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SUPERSEDING
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FEDERAL SPECIFICATIONS

CONTAINERS, PACKAGING AND PACKING FOR DRUGS, CHEMICALS, AND PHARMACEUTICALS

This specification was approved by the Commissioner, Federal Supply Service, General Services Administration, for use of all Federal agencies.

1. SCOPE AND CLASSIFICATION

1.1 Scope. This specification covers the requirements for immediate containers, closures, and seals used for the protection of drugs, chemicals, and pharmaceuticals, and the general requirements for the labeling, packaging, packing, and marking of such items.

1.2 Classification. Immediate containers shall be of the following groups, classes, types, styles, grades, closures, and seals, as specified (see 6.1):

1.2.1 Immediate container groups.

1.2.1.1 Group A. Bottles, jars, vials, tubes, and ampuls (see 3.3).

Class 1. - Glass (see 3.3.1).

Types of glass.

Type a. - Type I, USP.
Type b. - Type II, USP.
Type c. - Type III, USP.
Type d. - Commercial (Non-USP).
Type e. - Type NP, USP.

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Class 2. - Plastic (see 3.3.2).

Styles of containers for group A (see 3.3.3).

Style 1. - Bottle, narrow-mouth.
Style 2. - Bottle, wide-mouth.
Style 3. - Bottle for injectables.
Style 4. - Jar
Style 5. - Bottle, dropper.
Style 6. - Vial or tube.
Style 7. - Ampul
Style 8. - Bottle, ophthalmic.

Grades of light penetration for containers of group A (see 3.3.4).

Grade 1. - Light-resistant (USP).
Grade 2. - Nonlight-resistant (colorless).
Grade 3. - Special (colored).

Closures for containers of group A (see 3.3.5).

Closure A. - Screwcap, plastic, with liner.
Closure B. - Screwcap, metal, with liner.
Closure C. - Screwcap, plastic, with dropper and liner.
Closure D. - Screwcap, aluminum, with dropper and liner.
Closure E. - Screwcap, aluminum, pilferproof, with dropper and liner.
Closure F. - Screwcap, aluminum, screw-on or roll-on, with liner.
Closure G. - Screwcap, aluminum, roll-on, pilferproof, with liner.
Closure H. - Rubber diaphragm closure or rubber flanged stopper, secured with aluminum, roll-on, tamperproof seal.
Closure I. - Plastic plug-type cap.
Closure J. - Plastic snap-on cap.
Closure K. - Flame-sealed ampul.
Closure L. - Cork stopper.
Closure M. - Rubber stopper.
Closure N. - Screwcap, plastic, without liner, for ophthalmic bottle.

Closure O. - Special closure, as specified.
Closure P. - Child-resistant.
Closure Q. - Screwcap, metal, with dropper and liner.
Closure R. - Screwcap, polypropylene, with liner.

Seals for containers of group A (see 3.3.6).

Seal A. - Outer.
Seal B. - Inner.
Seal C. - Special, as specified.

1.2.1.2 Group B. - Tubes, collapsible (see 3.4).

Class 1. - Metal.
Class 2. - Plastic.
Class 3. - Laminate.

Types of opening for containers of group B (see 3.4.3).

Type a. - Round.
Type b. - Eye tip.
Type c. - Nasal tip.
Type d. - Screw eye.
Type e. - Mastitis.
Type f. - Blind end.
Type g. - Ribbon.
Type h. - Beveled grease tip.
Type i. - Nozzle and break off tip.

Closures for containers of group B (see 3.4.4).

Closure A. - Screwcap, rigid plastic, with liner.
Closure B. - Screwcap, nonrigid plastic, with or without liner.
Closure C. - Screwcap, metal, with liner.
Closure D. - Screwcap, rigid plastic or metal, with or without liner, and with penetrating tip.
Closure E. - Screwcap, rigid plastic, without liner (valve cap).
Closure F. - Special closure, as specified.
Closure G. - Screwcap, plastic, for sterile ophthalmic ointment.
Closure H. - Screwcap, polypropylene, with liner.

Seals (bottom end) for containers of group B (see 3.4.5).

1.2.1.3 Group C. - Cans, metal (see 3.5).

Types of cans for group C.

Type a. - Cans for liquids.
Type b. - Cans for solids and semisolids.
Type c. - Cans, key-opening type.
Type d. - Special, as specified.

1.2.1.4 Group D. - Canisters (see 3.6).

Class 1. - Fiber, with metal ends.
Class 2. - Fiber, with plastic ends.
Class 3. - All fiber.

1.2.1.5 Group E. Pails and drums (see 3.7).

Class 1. - Metal pails.

Type I. - Pails for liquids. - 5 gallon, tight head pail.

Type II. - Pails for solids and semisolids - 5 gallon (35 pound) lug cover pail.

Class 2. - Fiber drums.

1.2.1.6 Group F. - Bags or liners for containers (see 3.8).

Class 1. - Paper.
Class 2. - Plastic.
Class 3. - Laminated foil.

1.2.1.7 Group G. - Laminated foil molds and wrappers (see 3.8.2).

Type I. - Laminated aluminum foil strips.

Type II. - Molds or wrappers.

Class 1. - Mold.
Class 2. - Wrapper.

1.2.1.8 Group H. - Cartridge-needle units (see 3.8.3).

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

GG-N-196	Needles, Hypodermic, for Luer Syringes.
ZZ-S-751	Stoppers, Bottle, Rubber.
LLL-S-731	Stopper, Bottle, Cork.
PPP-B-566	Boxes, Folding, Paperboard.
PPP-B-601	Boxes, Wood, Cleated-Plywood.
PPP-B-621	Boxes, Wood, Nailed and Lock-Corner.
PPP-B-636	Boxes, Shipping, Fiberboard.
PPP-B-676	Boxes, Set-Up, Paperboard.
PPP-C-96	Cans, Metal, 28 Gage and Lighter.
PPP-C-1266	Container, Thermal, Shipping, for Medical Material Requiring Controlled Temperature Ranges.
PPP-D-723	Drums, Fiber.
PPP-P-704	Pails; Shipping, Steel (1 through 12 Gallon).

STANDARDS

Federal

Fed. Std. No. 102 - Preservation, Packaging, and Packing Levels.
Fed. Std. No. 123 - Marking for Shipment (Civil Agencies).
Fed. Std. No. 140 - Tablets (for Medicinal Purposes).
Fed. Std. No. 142 - Parenteral Preparations.
Fed. Std. No. 285 - Capsules (for Medicinal Purposes).
Fed. Test Method Std. No. 101 - Preservation, Packaging,and Packing Materials; Test Procedures.

(Activities outside the Federal Government may obtain copies of Federal Specifications, Standards, and Handbooks as outlined under General Information in the Index of Federal Specifications and Standards and at the prices indicated in the Index. The Index, which includes cumulative monthly supplements as issued, is for sale on a subscription basis by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

(Single copies of this specification and other Federal Specifications required by activities outside the Federal Government for bidding purposes are available without charge from Business Service Centers at the General Services Administration Regional Offices in Boston, New York, Washington, DC, Atlanta, Chicago, Kansas City, MO, Fort Worth, Denver, San Francisco, Los Angeles, and Seattle, WA.

(Federal Government activities may obtain copies of Federal Specifications, Standards, and Handbooks and the Index of Federal Specifications and Standards from established distribution points in their agencies.)

SPECIFICATIONS

Military

MIL-P-116 - Preservation, Method of.
MIL-L-10547 - Liners, Case Waterproof.

STANDARDS

Military

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

(Copies of Military 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.)

Laws and Regulations:

CONSUMER PRODUCT SAFETY COMMISSION

Title 16, Section 1500 et seq. - The Federal Hazardous Substances Act and Regulations.
Title 16, Section 1700 et seq. - The Poison Prevention Packaging Act and Regulations.

(Application for copies should be addressed to the Consumer Product Safety Commission, Washington, D. C. 20207.)

HAZARDOUS MATERIALS REGULATIONS OF THE DEPARTMENT OF TRANSPORTATION.

(Application for copies should be addressed to the Agent, 2 Penn Plaza, New York, NY 10001.)

U. S. DEPARTMENT OF AGRICULTURE, AGRICULTURAL RESEARCH SERVICE:

Code of Federal Regulations, Title 9, Chapter I, Subchapter E, Viruses, Serums, Toxins, and Analogous Products.

(Application for copies should be addressed to the Superintendent of Documents, Government Printing Office, Washington, D. C. 20402.)

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

Food and Drug Administration - Bureau of Biologics
Code of Federal Regulations - Title 21
Minimum Requirements (as applicable).

(Application for copies should be addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.)

FOOD AND DRUG ADMINISTRATION

Federal Food, Drug, and Cosmetic Act and Code of Federal Regulations, Title 21.

(Application for copies should be addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.)

U. S. DEPARTMENT OF JUSTICE:

Drug Enforcement Administration.

Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970.

(Application for copies should be addressed to the Department of Justice, P.O. Box 28083, Central Station, Washington, D.C. 20005.)

U. S. TREASURY DEPARTMENT, INTERNAL REVENUE SERVICE:

27-CFR-U. S. Treasury Department, Internal Revenue Service Regulations.
26-CFR (1954)-U. S. Treasury Department, Internal Revenue Service Regulations.

(Application for copies should be addressed to the Superintendent of Documents, Government Printing Office, Washington, D. C. 20402.)

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.

NATIONAL MOTOR FREIGHT TRAFFIC ASSOCIATION, INCORPORATED, AGENT:

National Motor Freight Classification.

(Application for copies should be addressed to the American Trucking Association, Inc., Tariff Order Section, 1616 P Street, N. W., Washington, D. C. 20036.)

UNIFORM CLASSIFICATION COMMITTEE, AGENT:

Uniform Freight Classification.

(Application for copies should be addressed to the Uniform Classification Committee, Room 1106, 222 South Riverside Plaza, Chicago, IL 60606.)

U. S. PHARMACOPEIAL CONVENTION, INC.

The United States Pharmacopeia.

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

The National Formulary.

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

3. REQUIREMENTS

3.1 Requirements of statutes. Unless otherwise specified, the contents, immediate container, closure, labeling, and marking of any commodity governed by the requirements of any of the following: U. S. Pharmacopeia; National Formulary, Food and Drug Administration; Agricultural Research Service; Internal Revenue Service; Drug Enforcement Administration; U. S. Consumer Product Safety Commission; Food and Drug Administration, Bureau of Biologics; Hazardous Materials Regulations of the Department of Transportation, or any other Federal or state laws or regulations, shall conform to the standards and requirements of the applicable regulations or laws (see 6.4).

When the circular (or other printed matter) is utilized to comply with the labeling requirements of statute, and the packaging of the circular(s) is not specified in the procurement document, the circular(s) shall accompany the individual item of issue in a manner acceptable to the Food and Drug Administration, or the Food and Drug Administration, Bureau of Biologics, or other cognizant regulatory agency.

3.1.1 For items where the labeling includes storage under refrigeration, it is required that prior to delivery to the Government, the final, filled, immediate containers shall be kept under constant refrigeration at a temperature between 2° - 8° C. (35° - 46° F.). (see 5.5.4.1.2 "Special labeling.)

3.2 Immediate container. An immediate container is the specified bottle, tube, vial, or other means hereinafter described, complete with liner, screwcap, stopper, coating, etc., which holds and is in direct contact with the drug, chemical, pharmaceutical, or other product described in the procurement document. In addition, the immediate container is one which shall be considered acceptable by the Food and Drug Administration as a container for the commodity it holds.

3.2.1 Compatibility. The immediate container shall not interact physically or chemically with the contained substance. The strength, quality, purity, and appearance of contents shall not be affected by the immediate container, nor shall the immediate container be altered in any manner by the contents.

3.2.2 Cleanliness. All immediate containers shall be free from dirt, foreign matter, or other contaminants, both before and after filling. In addition, all labels, immediate containers, individual cartons, and unit packages shall be free from stains, either from the product or other causes.

3.2.3 Uniformity. The immediate containers, holding like material, shall be uniform in size, shape, and color.

3.2.4 Capacity of fill. Except as may be required by statute, immediate containers shall be filled to an appropriate capacity of the containers.

3.2.4.1 (This paragraph is reserved for future use.)

3.2.4.2 Overfill. Liquids in immediate containers shall not be overfilled to a point where breakage potential exists as a result of temperature drop from 27° C. to -4° C.

3.2.5 (This paragraph is reserved for future use.)

3.2.6 Leakage. The immediate containers, with closures in place, and seals applied when specified, shall comply with 4.3.1 and sub-paragraphs, as applicable, and shall not leak or lose contents during ordinary handling, shipping, and storage.

3.2.6.1 For immediate containers which are required to be accompanied by a separate dropper closure, the contained medicament (solution or suspension) shall not overflow when the dropper closure is inserted, without compression of the dropper bulb, into the medicament for use and subsequent closing of the immediate container.

3.2.7 Maintenance of sterility. For those products required to be sterile, each immediate container shall maintain the sterility of the product.

3.2.8 Reuse of bottles and closures. The reuse of bottles which have been previously filled with the same or other material, even if subjected to cleaning process, is prohibited. The reuse of previously used closures is also prohibited. Bottles and their closures emptied for reinspection of contents for visual defects may be reused for refilling of the same lot numbers of material. Refilling of the contents into the bottles shall be limited to one (1) week after emptying of the containers.

3.2.8.1 All immediate containers, closures, seals, packaging and packing materials shall be new. Permission of 3.2.8 for reinspection of contents and for refilling is permitted.

3.2.9 Threaded portions. The threaded portions of all immediate containers shall be such that the screwcap cannot be removed without engaging the threaded portion of the screwcap with the threaded portion of the container. Thus, the screwcap cannot be lifted or slipped off.

3.3 Group A. Bottles, jars, vials, tubes, and ampuls.

3.3.1 Class 1, glass. Class 1, glass containers, shall be symetrically made, smoothly finished, and free from flaws or other defects which affect their appearance or serviceability.

3.3.1.1 Types of glass.

3.3.1.1.1 Types a, b, c, and e. Types a, b, c, and e glass shall conform to the requirements of the USP for types I, II, III, and NP, respectively.

3.3.1.1.2 Type d, commercial (non-USP). Type d, commercial (non-USP) glass, shall be of high quality and suitable for the purpose intended.

3.3.2 Class 2, plastic. Class 2, plastic containers, shall be symetrically made, smoothly finished, and free from flaws or other defects which affect their appearance or serviceability. Materials shall be as specified in the procurement document.

3.3.3 Styles of containers for group A.

3.3.3.1 Styles 1 and 2, bottles. Style 1 (narrow mouth) and style 2 (wide-mouth) bottles shall be cylindrical, oblong, or rounded square, with threaded finish. The bottles shall have a bead just below the threaded portion of the bottle. Lug-type finish shall be used only when specified in the procurement document. The opening of the bottle shall be sufficiently large to permit ready dispensing of the contents. A "pour lip" may be used for liquid preparations. Powder jars shall not be acceptable as meeting style 2, when the unit of issue will contain in excess of 100 tablets or capsules, or in excess of 2 fluid ounces of liquid.

Wide-mouth. Shall be considered wide-mouth if the diameter of the open portion (opening) is essentially the same dimension as the smallest width for a rectangular bottle, or more than 1/2 of the diameter of the base for a round bottle.

Narrow-mouth. Shall be considered narrow-mouth if the diameter of the pour portion (opening) is essentially less than 3/4 of the smallest width for a rectangular bottle, or not over 1/2 of the diameter of the base for a round bottle.

3.3.3.2 Style 3, bottle for injectables. Style 3, bottle for injectables, shall be cylindrical with narrow-mouth or wide-mouth opening, intended for multiple-dose injections, unless otherwise specified. Liquid parenterals shall be packaged in style 3, narrow-mouth bottles. Style 3 bottles are used with closure H (see 3.3.5.9).

3.3.3.3 Style 4, jar. Style 4, jar, shall be of the size and color as specified in the procurement document.

3.3.3.3.1 Ointment. Ointment jars shall be cylindrical in shape with threaded finish. The sidewalls of the jar shall be essentially perpendicular to the bottom, with the exception of the irregularity at the bottom of the finished area. The bottom shall be suitably rounded on the inside.

3.3.3.3.2 Powder. Powder jars shall be rounded square or cylindrical in shape with threaded finish.

3.3.3.4 Style 5, bottle, dropper. Style 5, bottle, dropper, shall be cylindrical, oval, square, or oblong in shape, with a narrow-mouth, and well defined, properly made threads for use with the specified closure(s).

3.3.3.5 Style 6, vial or tube. Style 6, vial or tube, shall be made of drawn tubing with walls of uniform thickness, and shall have a finish suitable for use with the closure specified in the procurement document.

3.3.3.6 Style 7, ampul. Unless otherwise specified, style 7, ampul shall be scored or unscored, and made of molded glass or drawn glass tubing, with walls of uniform thickness with drawn, rolled-in, or stuck-on necks. Ampuls shall stand upright, at right-angles to the supporting surface, without wobbling. Ampuls shall break cleanly on opening. Ampuls which are opened without the use of files shall bear an easily distinguishable colored band, measuring from 0.5 mm to 2 mm in width; the band forming a complete circle at approximate center of constriction where the ampul will break. Average thickness of band 0.012 mm, with maximum thickness of 0.02 mm. Ampuls which are opened without the use of files and do not bear a band around the constriction (constricted portion uncolored) are permitted, provided the labeling contains a notice or diagram indicating where the break will take place. The diagram or notice shall be included on the unit package, in the package insert, or on a separate notice contained in the unit package to show user where to break the ampul.

Note: Unscored ampuls are not permitted when the procurement document specifies the use of prescored, color break, or snap top type ampuls.

3.3.3.6.1 Files. Unless otherwise specified, one or more files shall be furnished with each multiple of six or less ampuls in a unit of issue. Files are not required with prescored, color break, snap-top type, or other ampuls which are opened without the use of files. Files shall be of steel, free from corrosion, at least 1-3/4 inches in length, and suitable for the purpose intended.

3.3.3.7 Style 8, ophthalmic bottle. Style 8, ophthalmic bottle, shall be a cylindrical, nonrigid plastic bottle with threaded finish and an ophthalmic dispenser inserted in the neck of the bottle.

defects and imperfections that will affect the ... free from

3.3.4 Grades of light penetration for containers of group A.

3.3.4.1 Grade 1, light-resistant. Grade 1, light-resistant containers shall be of amber or opaque glass, or amber or opaque plastic. The use of "colorless" glass, transparent or translucent plastic containers with individual cartons, sleeves, or other wrappings is not acceptable in lieu of grade 1, glass or plastic containers.

Grade 1, light-resistant glass or plastic containers for non-parenterals shall not transmit more than 10 percent of the incident radiation of any wavelength between 290 nm and 450 nm, when tested by the USP procedure. Light resistant glass for parenterals shall comply with the light transmission limits of the USP, when tested by the USP procedure.

3.3.4.2 Grade 2, nonlight-resistant. Grade 2, nonlight-resistant, glass or plastic containers shall not be colored. The glass shall be clear and colorless. The plastic shall be clear and colorless or may be translucent.

3.3.4.3 Grade 3, special. Grade 3, special, glass or plastic containers, shall be amber, blue, or green, unless otherwise specified in the procurement document.

3.3.5 Closures for containers of group A.

3.3.5.1 General requirements for closures. Closures as specified in 1.2.1.1 shall be suitable for use with the containers specified in 1.2.1.1.

3.3.5.1.1 Screwcap. Screwcap for immediate container shall be of the screw-on type, with the inner edges of the cap sufficiently threaded with a continuous-type thread formed as an integral part of the cap for a close fit with the specified container. A lug-type cap shall be used only when a lug-type finish is specified (see 3.2.9 and 3.3.3.1).

3.3.5.1.2 Liner. Unless otherwise specified, the screwcap shall be lined with a tight-fitting, resilient liner. A suitable, impervious facing shall be part of the liner, unless a rubber or plastic liner such as polyethylene or polystyrene is used. The facing material shall prevent the entrance of moisture as well as comply with 3.2.1. The liner shall be of sufficient thickness to form an effective seal. The screwcap shall be removed without loss of the liner

3.3.5.1.3 When overwrapping of a separate closure is required, the overwrapping shall completely cover the designated closure. The overwrapping material shall not be brittle, torn, or cracked. The overwrap for separate dropper closures for sterile products shall keep the separate closure sterile.

3.3.5.2 Closure A, screwcap, plastic, with liner. Unless otherwise specified, closure A, plastic screwcap, shall be phenol-resin, or urea resin, with side walls of adequate weight. With liner in place, screwcap shall not crack, split, or break, when applied to container at room temperature, to the degree of tightness required.

3.3.5.3 Closure B, screwcap, metal, with liner. Closure B, metal screwcap, shall be fabricated of 0.50 pound per base box or 0.75 pound per base box electrolytic tinplate, and further protected to resist corrosion. Metal screwcap shall have a rolled edge and shall contain a liner. One-quarter (0.25) pound electrolytic tinplate closures will be acceptable, provided they are protected with enamel paint to prevent and resist corrosion.

3.3.5.4 Closure C, screwcap, plastic, with dropper and liner. Closure C, screwcap, plastic, with dropper and liner, for use with dropper bottles, shall be a molded screwcap of rigid plastic having a pipet with attached, suitable nipple which is flanged to form a liner. Cap and dropper assembly shall fit snugly with the bottle employed. Pipet shall be fitted tightly and securely in the nipple and shall deliver at least the required dosage. Nipple shall be of such size as to fill the pipet to not less than one-half of its capacity; or if the pipet is graduated, it shall fill to the highest graduation mark. The markings on the graduated pipets shall be permanent, and shall be nontoxic when used in the product. The accuracy of the markings on the droppers shall be within the applicable tolerance, when tested as specified in 4.3.6. The markings shall comply with the test specified in 4.3.3. When in place, the tip of the pipet shall be within 1/4 inch from the bottom of the container, but shall not come in contact with the container. The tip (bottom) of the pipet shall be smooth and have no sharp surfaces.

3.3.5.5 Closure D, screwcap, aluminum, with dropper and liner. Closure D, screwcap, aluminum, with dropper and liner, shall be as specified in 3.3.5.4, except that the screwcap shall be of aluminum and further protected to resist corrosion. The aluminum closures shall not contain loose or adherent aluminum chips.

3.3.5.6 Closure E, screwcap, aluminum, pilferproof, with dropper and liner. Closure E, screwcap, aluminum, pilferproof, with dropper and liner, shall be as specified in 3.3.5.4, except that the pilferproof screwcap shall be of aluminum, and further protected to resist corrosion. The aluminum closures shall not contain loose or adherent aluminum chips.

3.3.5.7 Closure F, screwcap, aluminum, screw-on or roll-on, with liner. Closure F, screw-on or roll-on, aluminum screwcap, shall be fabricated of aluminum, and further protected to resist corrosion. Screwcap shall have a rolled edge and shall contain a liner. The aluminum closures shall not contain loose or adherent aluminum chips.

3.3.5.8 Closure G, screwcap, aluminum, roll-on, pilferproof, with liner. Closure G, roll-on, pilferproof, aluminum screwcap, shall be pilferproof closure, fabricated of aluminum, and further protected to resist corrosion. The side of the cap shall extend over the edge of the retaining shoulder (bead) of the bottle and rolled over in such a manner as to prevent the removal of contents without detection. A liner shall be utilized. The aluminum closure shall not contain loose or adherent aluminum chips.

3.3.5.9 Closure H, rubber diaphragm closure or rubber flanged stopper, secured with aluminum, roll-on, tamperproof seal. Closure H rubber diaphragm closure and rubber flanged stopper, for multiple-dose containers (unless otherwise specified) shall be secured to the immediate container with an aluminum roll-on, tamperproof seal. The overall seal shall be placed in such a manner as to cover completely the closure or stopper to prevent tampering with the contents. The aluminum shall be treated on the outside to resist corrosion. The aluminum closure shall not flake or peel. The rubber shall be of high quality and suitable in all respects for use with the contained material. For oil preparations, neoprene or other suitable material may be used in lieu of rubber.

3.3.5.10 Closure I, plastic, plug-type cap. Closure I, plastic, plug-type cap shall be a flexible, plug-type cap fabricated of suitable plastic.

3.3.5.11 Closure J, plastic, snap-on cap. Closure J, plastic, snap-on cap, shall be a flexible, snap-on type cap fabricated of suitable plastic.

3.3.5.12 Closure K, flame-sealed ampul. Closure K, flame-sealed ampul, shall be hermetically sealed by fusing the glass with flame until a smooth, uniform closure is effected.

3.3.5.13 Closure L, cork stopper. Closure L, cork stopper, shall conform to type I, grade C or D, of LLL-S-731, as specified in the procurement document.

3.3.5.14 Closure M, rubber stopper. Closure M, rubber stopper, shall conform to the requirements of ZZ-S-751 for the type and grade, as specified in the procurement document.

3.3.5.15 Closure N, screwcap, plastic, without liner, for ophthalmic bottle. Closure N, screwcap, plastic, without liner, for ophthalmic bottle, shall be a rigid plastic screwcap molded to cover the dispenser.

3.3.5.15.1 Dispenser, plastic for ophthalmic bottle. The dispenser for ophthalmic bottle shall permit the controlled dispensing of uniform drops of ophthalmic solution or suspension.

3.3.5.15.2 The color of the closure and dispenser for ophthalmic bottle shall be as specified in the procurement document.

3.3.5.16 Closure O, special closure. Closure O, special design closure, shall be as specified in the procurement document.

3.3.5.17 Closure P, child-resistant. Closure P is defined as a child-resistant closure, that is, one which has been tested in accordance with the Regulations under the Poison Prevention Packaging Act of 1970, as promulgated by the Consumer Product Safety Commission and found to comply with or exceed the standards and requirements therein. In addition, the closure shall be such that it will prevent pickup of moisture and contamination of the product.

3.3.5.18 Closure Q, screwcap, metal, with dropper and liner. Closure Q shall be as specified in 3.3.5.4, except in lieu of phenol resin, or urea resin, the screwcap portion shall be fabricated of metal as specified in 3.3.5.3.

3.3.5.19 Closure R, screwcap, polypropylene, with liner. Closure R, polypropylene, screwcap, shall conform to 3.3.5.2, except shall be fabricated from polypropylene.

3.3.6 Seals for containers of group A.

3.3.6.1 Seal A, outer. When specified, caps shall be secured with a cellulose hydrate band, heat-shrinkable polyvinyl chloride tubing, or equivalent, which covers the bead of the container and extends to at least one-half way up the sides of the screwcap. When dried, the band shall conform to contour of the cap and neck of the bottle to prevent loosening of the cap. Band shall be treated to inhibit the growth of fungus. The outer seals shall not crack, loosen, due to swelling, or become dislodged. As an alternate, caps may be secured with an acid-resistant, vinyl chloride, self-adhering, pressure sensitive tape, upon approval of the procuring activity.

3.3.6.2 Seal B, inner. When specified, an inner seal in the form of a disk, of suitable thickness and composition, shall be adhered completely to the mouth of the container so as to prevent loss of contents when the closure is removed and container is inverted. The inner seal shall have no holes, breaks, or tears.

3.3.6.3 Seal C, special. Seal C, special, shall be as specified in the procurement document.

3.4 Group B. Tubes, collapsible.

3.4.1 Class 1, metal. Class 1, metal tubes, shall be containers having a seamless, cylindrical body (wall) with integral shoulder and threaded neck, except for types d, e, and i, which do not have threaded neck. Tubes shall be fabricated of tin, tin-copper alloy, tin-lead alloy, or aluminum, and shall have suitable flexible characteristics, and an opening which shall permit ready dispensing of the material. Tube wall shall be of uniform thickness. Tubes may be treated with an interior protective coating. Tubes fabricated of tin-lead alloy must contain an interior protective coating. All interior protective coatings shall show no blistering, pocking, cracking, peeling, flaking, or blushing, and shall adhere to the tube when the tube is crushed or folded. The coating material shall adhere and be flexible at temperatures minus (-)34°C to plus(+) 54°C., except that for tubes fabricated of tin-lead alloy, the temperatures shall be from minus (-)34°C to plus (+) 71°C.

3.4.2 Class 2, plastic. Class 2, plastic tubes, shall be containers having a seamless, cylindrical body (wall) with integral shoulder, and threaded neck, except for types d, e, and i, which do not have threaded neck. Tubes shall be fabricated of plastic material as specified in the procurement document and shall have suitable flexible characteristics and an opening which shall permit ready dispensing of the material. Tube wall shall be of uniform thickness.

3.4.2.1 Class 3, laminate. Shall be tubes as specified in the procurement document.

3.4.3 Types of openings for containers of group B. Types of openings for containers of group B shall be as specified in 1.2.1.2. Design of opening shall be such as to permit ready dispensing of the contents for the intended end use of the item.

3.4.4 Closure for containers of group B.

3.4.4.1 General requirements for closures. Closures as specified in 1.2.1.2 shall be suitable for the applicable type opening specified in 1.2.1.2.

3.4.4.1.1 Screwcap. Screwcap for immediate container shall be of the screw-on type, the inner edges of the cap sufficiently threaded with a continuous-type thread formed as an integral part of the cap for a close fit with the specified container.

3.4.4.1.2 Liner. The screwcap shall be lined with a tight-fitting, resilient liner, with a suitable, impervious facing. The liner shall be of sufficient thickness to form an effective seal. Liner shall not be required when the neck of the tube and inner face of cap are designed to form an effective seal which shall permit reclosure and prevent loss of contents. When a liner is employed, the screwcap shall be removed without loss of the liner.

3.4.4.2 Closure A, screwcap, rigid plastic, with liner. Closure A, screwcap, rigid plastic, with liner, shall be a phenol-resin, or urea resin, screw-on type, the inner edges of the cap sufficiently threaded with a continuous-type thread formed as an integral part of the cap.

3.4.4.3 Closure B, screwcap, nonrigid, plastic, with or without liner. Closure B, screwcap, nonrigid plastic, with or without liner, shall be of the screw-on type, the inner edges of the cap sufficiently threaded with a continuous-type thread formed as an integral part of the cap.

3.4.4.4 Closure C, screwcap, metal, with liner. Closure C, screwcap, metal, with liner, shall be fabricated of 0.50 pound per base box or 0.75 pound per base box electrolytic tinplate, and further protected to resist corrosion. One-quarter (0.25) pound electrolytic tinplate closures will be acceptable, provided they are protected with an enamel paint to prevent and resist corrosion.

3.4.4.5 Closure D, screwcap, rigid plastic, or metal, with or without liner, and with penetrating tip. Closure D, screwcap, rigid plastic, or metal, with or without liner, and with penetrating tip, shall conform to the requirements specified for closures A or C and, in addition, shall have an integral penetrating tip.

3.4.4.6 Closure E, screwcap, rigid plastic, without liner (valve cap). Closure E, screwcap, rigid plastic, without liner, shall be phenol resin, or urea resin, screw-on type; the inner edges of the cap sufficiently threaded with a continuous type thread formed as an integral part of the cap; and the cap shall be molded to contain an integral plug conforming to the orifice of the tube.

3.4.4.7 Closure F, special closure. Closure F, special designed closure, shall be as specified in the procurement document.

3.4.4.8 Closure G, tamperproof closure for ophthalmic ointments. The cap and tube shall be so designed so as to maintain the sterility of the contents and, that once the cap is removed, it is readily evident that the tube has been opened or tampered with. A design that consists of cap with a pliable, flared skirt and a tube with a metal flange which is rolled over the flared skirt is considered an acceptable tamperproof closure. A wax seal at the ophthalmic end is not acceptable as a tamperproof closure.

3.4.4.9 Closure H, screwcap, polypropylene, with liner. Closure H, polypropylene screwcap, shall conform to 3.4.4.2, except shall be fabricated from polypropylene.

3.4.5 Seals (bottom end) for containers of group B. Unless otherwise specified, tubes shall be sealed on the bottom end by one of the following methods: Double or quadruple fold, clipless; double or quadruple fold, with clips; welded; or heat-sealed (for plastic tubes).

3.5 Group C. Cans, metal.

3.5.1 Cans, metal. Unless otherwise specified, metal cans shall be fabricated of 1.25 hot-dipped tinplate or 0.50 electrolytic tinplate. The minimum base weight of the sheet shall be 90 pounds per base box.

3.5.1.1 Type a, can for liquids. Type a, cans for liquids, shall conform to the requirements of PPP-C-96 for type V, class 4, with metal screwcap. Shape and protective coating shall be as specified in the procurement document. Cans for liquids shall be constructed with outside soldered, side seams. A plug-type inner seal shall be employed, unless otherwise specified. Liners in the closures shall be tinfoil faced. The seaming compounds used as the lining in the top and bottom double seams shall be impervious to, and shall not affect, the product. The supplier of the empty cans shall certify that all empty cans were tested for leakage by applying an internal air pressure of 3 pounds per square inch for a minimum of 5 seconds, and that all cans delivered did not leak. Notwithstanding the testing by the supplier of the empty cans for leakage, the filled cans shall be tested for leakage by the specified test method of this document.

3.5.1.2 Type b, cans for solids and semisolids. Type b, cans for solids and semisolids, shall conform to the requirements of PPP-C-96 for type V, class 1 or 2. Class, shape, and protective coatings shall be as specified in the procurement document.

3.5.1.3 Type c, cans, key-opening type. Type c, key-opening type cans shall conform to the requirements of PPP-C-96 for type III. Protective coating shall be as specified in the procurement document.

3.5.1.4 Type d, can, special. Type d can, special, shall be as specified in the procurement document.

3.6 Group D. Canisters.

3.6.1 Class 1, fiber, with metal ends. Class 1, fiber canisters, with metal ends, shall be as specified in the procurement document.

3.6.2 Class 2, fiber, with plastic ends. Class 2, fiber canisters, with plastic ends, shall be as specified in the procurement document.

3.6.3 Class 3, all fiber. Class 3, all fiber canisters, shall be as specified in the procurement document.

specified in the procurement document.

3.7 Group E. Pails and drums.

3.7.1 Class 1, metal pails.

3.7.1.1 Type I, pails for liquids. Type I, pails for liquids, shall conform to the requirements of PPP-P-704 for type I, class 2, with flexible spout closure and closure seal, as specified in the same specification. Unless otherwise specified, the interior of pails shall be lined with an interior coating as specified in the same specification.

3.7.1.2 Type II, pails for solids and semisolids. Type II, pails for solids and semisolids, shall conform to the requirements of PPP-P-704 for type II, class 2. Unless otherwise specified, the interior of all pails shall be lined with an interior coating as specified in the same specification.

3.7.2 Class 2, fiber drums. Class 2, fiber drums, shall conform to the requirements of PPP-D-723 for the type, grade, and class, as specified in the procurement document.

3.8 Group F. Bags or liners for containers.

3.8.1 Bags or liners. When specified, open-top cans, canisters, pails, or drums, shall be fitted with a suitable bag or liner to prevent interaction between the container and contents. Bag or liner closures shall be effected by means of a triple drug store fold, twisting and tying with cord, heat-sealing, or any other suitable method which will retain the contents within the bag or liner.

3.8.1.1 Class 1, paper. Class 1, paper bags or liners, shall be pasted, sewn, or heat-sealed, with flat or square bottom and of appropriate size to fit within the container. Weight of paper and design of bag or liner shall be consistent with the size of container and weight of contents. Bag or liner shall not tear and shall afford the required degree of protection for storage and shipment.

3.8.1.2 Class 2, plastic. Class 2, plastic bags or liners, shall be fabricated of not less than 0.002 inch virgin polyethylene, heat-sealed, with flat or square bottom. The plastic bag or liner shall be free from tears, holes, or slits.

3.8.1.3 Class 3, laminated foil. Class 3, laminated foil bags or liners, shall be as specified in the procurement document.

3.8.2 Group G. Laminated foil, molds, and wrappers.

3.8.2.1 Type I. Laminated aluminum foil strip. The quantity of product in each pocket (cell) and the number of pockets (cells) of the laminated foil strip shall be as designated in the procurement document. The strips shall be continuous (single-line), hermetically sealed, laminated, aluminum foil. The aluminum foil shall be not less than 0.7 mil (0.0007 inch) in thickness. Each quantity of product, as designated in the procurement, shall be hermetically heat-sealed within its own pocket (cell). Each pocket (cell) shall be of the minimum size necessary to protect the product and meet specified tests (see 4.3.1.5). The size of the pocket shall be designated in the procurement document. The size of the pocket includes the heat-sealed area. If pocket size is not specified in the procurement document, it shall not exceed 1-1/4 by 1-1/4 inches. Each pocket (cell) shall be separated from the adjoining pocket by perforations, enabling one pocket to be removed from the strip easily, without disturbing the heat-seal of the adjoining pocket. The pockets shall not become separated when folded at the perforation. However, when being used, each pocket shall be easily removed from the strip, at the perforation, without disturbing the heat seal of the adjoining pocket. The layers of the laminated foil shall not separate in handling, storage, and use.

3.8.2.2 Type II. Molds or wrappers.

3.8.2.2.1 Class 1. Mold (cell). Each suppository shall be packaged in an individual, hermetically sealed, close-fitting mold (cell) of such design that none of the contents will escape if the suppository is stored in a warm place. Further, the suppository shall resolidify in substantially its original shape when cooled or held under cold, running water. The suppositories shall comply with the test specified in 4.3.1.4. This paragraph shall also be applicable to suppositories which are premolded and then packaged as specified herein.

3.8.2.2.2 Class 2. Wrapper. Each suppository shall be individually foil-wrapped and shall be completely covered by the foil wrapper. Note: The wrapped suppository is not hermetically sealed.

3.8.3 Group H. Cartridge-needle unit.

3.8.3.1 Cartridge-needle unit. Unless otherwise specified, the size of the glass cartridge shall be as designated in the item identification shown in the procurement document. The length, bevel, and gage of the hypodermic needle shall be as designated in the procurement document. If not designated, a regular bevel point needle shall be furnished. The hypodermic needle shall be firmly secured. The needle shall be in accordance with the dimensions of GG-N-196. The needle cannula shall comply with the test requirements of GG-N-196. Epoxy sealing of needle cannulae to the hubs is acceptable, provided it complies with this paragraph. The needle shall be covered with a suitable cover which shall be capable of maintaining the sterility of the injection and the needle cannula, and prevent leakage.

3.8.3.2 The number of cartridge-needle units required shall be as specified in the procurement document.

3.9 Required labeling terms.

3.9.1 Stock number. The stock number shall be the exact stock number specified in the procurement document. The National Stock Number shall be used when provided and shall not be preceded by the abbreviation "NSN" or "Stock No." unless otherwise specified.

3.9.2 Item identification. Item identification shall be the name designated in the procurement document for the item specified, and shall include all modifiers to the name.

3.9.3 Unit of issue. The unit of issue shall be as specified in the procurement document. Example: Each, Bottle, Set, or other term.

3.9.3.1 When components or accessories are required in addition to one or more immediate containers, such requirements will be specified in the procurement document.

3.9.4 Quantity. The quantity shall be the number of units of issue contained in a package as specified in the procurement document. The designation of quantity shall be as required in the procurement document.

3.9.5 Lot, control, batch, or serial number. The lot, control, batch, or serial number, shall be that series of numbers, letters, or combination of numbers and letters, established by the manufacturer to record production and control of product. The lot, control batch, or serial number on collapsible tubes may be applied to the crimped end providing the label of the tube states "See crimp for Lot No." or a similar statement.

mpliance with transportation regulations. All shipments shall comply

For Defense Personnel Support Center procurement, a lot, batch, or control is that single, uniform, and homogeneous quantity of product produced from one formulation, in one manufacturing and production operation, and which quantity has received entirely the same processing and treatment. For tablets, the definition of Fed. Std. No. 140 applies; for parenterals, the definition of Fed. Std. No. 142 applies; and for capsules, the definition of Fed. Std. No. 285 applies.

3.9.5.1 Imprinting of lot numbers. The imprinting (debossing) of lot numbers into individual cartons and/or unit package, in lieu of printing by ink, will be acceptable.

3.9.5.2 Imprinting of expiration dates. The imprinting (debossing) of the expiration date into individual cartons and/or unit package, in lieu of printing by ink, will be acceptable.

3.9.5.3 Imprinting of date of manufacture. The imprinting (debossing) of the date of manufacture into individual carton and/or unit package, in lieu of printing by ink, will be acceptable.

3.9.6 Date of manufacture. When the date of manufacture is required, it shall be indicated by month and year (such as: "MFD 4/76"), or month, date, and year (such as: "MFD April 6, 1976"). When the date of the month is included in the date of manufacture, the month shall be designated by the name of the month and not by numeral designation for the month.

The date of manufacture is defined as follows:

3.9.6.1 For parenterals. The date of manufacture shall comply with the definition stated in S4.7 (S4.7.1, S4.7.2, or S4.7.3, as applicable) of Fed. Std. No. 142.

3.9.6.2 For tablets, capsules, and pills. The date of manufacture shall comply with the definition stated in S4.3 (S4.3.1, S4.3.2, or S4.3.3) in Fed. Std. No. 140 for tablets, and in Fed. Std. No. 285 for capsules, as applicable.

3.9.6.3 For all items other than parenterals, tablets, capsules, and pills. The date of manufacture shall be the date when the item is placed within the immediate container. Pills comply with Fed. Std. No. 140.

3.9.6.3.1 Date of manufacture on collapsible tubes. Date of manufacture on collapsible tubes may be applied to the crimped end, without the prefix "MFD," providing the label on the tube states: "See crimp closure for date of manufacture" or a similar statement.

3.9.7 Expiration dating period. The expiration dating period shall be that dating period which is specified in the procurement document. An expiration date shall be used only when an expiration dating period is stated in the procurement document for the item or when required by statute (see 5.5.2.2). When the date of the month is included in the expiration date, the month shall be designated by the name of the month and not by numeral designation for the month.

The expiration date shall be stated as required in this paragraph (3.9.7). The expiration date as shown on the immediate container label shall appear in the same manner on all other containers used in the packaging and packing of the item.

3.9.7.1 Expiration date on collapsible tubes. The expiration date on collapsible tubes may be applied to the crimped end, providing the label on the tube states: "See crimp closure for expiration date" or a similar statement.

3.9.7.2 For combination packages which bear an expiration date on at least one item, all other components shall bear no dating or the same expiration date.

3.9.7.3 The expiration dates of antibiotics shall be based upon the first or original Food and Drug Administration certification. This certification shall not be later than 6 months after date of manufacture which, for this purpose, is the date of tableting, capsulating, or otherwise forming the final dosage form.

3.9.8 Extended potency lines. When specified, labels for antibiotic items shall include three (3) lines to permit the insertion of extended dating periods. Lines may be positioned horizontally or vertically. The three lines shall be placed below, or adjacent to, the expiration date. If the three lines are not so placed, the lines shall be preceded by the phrase "Potency Extended To:."

3.9.9 Precautionary markings and antidotes. Precautionary markings and antidotes, as required by statute or as specified in the procurement document, shall appear on the labels.

3.9.10 Storage information. Storage information, as required by statute or as specified in the procurement document, shall appear on the labels (see 5.5.2.2).

3.9.11 Preservatives and buffers.

3.9.11.1 Preservatives. The presence and proportion(s) of preservative(s), as required by statute or as specified in the procurement document, shall appear on the labels.

3.9.11.2 Buffers. The presence and proportion(s) of buffer(s), as required by statute or as specified in the procurement document, shall appear on the labels.

3.10 Labeling. Labeling shall be as specified in 5.5.2.1 and the procurement document.

3.10.1 (This paragraph is reserved for future use.)

3.10.2 (This paragraph is reserved for future use.)

3.10.2.1 Placement of ampul labels. The ampul shall be so labeled that a sufficient area of the ampul remains uncovered for its full length or circumference to permit inspection of the contents.

3.10.3 (This paragraph is reserved for future use.)

3.10.4 Red print. When red printing is specified for a particular portion of the label, no other medical and technical information shall be in red print.

3.10.5 Controlled substance schedule symbol. The controlled substance schedule symbol shall appear in the labeling as required by the Drug Enforcement Administration regulations. The symbol shall not appear on intermediate and exterior containers.

3.10.5.1 All labeling information required by Federal Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act shall appear. Note that narcotic strip stamps are no longer required.

3.10.6 (This paragraph is reserved for future use.)

3.10.7 Use of "cc" versus "ml". The designations "cc" and "ml" shall be considered interchangeable. However, the designation used, "cc" or "ml" shall be used consistently in the labeling and MIL-STD-129 marking information on intermediates and exteriors.

3.10.8 Designation of gram(s). The abbreviation "Gm" for "gram(s)", if it appears in any procurement document shall not be used. The word "Gram" or "grams," as applicable, shall be used. The official abbreviation "g" may be used in lieu of the word "gram" or "grams" in the labeling.

3.10.9 Applicable to all items under Bureau of Biologics-Food and Drug Administration control. The contractor shall certify for each delivery that the labeling (immediate container label, unit package label, and package insert) is the same as that which has been submitted to, and approved by, the Bureau of Biologics, and is in conformance with all requirements of the procurement document. The certificate shall be submitted as directed in paragraph S9.1.1 of Fed. Std. No. 142.

3.11 Clarity and durability of markings.

3.11.1 Clarity of marking. Labelings and markings on all containers shall be clear and legible.

3.11.2 Durability of markings on the labels. The markings on the labels shall comply with the requirements of 3.11.4. See 4.3.2 for test sample.

3.11.3 Durability of markings on glass, plastic, and metal surfaces. Markings on glass, plastic, and metal surfaces, shall comply with the requirements of 3.11.4. See 4.3.3 for test sample.

3.11.4 All markings on all containers shall be durable and shall not smear or be removed during normal handling of the containers. The labels, the markings on the labels, or the markings directly on the containers shall be clear and legible; and shall comply with the requirements of this paragraph at any time during the normal storage period.

3.12 Quantity of contents. Unless specified elsewhere in the procurement document, the net contents of the material supplied, as determined from the samples tested (see 4.3.4), shall average not less than that stated in the purchase description. Unless otherwise specified or required elsewhere in the procurement document, no one immediate container, of the samples tested, shall contain less than 95 percent of the required contents. The quantity of contents shall be determined for tablets as stated in Fed. Std. No. 140; for parenterals, as stated in Fed. Std. No. 142; and for capsules, as stated in Fed. Std. No. 285.

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

4. QUALITY ASSURANCE PROVISIONS

4.1 Sampling. Unless otherwise specified, sampling procedures shall be conducted in accordance with MIL-STD-105.

4.1.1 Inspection lot. Each lot of material offered by the contractor shall be sampled for examination and tests to determine compliance with all requirements contained in this specification.

4.2 Examination. The containers shall be examined to determine compliance with all requirements contained in this specification.

4.3 Test procedures. Test procedures shall be conducted, as applicable, to determine compliance with specification requirements. When a temperature is specified for a particular test, the test equipment shall be set at the designated temperature. The plus or minus (+) tolerance is given in the test only to allow for the variation or cycling range of the test equipment.

4.3.1 Leak test. Immediate containers, with closures in place, and seals applied, when specified, shall comply with the applicable tests.

4.3.1.1 Immediate containers holding nonflammable liquids. Immediate containers holding nonflammable liquids shall be subjected to the following test:

> The filled immediate container, with seals applied when specified, shall be selected at random from each lot; suspended in an inverted position for 2 hours at room temperature; and then for 4 hours at 49° C. ± 3° C. No leakage of contents shall be evidenced during, or at the completion of the test. When the quantity of contents is one gallon or more, the full testing (6 hours) shall be at room temperature.

Notes:

1. Nonflammable liquids are those which are not designated as flammable in the procurement document.

2. The above test is not applicable to flame-sealed ampuls which are tested by other methods (see 4.3.1.2).

3. Test samples of items, requiring refrigerated storage in the procurement document, shall not be offered to the Government after being subjected to the leakage test. Test samples of items, requiring storage at controlled room temperature 15° - 30° C (59° - 86° F), may be offered to the Government after being subjected to the elevated temperature of the test, unless otherwise prohibited in the procurement document or the specification.

4. Unit of product for sampling - Filled immediate container.

Sampling criteria. Immediate containers holding nonflammable liquids shall be tested in accordance with the following sampling criteria:

TABLE I. Sampling criteria-immediate containers holding nonflammable liquids.

Categories	Inspection level	Sample size	Rejection number	AQL	Minimum sample
A. Items not designated for refrigerated storage:					
Less than 1 pint	S-4	-	-	1/	32
1 pint but less than 1 gallon	-	20	1	-	-
1 gallon and over	-	10	1	-	-
B. Items designated for refrigerated storage:					
All sizes	-	8	-	1/	-

1/ Applicable to sterile and nonsterile products.

(1) Sterile.

The rejection number for the leakage test shall be one (1). Resubmission and retesting of any lot failing the above test is permitted only with the expressed approval of the Defense Personnel Support Center.

(2) Nonsterile.

The rejection number for the leakage test shall be one (1). If one or more leakers are found, such leakers shall not be offered to the Government. The lot shall be re-examined to remove leakers and shall have the closures adequately tightened, prior to being resubmitted for re-inspection and retest. When retested, using twice the sample, none of the containers shall leak.

4.3.1.1.1 Immediate containers holding flammable liquids (so labeled in the procurement document). Immediate containers holding flammable liquids (so labeled in the procurement document) shall be subjected to the following test:

The filled immediate containers, with seals applied when specified, shall be selected at random from each lot and suspended in an inverted position for 6 hours at room temperature (20° C. + 2° C.). No leakage or loss of weight of contents shall occur during or at the completion of the test.

Sampling criteria. Immediate containers holding flammable liquids shall be tested in accordance with the sampling and rejection criteria and Notes designated in 4.3.1.1 of this document.

4.3.1.2 Flame-sealed ampuls. Prior to offering the material to the Government, all flame-sealed ampuls shall be tested by the manufacturer for leakage in accordance with either A, B, or C, below. If ampuls are sealed by the tip sealing (bead seal) method, then the required leakage test(s) shall not be performed sooner than 14 days after the ampuls have been filled and sealed. Ampuls failing the manufacturer's test shall not be offered to the Government. For inspection purposes, the Government may, at its discretion, test the ampuls by one of these tests. Any leakage of ampuls shall be cause for rejection of the entire lot.

A. - Thoroughly wash all ampuls with a suitable detergent and then rinse. The ampuls are completely immersed in a hydroalcoholic solution (containing about 10 percent denatured alcohol) that is highly colored with a suitable dye or combination of dyes, yielding a color that is different from the injection. The solution containing the ampuls is heated between 41° C. and 43° C., for 10 minutes, and then allowed to cool to room temperature. The contents of each ampul is examined for color change or presence of dye. No ampul shall show a color change or presence dye.

B. - Thoroughly wash all ampuls with a suitable detergent and then rinse. The ampuls are completely immersed in an aqueous solution that is highly colored with a suitable dye or combination of dyes, yielding a color that is different from the injection. A vacuum of at least 25 inches is applied on the vessel containing the ampuls and dye solution, and the vacuum is maintained for at least 5 minutes. After releasing the vacuum, the contents of each ampul is examined for color change or presence of dye. No ampul shall show a color change or presence of dye.

C. - The ampuls are completely immersed in water that is highly colored with a suitable dye or combination of dyes, yielding a color that is different from the injection. Apply at least 10 inches of vacuum for at least 5 minutes and follow with 35 pounds air pressure for 15 minutes. After releasing the air pressure, the contents of each ampul is examined for color change or presence of dye. No ampul shall show a color change or presence of dye.

Note applicable to the leak test for flamed sealed ampuls: Parenterals in flame-sealed ampuls that require refrigerated storage by the procurement document shall be tested in accordance with test B or C.

4.3.1.3 Immediate containers holding semisolid products. Immediate containers (metal tubes, plastic tubes, jars, foil, etc.) holding semisolid products, e.g., ointments, creams, and pastes, shall be subjected to the following test:

The filled immediate containers, with seals applied when specified, shall be selected at random from each lot; exterior surfaces thoroughly cleaned; and stored for 8 hours (in a horizontal position for tubes and foil containers, and in an inverted position for jars) at a temperature of 60° C. + 3° C. No leaking, except that minute quantity that could come only from within the crimp of the tubes or thread of the screwcaps, shall be evidenced during or at the completion of the test.

Sampling criteria. Immediate containers holding semisolid products shall be tested in accordance with the following sampling criteria:

TABLE II. Sampling criteria-immediate containers holding semisolid products.

Immediate container	Range of sizes	Inspection level	Sample size	Rejection number	AQL	Minimum sample
Tube	Less than 1 pound	S-4	(32 (50 (80	1 2 2	- - -	32
Other than tube	Less than 1 pound	S-4	-	-	2.5	32
All types	1 pound but less than 5 pounds	-	20	2	-	-
All types	5 pounds or over	-	2	1	-	-

4.3.1.4 Hermetically sealed, filled, immediate containers (suppositories). Hermetically sealed, filled, immediate containers holding suppositories shall be subjected to the leakage test in accordance with inspection level. as follows:

TABLE III. Hermetically sealed, filled, immediate container.

Lot size	Sample size	Rejection number
To 3,200	24	2
3,201 to 5,000	36	3
5,001 to 22,000	48	4
22,001 and over	72	5

Leakage test. The filled, hermetically sealed, immediate containers shall be selected at random from each lot and all exterior surfaces thoroughly cleaned. Accurately weigh each filled, hermetically sealed, immediate container and store for 8 hours in a horizontal position at a temperature of 43° C. ± 2° C. At the end of that time, no leakage, except that minute quantity that may have been trapped within the heat seal, shall be evidenced during or at the completion of the test. Return fill d, hermetically sealed, immediate containers to room temperature and accurately weigh each. The loss in weight of each filled, hermetically sealed, immediate container shall not exceed 0.02 gram.

4.3.1.5 Laminated aluminum foil strip. Each cell of the aluminum foil strips shall be capable of passing tests 4.4.3.1, 4.4.3.1.1, and for results, 4.4.3.2 and 4.4.3.4 of MIL-P-116. The required test techniques are in paragraph 6.2 and all subparagraphs, and in paragraph 6.6 and all subparagraphs, with the exception of subparagraph 6.6.2 of referenced method 5009 of Fed. Test Method Std. No. 101.

4.3.2 Durability of markings on the labels. The test sample for durability of markings on the labels shall be as follows (see 3.11):

Ten (10) to twenty (20) labeled immediate containers shall be selected at random from each lot.

4.3.3 Markings on glass, plastic, and metal surfaces. The test sample for durability of markings on glass, plastic, and metal surfaces, shall be as follows (see 3.11):

Ten (10) to twenty (20) labeled (marked) containers shall be selected at random from each lot.

4.3.4 Quantity of contents. Except for tablets, parenterals, and capsules, which reference Fed. Std. No. 140, Fed. Std. No. 142, and Fed. Std. No. 285, respectively, the weight, volume, or count, of contents (see 3.12) in immediate containers shall be determined on randomly selected samples of each lot. Unless otherwise specified or required elsewhere in the procurement document, inspection level shall be S-2; minimum sample size shall be 10.

4.3.5 (This paragraph is reserved for future use.)

4.3.6 Accuracy of markings on droppers (pipets). A sample of not less than ten (10) graduated droppers (pipets) shall be randomly selected. The droppers shall be individually tested at each graduation into a graduate cylinder. As an alternate, a graduated tuberculin syringe of appropriate capacity may be used. The delivery for each graduation, for each graduated dropper, shall be not less than 90.0 percent and not more than 110.0 percent of the marking at that graduation.

5. PREPARATION FOR DELIVERY

5.1 Packaging, packing, and marking.

5.1.1 Packaging and packing quantities. Unless otherwise specified, packaging and packing quantities shall be shown in Tables IV, V, VI, as applicable. The packaging and packing quantities specified in Tables IV, V, and VI, were established to meet the particular needs of the Medical Services of the Armed Forces, consistent with the requirements for storage and redistribution. In the interest of economy, each activity using this specification should investigate the various available standard manufacturers' packs, and specify packaging and packing quantities to meet the best needs of the particular activity. For example, a common item, such as, penicillin, is available in an individual box for consumer use, and in bulk packs of 50 to 100 bottles for hospital use.

Note: The packing quantities indicated in column 4 of the applicable table for the specified procedure code number are interpreted as follows: The numeral preceding the slash (/) indicates the number of units of issue contained in the intermediate package. The number suffixing the slash (/) indicates the total number of units of issue contained in the exterior container. Example: "12/432" indicates 12 units of issue packaged to each intermediate package, and a total of 432 units of issue are to be overpacked in an exterior container.

5.1.1.1 Packaging or packing variations permitted. If the required number of units in the entire shipment is less than the number of units specified to be overpacked in an intermediate or an exterior container, such units will be packed in an exterior container of suitable size and design, acceptable to a common carrier, which will insure safe delivery to destination.

PACKAGING AND PACKING QUANTITIES

TABLE IV. Group A, Classes 1 & 2, glass; plastic; bottles or jars

1	2	3	4	5	6
	Intermediate packaging				
Procedure code No.	No. of units of issue	See paragraph	Total No. of units in intermediate and exterior container	Level B packing See paragraph	Level A packing See paragraph
1.....	12	5.2.7.1	12/432	5.4.3.1.1	5.4.4
2.....	12	5.2.7.1	12/288	5.4.3.1.1	5.4.4
3.....	12	5.2.7.1	12/144	5.4.3.1.1	5.4.4
4.....	12	5.2.8	12/96	5.4.3.2	5.4.4
5.....	12	5.2.8	12/48	5.4.3.2	5.4.4
6.....	12	5.2.9	12/24	5.4.3.2	5.4.4
7.....	12	5.2.9	12/12	5.4.3.3	5.4.4
8.....	1 1/	5.2.10	1/4	5.4.3.4	5.4.4

1/ For Procedure Code 8, under column 2, the quantity shown denotes the unit package, in lieu of the intermediate package.

NOTE: Procedures codes are not applicable when container conforming to PPP-C-1266 is used for refrigerated shipments.

TABLE V. Group B, classes 1 and 2, metal and plastic collapsible tubes

1	2	3	4	5	6
	Intermediate packaging				
Procedure code No.	No. of units of issue	See paragraph	Total No. of units in intermediate and exterior container	Level B packing See paragraph	Level A packing See paragraph
9.....	12	5.2.12.1	12/1728	5.4.3.5.1	5.4.4
10.....	12	5.2.12.1	12/1152	5.4.3.5.1	5.4.4
11.....	12	5.2.12.1	12/864	5.4.3.5.1	5.4.4
12.....	12	5.2.12.1	12/576	5.4.3.5.1	5.4.4
13.....	12	5.2.13	12/432	5.4.3.5.1	5.4.4
14.....	12	5.2.13	12/288	5.4.3.5.1	5.4.4
15.....	12	5.2.13	12/144	5.4.3.5.1	5.4.4

NOTE: Procedure codes are not applicable when container conforming to PPP-C-1266 is used for refrigerated shipments.

TABLE VI. Group C and D, metal cans and fiber canisters

1	2	3	4	5	6
	Intermediate packaging				
Procedure code No.	No. of units of issue	See paragraph	Total No. of units in intermediate and exterior container	Level B packing See paragraph	Level A packing See paragraph
16.....	12	5.2.14.1	12/192	5.4.3.6.1.1	5.4.4
17.....	12	5.2.14.1	12/96	5.4.3.6.1.1	5.4.4
18.....	12	5.2.14.1	12/72	5.4.3.6.1.1	5.4.4
19.....	12	5.2.14.1	12/48	5.4.3.6.1.1	5.4.4
20.....	12	5.2.14.1	12/24	5.4.3.6.1.1	5.4.4
21.....	4	5.2.15	4/4	5.4.3.6.2	5.4.4
22.....	6	5.2.15	6/6	5.4.3.6.2	5.4.4

NOTE: Procedure codes are not applicable when container conforming to PPP-C-1266 is used for refrigerated shipments.

TABLE VII. Group E, classes 1 and 2, drums; metal and fiber.

Shall be as specified in the procurement document.

5.2 Packaging.

5.2.1 Level A.

5.2.2 Unit of issue. The number of immediate containers specified in the procurement document constitutes one (1) unit of issue.

5.2.3 Immediate container. When individual or unit packaging of immediate containers is specified in the procurement document, the individual packaging shall conform to 5.2.4 and the unit packaging shall conform to 5.2.5. When only one (1) immediate container constitutes one (1) unit of issue, and unit packaging is not specified in the procurement document, the specified number of immediate containers shall be packaged in an intermediate container in accordance with Tables IV, V, or VI, for the applicable group and the class designation of the item.

5.2.4 Individual carton (box). Individual carton (box) shall be set-up or folding box of suitable size and design. Closure shall be adequate to prevent spilling of contents during normal handling operations.

5.2.5 Unit package. Unit package shall be a box of appropriate size constructed in accordance with PPP-B-566, PPP-B-676, or PPP-B-636, type CF, class domestic, except that commercial colors will be acceptable. As an alternate, a folding reverse tuck corrugated fiberboard box of "C" or "E" flute may be used. Unit box may be supplied with a die-cut window which will permit disclosure of label information (see 5.5.2.1). For glass bottles, 1 pint and larger, a corrugated fiberboard sleeve with die-cut window and designed with a snap-in feature which will hold the bottle firmly in place may be used. Four (4) snap-ins shall be provided, two (2) at the shoulder of the bottle and two (2) at the bottom of the bottle.

5.2.5.1 Partitions. When two or more immediate containers are packaged in a unit package, the box design shall include full or shoulder height partitions so arranged that each immediate container is contained in an individual cell. When individual boxes are used, partitions will not be required.

5.2.5.1.1 Undulated partitions. As an alternate for glass ampuls, tubes, and vials, box design shall include one or more rigid trays with undulated partitions which shall hold and cushion each ampul, tube, or vial, by means of the grip action of the individual flute. The flutes shall be adhered to the tray.

5.2.5.1.2 Component parts. When component parts such as files, applicators, or other accessories are required, they shall be positioned within the unit package so as to prevent damage to the immediate containers.

5.2.5.1.3 Closure. Unit package shall be closed as specified in the appendix of the applicable box specification.

5.2.6 Intermediate packaging.

5.2.6.1 Packaging quantities. Unless otherwise specified, the number of units of issue specified in Tables IV, V, or VI, column 2, shall be packaged in intermediate containers for the applicable procedure code number as specified in the procurement document. The intermediate containers shall conform to the requirements of the applicable paragraph referenced in column 3.

5.2.7 Table I, group A, classes 1 & 2, glass; plastic; bottles or jars. The specified number of units of issue shall be packaged in intermediate containers as hereinafter specified for the applicable procedure code number.

5.2.7.1 Intermediate package for Procedure Code Nos. 1, 2, or 3. Bottles or jars shall be packaged in a box of appropriate size and design, constructed in accordance with PPP-B-566 or PPP-B-676, or PPP-B-636, type CF, class domestic, except that commercial colors shall be acceptable. Box design shall include partitions.

5.2.7.2 Partitions. Box design shall include full-height partitions, half-slotted style. The partitions shall form an individual snug-fitting cell for each immediate container. Partitions shall be fabricated of material equal to the strength of board used for the fabrication of the box. When unit boxes are used, partitions shall not be required. In addition, partitions shall not be required when plastic bottles or plastic jars are specified in the procurement document.

5.2.7.3 Closure. Closure shall be effected in accordance with appendix of the applicable box specification.

5.2.8 Intermediate package for Procedure Code Nos. 4 or 5. Bottles or jars shall be packaged in a fiberboard box of appropriate size and design having a minimum bursting strength test of 200 pounds in accordance with PPP-B-636, type CF, class domestic. Box design shall include partitions. When unit boxes are used, partitions shall not be required. In addition, partitions shall not be required when plastic bottles or plastic jars are specified in the procurement document.

5.2.8.1 Partitions. Partitions shall be full or shoulder height, half-slotted style, fabricated of material equal to the strength of board used for the fabrication of the box. The partitions shall form an individual snug-fitting cell for each immediate container.

5.2.8.2 Closure. Closure shall be effected in accordance with Appendix of PPP-B-636.

5.2.9 Intermediate package for Procedure Code Nos. 6 or 7. Bottles or jars shall be packaged in a fiberboard box, of appropriate size and design, having a minimum bursting strength test of 200 pounds in accordance with PPP-B-636, type CF, class domestic. Box design shall include partitions, liners, and top and bottom pads.

5.2.9.1 Partitions. Partitions shall be full or shoulder height, half-slotted style, and fabricated of material equal to the strength of board used for the fabrication of the box. The partitions shall form an individual, snug-fitting cell for each immediate container. When unit boxes are used, partitions shall not be required. Partitions shall not be required when plastic bottles or plastic jars are specified in the procurement document.

5.2.9.2 Liner. Liner shall be of one-piece, covering the sides and ends of the box, and fabricated of material equal to the strength of board used for the fabrication of the box. Liners shall be of the same height as the bottles. For Procedure code No. 6, liners shall not be required when plastic bottles or plastic jars are specified in the procurement document.

5.2.9.3 Pads. Top and bottom pads shall be fabricated of material equal to the strength of board used for the fabrication of the box and not more than 1/4 inch less than the inside length and width of the box and positioned on bottom and top of liners and partitions. For Procedure code No. 6, top and bottom pads shall not be required when plastic bottles or plastic jars are specified in the procurement document.

specified (see 6.2).

5.2.9.4 Closure. Closure shall be in accordance with Appendix of PPP-B-636.

5.2.10 Intermediate package for Procedure Code No. 8. Bottles or jars shall be packaged in a fiberboard box, of appropriate size and design, having a minimum bursting strength test of 275 pounds in accordance with PPP-B-636, type CF, class domestic. Box design shall include liner, and top and bottom pad .

5.2.10.1 Liner. Liner shall be of one-piece, covering the sides and ends of the box, and fabricated of material equal to the strength of board used for the fabrication of the box. Liner shall be the same height as the bottle.

5.2.10.2 Pads. Top and bottom pads shall be fabricated of material equal to the strength of board used for the fabrication of the box and not more than 1/4 inch less than the inside length and width of the box, and positioned on bottom and top edge of liner.

5.2.10.3 Closure. Closure shall be effected in accordance with Appendix of PPP-B-636.

5.2.11 Group A, class 1, glass vials, tubes, and ampuls, and Group B, class 2, plastic containers, shall be packaged as specified in the procurement document.

5.2.12 Table II, group B, class 1 or 2. Tubes collapsible, metal or plastic. The specified number of units of issue shall be packaged in intermediate containers as hereinafter specified for the applicable procedure code number. Unless otherwise specified, all tubes shall be packaged in individual cartons (boxes) (see 5.2.4 and 5.2.5).

5.2.12.1 Intermediate package for Procedure Code Nos. 9, 10, 11, or 12. Tubes, collapsible, metal or plastic, shall be packaged in a box of appropriate size and design, constructed in accordance with PPP-B-566 or PPP-B-676, except that commercial colors will be acceptable, or PPP-B-636, type CF, class domestic.

5.2.12.2 Closure. Boxes shall be of such design or secured in a manner as to prevent spilling of contents under normal handling.

5.2.13 Intermediate package for Procedure Code Nos. 13, 14, or 15. Tubes, collapsible, metal or plastic, shall be packaged in a fiberboard box of suitable size and design, constructed in accordance with PPP-B-636, type CF, class domestic.

5.2.13.1 Closure. Closure shall be effected in accordance with Appendix of PPP-B-636.

5.2.14 Table III, groups C and D, metal cans and fiber canisters. The specified number of units of issue shall be packaged in intermediate containers as hereinafter specified. The applicable size shall be as specified in the procurement document.

5.2.14.1 Intermediate package for Procedure Code Nos. 16, 17, 18, 19, or 20. Metal cans or fiber canisters shall be packaged in a fiberboard box of appropriate size and design, constructed in accordance with PPP-B-636, type CF, class domestic.

5.2.14.2 Closure. Closure shall be effected in accordance with Appendix of PPP-B-636.

5.2.15 Intermediate package for Procedure Code Nos. 21 or 22. Metal cans or fiber canisters shall be packaged in a corrugated fiberboard box of suitable size and design, having a minimum bursting strength test of 275 pounds in accordance with PPP-B-636, type CF, class domestic. When cans are fitted with bridge type handles, or screwcaps which are not flush with the top edge of the can body, the handles or caps shall be protected by fiberboard pads, aircells, or other suitable means, to prevent damage to the cans. Key-opening type cans (type c) shall be protected in such a manner as to prevent rupture of the tear strip.

5.2.15.1 Closure. Closure shall be effected in accordance with Appendix of PPP-B-636.

5.3 Commercial packaging (Level C). The subject commodity shall be packaged in accordance with Fed. Std. No. 102.

5.4 Packing.

5.4.1 Packing quantities. Unless otherwise specified, the number of intermediate containers containing the required number of units of issue indicated in column 4, of Tables I, II, or III, shall be overpacked in an exterior container for the specified procedure code. The level of protection shall be as specified in the procurement document.

5.4.2 Levels of protection. The required levels of protecti are indicated by level B, column 5, and level A, column 6, of tables IV, V, or VI, and the required degree of protection shall be in accordance with the referenced paragraph for the specified procedure code number.

5.4.3 Level B.

5.4.3.1 Bottles or jars.

5.4.3.1.1 Exterior container for Procedure Code Nos. 1, 2, or 3. Intermediate boxes, as indicated for specified procedure code, shall be overpacked in a fiberboard box of appropriate size and design constructed in accordance with PPP-B-636, type CF, class domestic. Bursting strength of box shall be in accordance with Special Requirements of the applicable table of PPP-B-636. Box design shall include liner, and top and bottom pads. When intermediate boxes are stacked in two or more tiers, a pad shall be interposed between each tier.

Note: Liners and pads will not be required when intermediate boxes are fabricated of fiberboard conforming to the requirements of PPP-B-636, type CF, class domestic.

5.4.3.1.2 Liners. Liners shall be one-piece, covering the sides and ends of the box, fabricated of double-faced corrugated fiberboard having a minimum bursting strength test of 200 pounds in accordance with PPP-B-636, type CF, class domestic.

5.4.3.1.3 Pads. Top, bottom, and tier pads, shall be fabricated of double-faced fiberboard, having a minimum bursting strength test of 200 pounds in accordance with PPP-B-636, type CF, class domestic.

5.4.3.1.4 Closure. Closure shall be effected in accordance with the appendix of PPP-B-636.

5.4.3.2 Exterior container for Procedure Code Nos. 4, 5, or Intermediate boxes, as indicated for the specified procedure code, shall be overpacked in a box of appropriate size and design constructed in accordance with PPP-B-636, type CF, class domestic. Bursting strength of box shall be in accordance with Special Requirements in the applicable table of PPP-B-636.

5.4.3.2.1 Closure. Closure shall be effected in accordance with the appendix of PPP-B-636.

5.4.3.3 Exterior container for Procedure Code No. 7. Unless otherwise specified, no overpacking will be required for level B protection.

5.4.3.4 Exterior container for Procedure Code No. 8. Intermediate boxes, as required for procedure code No. 8, shall be overpacked in a box of appropriate size and design constructed in accordance with PPP-B-636, type CF, class domestic. Bursting strength of box shall be in accordance with Special Requirements of the applicable table of PPP-B-636.

5.4.3.4.1 Closure. Closure shall be effected in accordance with the appendix of PPP-B-636.

5.4.3.5 Collapsible tubes.

5.4.3.5.1 Exterior container for Procedure Code Nos. 9, 10, 11, 12, 13, 14, or 15. Intermediate boxes, as required for the specified procedure code, shall be overpacked in a fiberboard box of appropriate size and design, constructed in accordance with PPP-B-636, type CF, class domestic.

5.4.3.5.1.1 Closure. Closure shall be effected in accordance with the appendix of PPP-B-636.

5.4.3.6 Metal cans and fiber canisters.

5.4.3.6.1 Level B packing for group C, metal cans, and group D, fiber canisters, shall be as shown in table III, column 5.

5.4.3.6.1.1 Exterior container for Procedure Code Nos. 16, 17, 18, 19, or 20. Intermediate boxes, as indicated for the specified procedure code, shall be overpacked in a fiberboard box of appropriate size and design constructed in accordance with PPP-B-636, type CF, class domestic. Bursting strength of box shall be in accordance with Special Requirements of the applicable table of PPP-B-636.

5.4.3.6.1.2 Closure. Closure shall be effected in accordance with the appendix of PPP-B-636.

5.4.3.6.2 Exterior container for Procedure Code Nos. 21 or 22. Unless otherwise specified, no overpacking will be required for level B protection.

5.4.3.7 Drums.

5.4.3.7.1 Metal or fiber. Unless otherwise specified, group E, classes 1 and 2 type drums, no overpacking will be required.

5.4.4 Level A.

5.4.4.1 Exterior containers. Bottles, jars, collapsible tubes, metal cans, and fiber canisters shall be packed for the degree of protection specified for level B. Each level B exterior container shall be further protected by being individually overpacked in an exterior container designed for type 1 load, and constructed in accordance with PPP-B-601, overseas type; PPP-B-621, class 2; or PPP-B-636, type CF, class weather resistant. Grade W5c shall not be permitted for exterior container. Bursting strength of fiberboard box shall be in accordance with Special Requirements of the applicable table of PPP-B-636.

5.4.4.2 Waterproof barrier. Each level A wood box shall be lined with a waterproof barrier conforming to MIL-L-10547. Closure and sealing shall conform to applicable paragraphs of appendix thereto.

5.4.4.2.1 Closure. Closure of wood boxes shall be in accordance with Appendix of applicable box specification. Closure and waterproofing of each fiberboard box shall be accomplished in accordance with Appendix of PPP-B-636.

5.4.4.3 Strapping. Strapping, when required, shall be in accordance with Appendix of applicable box specification.

Note: Strapping or banding shall not be required for shipments forwarded to a receiving activity within the continental limits of the United States for storage and redistribution. All overseas shipments shall be strapped or banded in accordance with the appendix of the applicable box specification.

5.4.4.4 Frozen, chilled, or limited unrefrigerated shipments. For frozen, chilled, or limited unrefrigerated shipments packaging and packing shall be level A/A. Immediate container, unit packages, and intermediate package shall be packed in a level A exterior container conforming to PPP-B-636, class weather-resistant. Level B exterior container shall not be required, however, liners and pads, as specified for level B packing, shall be furnished.

5.4.5 Commercial packing. The subject commodity shall be packed in accordance with Fed. Std. No. 102.

5.5 Marking.

5.5.1 Civil agencies. Unless otherwise specified, marking of shipments shall be in accordance with Fed. Std. No. 123.

5.5.2 Military activities.

5.5.2.1 Immediate containers, individual cartons (boxes), and unit packages. Immediate containers, individual cartons (boxes), when specified, and unit packages, when specified, shall be labeled as required by statute and shall also bear the labeling and marking specified in the procurement document. When specific information is required on the unit package, but not required on the immediate container, and a die-cut window type box is used, the required information must then appear on the immediate container.

5.5.2.2 The labeling (on the immediate containers, the individual carton (box), and unit packages) and other accompanying data, shall not include any statement with respect to refrigerated storage, storage at 2^{o} - 10^{o} C. or at 2^{o} - 8^{o} C., or in a freezer, unless specifically required in the procurement document; and such labeling, and other accompanying data, shall not bear an expiration date if the procurement document does not include an expiration dating period for the item. When an expiration dating period is specified in the procurement document, the labels shall not set forth an expiration date which is longer or shorter than the dating specified by such procurement document, unless specifically authorized in writing by the procuring activity.

5.5.2.3 The package insert, if required by statute or by the procurement document (see 3.1) shall be furnished with each unit of issue.

5.5.2.4 Size of type for labeling. Shall be in easily readable style of type and of sufficiently large size of type commensurate with the size of the container.

5.5.2.5 The trademarking and identity coding of dosage forms are not prohibited. The inclusion of trade names and company logographs in the labeling of products is not prohibited.

By including trade names or trademarks in the labeling, the contractor specifically warrants that the dosage form of the commercial product identified by the trade name included on the label is of the same composition and formulation and will regularly meet all tests required by the specification of the item being supplied. When it is found that the trade name does not comply with the above stated warranty, the contractor will relabel with a label that does not contain the trade name, and will be responsible for all expenses of relabeling, to include transportation costs to and from the contractor's plant.

5.5.3 Intermediate packages. Intermediate packages shall be marked in accordance with MIL-STD-129, and, when specified, with other requirements in the procurement document. Lot (control) number, contract or purchase order number, and name of contractor shall be shown. When the intermediate package is used as the exterior container, markings applicable to exterior containers shall be used in lieu of intermediate package markings. For items requiring an expiration date, the expiration date shall be preceded by "EXPIRES" or "EXP".

5.5.4 Exterior containers. Exterior containers shall be marked in accordance with MIL-STD-129, and, when specified, with other requirements in the procurement document. Lot (control) number shall be shown. Marking of the level B exterior container shall not be required when the level B exterior container is overpacked in a level A exterior container. For items requiring an expiration date, the expiration date shall be preceded by "EXPIRES" or "EXP".

5.5.4.1 For perishable drugs.

5.5.4.1.1 Shipping instructions. Perishable drugs not requiring constant refrigeration shall be forwarded by surface or air transporation which will insure receipt of the shipment by the consignee in less than the number of hours indicated as the maximum allowable shipping time, from the time the material was removed from refrigeration. The maximum allowable shipping time shall be stated in the procurement document. When it is anticipated that the intransit period will exceed the maximum allowable shipping time, such shipments may be forwarded in refrigerated containers which will maintain the required temperature range of 2° - 8° C (35° - 46° F) while enroute to consignee.

Refrigerated (chill) containers shall conform to PPP-C-1266, type II. Freeze containers shall conform to PPP-C-1266, type I. When refrigerated transportation is available from the consignor to the consignee, such transportation may be used in lieu of refrigerated containers. Perishable drugs requiring constant refrigeration shall be shipped by refrigerated transportation or in refrigerated containers which will maintain the required temperature while enroute to consignee. Perishable drugs required to be frozen shall be shipped by freezer transportation or in freeze containers which will maintain the required temperature when enroute to the consignee.

5.5.4.1.2 Special labeling.

5.5.4.1.2.1 For refrigerated (chilled or frozen) shipment. Each exterior container shall be marked as indicated in MIL-STD-129 for chilled or frozen material, as applicable. When refrigerated or freezer transportation is utilized, in lieu of chilled or freeze exterior containers, the chilled or frozen shipment markings of MIL-STD-129 are not required.

5.5.4.1.2.2 For limited unrefrigerated shipment. Each limited unrefrigerated exterior container shall be marked as indicated in MIL-STD-129.

5.5.4.2 Scheduling of shipments. Shipments should be scheduled to arrive at destination on a working day. Advance notice should be expeditiously forwarded to the consignee regarding the shipment and the estimated time of arrival.

5.5.5 Applicable to Defense Personnel Support Center procurements for frozen, refrigerated, and limited unrefrigerated medical material shipments. The contractor shall place one copy of the applicable notice (indicated below) inside of the shipping container, under the inner top flaps, before sealing. The forms may be obtained upon request to the contracting officer, Defense Personnel Support Center, as follows:

DPSC Form 2770	NOTICE FOR FROZEN SHIPMENTS
DPSC Form 2270-1	NOTICE FOR REFRIGERATED MEDICAL MATERIAL SHIPMENTS
DPSC Form 2270-2	NOTICE FOR LIMITED UNREFRIGERATED MEDICAL SHIPMENTS.

5.5.6 Applicable to Defense Personnel Support Center procurements. The contractor shall comply with the following:

5.5.6.1 In order to assure that all controlled substances can be properly identified by receiving activities, the contractor shall annotate the Material Inspection and Receiving Report, DD Form 250, as follows:

"CONTROLLED SUBSTANCE-REQUIRED ___1/___ STORAGE"

1/(The space shall be filled in with the word(s) "VAULT" or "LIMITED ACCESS".)

The statement shall be in CAPITAL LETTERS and entered in Block 16 of the DD Form 250.

A copy of the DD Form 250 shall be placed in an envelope and forwarded with the shipment, as required. The envelope containing the shipping documents accompanying the shipment shall be marked in CAPITAL LETTERS with the notation:

"CONTAINS SPECIAL INSTRUCTIONS"

In accordance with Federal regulations, these drugs are identified by a distinctive Controlled Substance Schedule Symbol. This symbol appears only on the immediate container and carton. "VAULT" is to be used for items bearing Symbol C-II; "LIMITED ACCESS" is to be used for items bearing Symbols C-III, C-IV, or C-V.

5.5.6.2 In order to assure that all receiving activities can properly identify items requiring special handling and storage, the contractor shall annotate the Material Inspection and Receiving Report, DD Form 250, with the storage and handling instructions required on the exterior (shipping) containers. The statement(s) shall be in CAPITAL LETTERS and entered in Block 16 of the DD Form 250.

In addition, a copy of the DD Form 250 shall be placed in an envelope and forwarded with the shipment as required. The envelope containing the shipping documents accompanying the shipment shall be marked in CAPITAL LETTERS with the notation:

"CONTAINS SPECIAL HANDLING AND STORAGE INSTRUCTIONS."

Examples of the special handling and storage statements include the following:

"STORE AT CONTROLLED ROOM TEMPERATURE 15° - 30° C. (59° - 86°F.)."
"STORE BETWEEN 2° - 8° C. (35° - 46° F.)."
"DO NOT FREEZE."
"KEEP FROZEN."
"KEEP FROM HEAT."
"FLAMMABLE."
"FRAGILE."

for level B protection.

For unrefrigerated medical material shipments, the DD Form 250 shall be annotated in Block 16 to state the maximum unrefrigerated shipping time, as designated in the procurement document. If refrigerated transport is used, the following shall appear:

"REFRIGERATED TRANSPORT UTILIZED."

For drugs, chemicals, and sterile items, the contractor shall also annotate the DD Form 250 to show the quantity shipped, the expiration date or date of manufacture, whichever is applicable, for each lot, batch, or control number.

5.5.7 Commercial containers and labeling. When the procurement document requires the immediate container to be a commercially available immediate container, paragraphs 1.2 thru 1.2.1.8 and 3.3 thru 3.8.3.2 shall not be applicable. In addition, paragraph 4.3.6 shall not apply.

When the procurement document requires labeling to be in accordance with the Federal Food, Drug and Cosmetic Act and the label information to be in accordance with commercial practice, the following paragraphs or parts thereof shall not apply: paragraphs 3.9.5 (pg. 24) starting with "providing the label" thru "similar statement"; 3.9.6 (pg. 25) starting with "When the date" thru "designation for the month"; 3.9.7 (pg. 26) starting with "When the date" thru "packing of the item."; 3.9.7.1 starting with "providing the label" thru "similar statement."; and 3.9.7.2.

Upon approval of the contracting officer, leakage test need not be performed. Should leakage occur during the expiration dating period, replacement of the complaint material shall be made by the contractor without cost to the Government.

5.5.8 Shelf-Life markings.

5.5.8.1 Type I Shelf-Life. Type I Shelf-Life markings as specified in MIL-STD-129 shall be shown.

5.5.8.2 Type II Shelf-Life. Type II Shelf-Life markings as specified in MIL-STD-129 shall be shown. The "INSPECTION/ TEST DATE" markings shall include a blank space for the inclusion of data at a later date.

6. NOTES

6.1 Ordering data. Purchasers should exercise any desired options offered herein and procurement documents should specify the following:

(a) Title, number, and date of this specification.
(b) Group, class, type, style, grade, closure, and seal required (see 1.2).
(c) Quantity of product in pocket and number of pockets (cells) in strip (see 3.8.2.1).
(d) Length and gage of needle; the bevel, if other than regular (see 3.8.3.1).
(e) Extended potency lines, if required (see 3.9.8).
(f) Selection of applicable levels of packaging, packing, and marking (see 5.1, 5.2.1, 5.3, 5.4.3, and 5.4.5).
(g) Label and labeling information (see 5.5.2.1).
(h) Storage and expiration dating period, if applicable (see 5.5.2.2).
(i) Maximum unrefrigerated shipping time, as applicable (see 5.5.4.1.1).
(j) Shelf-Life markings (see 5.5.8).

6.2 Procedure code. Procedure code numbers are intended for reference by procuring activities as means of designating the desired packaging and packing procedures. In the absence of a procedure code number specified in the procurement document, an appropriate procedure may be determined from the weight of contents, as follows:

Bottles or Jars

Net weight of contents	Procedure code No.
1/2 oz.	1
1 oz.	2
2 oz.	3
4 oz.	4
8 oz.	5
16 oz.	6
32 oz.	7
128 oz.	8

Collapsible Tubes

Net weight of contents	Procedure code No.
1/8 oz.	9
1/4 oz.	10
1/2 oz.	11
3/4 oz.	12
1 oz.	13
2 oz.	14
4 oz.	15

Metal Cans and Fiber Canisters

Net weight of contents	Procedure code No.
2 oz.	16
4 oz.	17
8 oz.	18
16 oz.	19
32 oz.	20
1 gal. round	21
1 gal. oblong	22

6.3 For Defense Personnel Support Center procurement. Any inconsistency which exists, or may appear to exist, between the requirements of statutes and the requirements of the procurement document, shall be brought to the attention of the Defense Personnel Support Center.

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

Review Activities:
Army - EA, SM
DSA - GS

Preparing activity:
DSA-DM

Project PACK 0444

Civil Agency Coordinating Activity:
GSA-FSS
HEW-FDA, HSM, NIH
IRS
OAP
USDA-AMS, ARS
VA-DMS

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(See Instructions – Reverse Side)

1. DOCUMENT NUMBER	2. DOCUMENT TITLE

3a. NAME OF SUBMITTING ORGANIZATION	4. TYPE OF ORGANIZATION *(Mark one)*
	☐ VENDOR
b. ADDRESS *(Street, City, State, ZIP Code)*	☐ USER
	☐ MANUFACTURER
	☐ OTHER *(Specify)*: _____

5. PROBLEM AREAS

a. Paragraph Number and Wording:

b. Recommended Wording:

c. Reason/Rationale for Recommendation:

6. REMARKS

7a. NAME OF SUBMITTER *(Last, First, MI)* – Optional	b. WORK TELEPHONE NUMBER *(Include Area Code)* – Optional
c. MAILING ADDRESS *(Street, City, State, ZIP Code)* – Optional	8. DATE OF SUBMISSION *(YYMMDD)*

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