shall be packaged in standard commercial containers of the size and kind commonly used, which will afford the degree of protection required for shipment and use of the product for its intended purpose.

5.3 Packing. Packing shall be level A, B or C, as specified (see 6.1).

5.3.1 Level A. Four intermediate packages (48 units) of size 1 or two intermediate packages (12 units) of size 2 shall be packed as specified in 5.4.4 of PPP-C-186.

5.3.2 Level B. Four intermediate packages (48 units) of size 1 or two intermediate packages (12 units) of size 2 shall be packed as specified in 5.4.3.6.1.1 of PPP-C-186.

5.3.3 Level C. The subject commodity shall be packed in substantial commercial containers of the type, size, and kind commonly used for the purpose, so constructed as to insure acceptance and safe delivery by common or other carriers, at the lowest rate, to point of delivery called for in the contract or purchase order.

5.4 Marking.

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

5.4.1.1 Immediate container. Each immediate container label shall bear the following information:

(a) label information in accordance with commercial practice.
(b) the date of manufacture prefixed by "MFD".

5.4.1.2 Unit package. Each unit package label shall bear the following information:

(a) label information in accordance with commercial practice.
(b) the National Stock Number.

NOTES: (1) The National Stock Number shall not be preceded by any prefix.
(2) Strip labeling may be used.
(3) Label adhesion test shall not apply.
(4) If a unit package is not supplied, the National Stock Number shall appear on the immediate container label.

5.4.2 Intermediate package. Each intermediate package shall be marked in accordance with 5.5.3 of PPP-C-186 except that the date of manufacture shall be shown in lieu of the date packed.

5.4.3 Exterior container. Exterior containers shall be marked as specified in 5.5.4 of PPP-C-186 except that the date of manufacture shall be shown in lieu of the date packed.

6. NOTES

6.1 Ordering data. Procurement documents should specify the following:

(a) Title, number and date of this specification.
(b) National Stock Number.
(c) Selection of applicable levels of packaging and packing (see 5.2 and 5.3).

6.2 This specification covers the following items:

National Stock Number	Item Identification	Specification Designation
6505-00-133-8025	PETROLATUM, WHITE, USP, 1 lb (453.6 Gram)	Size 1
6505-00-527-2482	PETROLATUM, WHITE, USP, 5 lb (227 kg)	Size 2

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

Review activity:
DoD - MB

Preparing activity:
DLA-DM

Project No. 6505-1791

STANDARDIZATION DOCUMENT IMPROVEMENT PROPOSAL

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DOCUMENT IDENTIFIER *(Number)* AND TITLE
MIL-P-37649 PETROLATUM, WHITE, USP

NAME OF ORGANIZATION AND ADDRESS OF SUBMITTER

☐ VENDOR ☐ USER ☐ MANUFACTURER

1. ☐ HAS ANY PART OF THE DOCUMENT CREATED PROBLEMS OR REQUIRED INTERPRETATION IN PROCUREMENT USE? ☐ IS ANY PART OF IT TOO RIGID, RESTRICTIVE, LOOSE OR AMBIGUOUS? PLEASE EXPLAIN BELOW.

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B. RECOMMENDED WORDING CHANGE

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2. REMARKS

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

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DD FORM 1 OCT 76 1426

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