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FEDERAL STANDARD

PARENTERAL PREPARATIONS

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FEDERAL STANDARD

PARENTERAL PREPARATIONS

Authority. *This standard is issued pursuant to the Federal Property and Administrative Services Act of 1949, as amended, and its application to the commodities referred to herein is mandatory on all Federal agencies.*

S1. Purpose and scope. This standard describes sterile, parenteral preparations in final containers, for sale, barter, or exchange, intended for human consumption.

S2. Classification. Parenteral preparations shall be of the following types, classes, and styles:

Type I—Aqueous.
  Class 1—Solution.
  Class 2—Suspension.

Type II—Nonaqueous
  Class 1—Solution.
  Class 2—Suspension.

Type III—Emulsions.

Type IV—Dry solids intended for solution or suspension prior to injection.

  Class 1—Soluble.
    Style A—In aqueous vehicle.
    Style B—In nonaqueous vehicle.

  Class 2—Suspendible.
    Style A—In aqueous vehicle.
    Style B—In nonaqueous vehicle.

S3. Referenced documents.

S3.1 *Specifications.* The following documents of the issue in effect on date of invitation for bids, or request for proposal, form a part of this standard:

Federal Specification:

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

(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, D. C. 20402.

(Single copies of this specification and other product specifications required by activities outside the Federal Government for bidding purposes are available without charge at the General Services Administration Regional Offices in Boston, New York, Washington, D. C., Atlanta, Chicago, Kansas City, Mo., Dallas, Denver, San Francisco, Los Angeles, and Seattle, Wash.

(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.)

Military Standard:

MIL-STD-105—Sampling Procedures and Tables for Inspection by Attributes.

(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.)

S3.2 *Other publications.* The following documents form a part of this standard. Unless otherwise indicated, the issue in effect on date of invitation for bids shall apply.

American Pharmaceutical Association

National Formulary.

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

U.S. Department of Health, Education, and Welfare, Food and Drug Administration:

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

(Application for copies should be addressed to the Food and Drug Administration, U. S. Department of Health, Education, and Welfare, Washington, D. C., 20204.)

U. S. Department of Health, Education, and Welfare, National Institutes of Health:

Public Health Service Regulations—
Part 73.
Minimum Requirements (as applicable).

(Application for copies should be addressed to the National Institutes of Health, Bethesda, Maryland, 20014.)

U. S. Pharmacopeial Convention, Inc.

Pharmacopeia of the United States.

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

S4. Definitions.

S4.1 *Type I.* Type I, aqueous parenteral preparations, are sterile injections of two classes.

S4.1.1 *Class* 1. Class 1 injections contain medicaments that are dissolved and in solution.

S4.1.2 *Class* 2. Class 2 injections contain medicaments that are in suspension.

S4.2 *Type II.* Type II, nonaqueous parenteral preparations, are sterile injections of two classes.

S4.2.1 *Class* 1. Class 1 injections contain medicaments that are dissolved and in solution.

S4.2.2 *Class* 2. Class 2 injections contain medicaments that are in suspension.

S4.3 *Type III.* Type III, emulsions for parenteral use, are sterile injections containing liquid medicament(s) and suitable immiscible liquid(s) in a dispersed system(s). One liquid is Water for Injection or aqueous solution(s) and the other liquid is oil or oleaginous material(s).

S4.4 *Type IV.* Type IV, dry solids are sterile medicaments, of two classes, intended for solution or suspension prior to injection.

S4.4.1 *Class* 1. Class 1 soluble (dry powder or freeze-dried solid) medicaments are of two styles.

S4.4.1.1 *Style A.* Style A medicaments are soluble in aqueous vehicles.

S4.4.1.2 *Style B.* Style B medicaments are soluble in nonaqueous vehicles.

S4.4.2 *Class* 2. Class 2 suspendible (dry powder) medicaments are of two styles.

S4.4.2.1 *Style A.* Style A medicaments are suspendible in aqueous vehicles.

S4.4.2.2 *Style B.* Style B medicaments are suspendible in nonaqueous vehicles.

S4.5 *Lot.* For purposes of this standard, a lot, batch, control, or pharmaceutical lot is that single, uniform, and homogeneous quantity of parenteral produced from one formulation, subjected to the same compounding and manufacturing operation, and filled into final containers. For Water for Injection, that is produced on a continuous distillation process, a lot of Water for Injection shall not exceed that quantity which is distilled from the still(s) into one container during a 24-hour period.

S4.5.1 *Sterility lot.* A sterility lot is a lot or portion of a lot which (a) is sterilized in the same sterilizer load; (b) is filtered through a bacterial filter or filters into a retaining container, mixed and filled aseptically into final containers through a single filling apparatus or assembly in a period of time not to exceed one working day or shift; or (c) is subjected to some other sterilizing process which shall be acceptable to the procuring activity.

S4.5.1.1 Upon approval of the procuring activity, the assigning of pharmaceutical lot (quality control) numbers without showing individual load (charge) designation will be acceptable, provided samples from each sterilizer charge are tested and reserve samples representing each sterilizer charge are retained for future testing, as needed.

Approval will not be granted, in any case, for intravenous solutions of 100 cc. or more.

S4.5.2 *Lot, batch, or control number.* Lot, batch, or control number is a series of numbers and/or letters that identifies the lot.

S4.6 *Final container.* For purposes of this standard, the term "final container" is synonymous with immediate container that is filled with the designated material.

S4.7 *Date of manufacture.* The date of manufacture is defined as follows:

4.7.1 For those parenterals that are manufactured under N.I.H. license, the date of manufacture conforms to the definition established by the N.I.H.

S4.7.2 For those parenterals that are submitted to F.D.A. for certification prior to release, the date of manufacture is the date of the official certification notice.

S4.7.3 For all other parenterals, not covered by S4.7.1 and S4.7.2, the date of manufacture is the date of filling or of sterilizing the final containers, or the date of manufacturer's or contractor's final quality approval of the final containers, which shall be not later than one month after the date of filling.

S4.8 *Expiration dating period (potency period).* The expiration dating period (potency period) shall be designated by the procuring activity and represents the period beyond which the parenteral cannot be expected, beyond reasonable doubt, to yield its specific result(s) or retain its required potency.

S4.9 *Expiration date.* The expiration date is the date of termination of the expiration dating period.

S5. General requirements.

S5.1 The ingredients entering into the preparation or manufacture of the parenterals shall comply with the tests, standards, and requirements of the U.S.P. or N.F., and the procurement document. If the ingredients are not monographed in the U.S.P. or N.F., and standards for the ingredients are not included in the procurement document, the ingredients shall be of a high quality and purity and suitable for use in the parenterals (see S6.7.1.1).

S5.2 *Finished parenterals.*

S5.2.1 Parenterals that are official articles in the U.S.P. or N.F. shall comply with the tests, standards, and requirements of the U.S.P. or N.F., and the procurement document. The parenterals shall also comply with all specifications of the U.S.P. or N.F., relating to the article, whether incorporated in the monograph itself, in the General Notices or in the section on General Tests, Processes and Apparatus (see S6.7.1.2.1).

S5.2.2 Parenterals that are not official articles in the U.S.P. or N.F. shall comply with all requirements of the procurement document (see S6.7.1.2.2).

S5.3 Parenterals that require from F.D.A., either a Certification or an Approved New Drug Application shall comply with the applicable requirements of F.D.A. and the procurement document.

S5.4 Parenterals manufactured under N.I.H. license shall comply with all requirements of N.I.H. and the procurement document.

S5.5 Parenterals shall not contain coloring agent(s) for the sole purpose of coloring the finished preparation.

S5.6 *Workmanship.* The materials shall be free from any defects which detract from their appearance or may impair their usefulness.

S5.7 *Labeling, packaging, and packing of parenterals.* Labeling, packaging, and packing of parenterals shall be as specified in the procurement document (also see S6.5).

Note: Attention is directed to S6.6, S6.7, S6.10, and S6.11 for inprocess and

final product testing and examination.

S6. Detail requirements.

S6.1 Ingredients entering into the preparation of parenterals.

S6.1.1 All ingredients shall conform to the requirements of S5.1. Each ingredient, and all ingredients combined, shall be nontoxic in the amounts administered.

S6.1.2 *Vehicles.* Vehicles used in the preparation or manufacture of parenterals are aqueous or nonaqueous. The vehicles shall not adversely affect the intended therapeutic efficacy of the products, and shall not interfere with the applicable tests and assays.

S6.1.2.1 *Aqueous vehicles.* Aqueous vehicle shall be Water for Injection. Sodium Chloride Injection or Ringer's Injection may be used in whole or in part instead of Water for Injection, unless otherwise specified in the procurement document. Aqueous vehicles may contain such substances as alcohol, gylcerin, and propylene glycol, when specified.

S6.1.2.2 *Nonaqueous vehicles.* Nonaqueous vehicles shall be oils of vegetable origin or other suitable nonaqueous vehicles. The vehicles shall conform to the requirements and intent as described in "Other Vehicles" under "Injections" in the U.S.P.

S6.1.3 *Added substances.* Unless otherwise specified, added substances, in the quantities and proportions commonly used commercially for the specific preparation, may be included in the formulation of parenteral preparations to make them isotonic, to adjust pH, or to produce a buffered preparation. In addition, bacteriostatic agent(s), preservative(s), solubilizer(s), stabilizer(s), or antioxidant(s) may be used to increase the stability or usefulness of the product. Unless otherwise specified in the individual monograph of the U.S.P. or N.F., or in the procurement document; (a) parenterals packaged in multiple dose containers shall contain added substance(s) used in concentrations which will prevent the growth of, or kill, micro-organisms, and (b) parenterals packaged in single dose containers of more than 5 milliliters shall not contain added substance(s) that are intended to prevent the growth of, or kill, microorganisms. Added substances shall not adversely affect the intended therapeutic efficacy of the products, and shall not interfere with the applicable tests and assays.

S6.2 *Properties of parenteral preparations.*

S6.2.1 *Clarity of solutions.* Applicable to type I, class 1; type II, class 1; and solutions of dry solids (type IV, class 1). Solutions of parenteral preparations shall be clear and free from undissolved or particulate matter within the limits permitted in the classification of defects and the applicable acceptable quality level (AQL), when examined without accessory magnification (except for such optical correction as may be required to establish normal vision) against a black background and against a white background with illumination from a light which at a point 25.4 centimeters (10 inches) from its source, provides an intensity of illumination of not less than 100 and not more than 350 foot-candles. Some biological products need not be clear and entirely free from turbidity, provided this is characteristic of the product. The clarity standards for such products shall be judged on an item for item basis with the characteristic properties of the product considered in each case.

S6.2.2 *Suspensions.* Applicable to type I, class 2; type II, class 2; and suspensions of dry solids (type IV, class 2). Suspensions shall contain fine, evenly dispersed, powder or crystalline materials in suitable vehicles. Suspensions shall be free from foreign matter when examined, without accessory magnification, under conditions of ordinary room lighting. If separation of the suspensions occurs, a uniform suspension

shall be obtained after moderate shaking of the container for 20 seconds. The suspension shall remain homogeneous for at least 3 minutes. Suspensions in aqueous vehicles, after shaking as above, shall flow freely without binding when the contents of the final containers are aspirated through a 22 gage, 1 inch hypodermic needle using a suitable hypodermic syringe. Suspensions in nonaqueous vehicles, after shaking as above, shall flow freely without binding when the contents of the final containers are aspirated through an 18 gage, 1-1/2 inch hypodermic needle using a suitable hypodermic syringe. Requirements for suspensions needing special treatment will be described in the procurement document when such is considered applicable by the procuring activity.

S6.2.3 *Emulsions.* Emulsions shall be stable preparations suitable for parenteral use. Emulsions shall be free from foreign matter when examined, without accessory magnification, under conditions of ordinary room lighting. The "dispersed" or "internal" phase of the emulsions shall be uniformly distributed in small globules throughout the body of the "dispersion medium" or "external phase" after moderate shaking of the container for 10 seconds. The emulsion shall remain homogeneous for at least 10 minutes.

S6.2.4 *Dry solids intended for solution or suspension prior to injection.* Dry solids intended for solution or suspension prior to injection shall be free from foreign matter when examined, without accessory magnification, under conditions of ordinary lighting.

S6.2.4.1 *Solutions of soluble dry solids for injection.* Applicable to type IV, class 1. Unless otherwise specified, solutions of dry solids for injection shall comply with the applicable requirements in S6.2.1 when the specified or labeled volumes of designated vehicles are added to the containers, and the containers are moderately shaken for 20 seconds.

S6.2.4.2 *Suspensions of dry solids for injection.* Applicable to type IV, class 2. Unless otherwise specified, suspensions of dry solids for injection shall comply with the applicable requirements in S6.2.2 when the specified or labeled volumes of designated vehicles are added to the containers, and the containers are moderately shaken for 20 seconds.

S6.3 *Volume in final container (types I, II, and III).* Final containers for types I, II, and III shall contain a volume in excess of the required (labeled) volume. The amount of fill volume in final containers shall be not less than that stated in the table in the U.S.P. under "Volume in Container." The method for determination of volume in final containers shall be performed as specified in the U.S.P. under "Volume in Container" and the volume in container shall comply with the requirements of the U.S.P.

S6.4 *Dry solids in final container (type IV).* Final containers for type IV shall contain the required amount of ingredient(s). The weight of the contents in final containers shall comply with the Weight Variation requirement for "Sterile Solids" as described in the U.S.P. This requirement shall apply to sterile solids, with or without diluent(s) (added substances) unless otherwise specified. In addition, sterile solids, with or without diluent(s) (added substances), shall comply with the applicable paragraph under "Container Content."

Notes:

1. The term diluent(s), as used in this paragraph and in the U.S.P. Weight Variation, is synonymous with the term "Added Substances," as described in S6.1.3 of this standard, and in the U.S.P. under "Injections."
2. Type IV items monographed in the N.F. and nonofficial articles shall also comply with S6.4.

S6.5 *Final containers for injectables.* Final containers (immediate containers) for injectables shall conform to the requirements of PPP-C-186, when applicable, the U.S.P. or N.F., when referenced, and the pro-

curement document. The final containers shall be sealed by fusion or by other suitable means (whichever is specified in the procurement document) so that the contents shall not escape or become contaminated by the entrance of extraneous substances. In addition, the final containers shall maintain sterility of the contents until the containers are opened or punctured.

S6.5.1 *Air in final containers.* Unless otherwise specified, the air in the final containers may be evacuated or displaced by an inert gas.

S6.6 *Examination of final containers.* All final containers shall be individually subjected to a visual and physical (ocular or suitable mechanical device) examination by the manufacturer and all final containers that are judged to be in noncompliance with any requirement in this standard, or other provisions of the procurement document, as can be determined by visual and physical examinations, shall be deemed rejected. Such rejected final containers shall not be included with the material offered to the Government. The type of defect and the number of defective final containers shall be recorded.

S6.7 *Tests.*

S6.7.1 *Testing of ingredients and finished parenterals.*

S6.7.1.1 *Ingredients.* Ingredients that are official in the U.S.P. or N.F., shall be tested by the methods described in the U.S.P. or N.F., and the procurement document, and the ingredients shall comply with S5.1. Ingredients that are not official in the U.S.P. or N.F. shall be tested by methods specified in the procurement document or, if not specified therein, the nonofficial ingredients shall be tested by suitable methods to determine their identity and compliance with S5.1.

S6.7.1.2 *Finished parenterals.*

S6.7.1.2.1 *Parenterals official in the U.S.P. or N.F.* Each lot of parenterals that are official in the U.S.P. or N.F. shall be tested by methods described in the U.S.P. or N.F., and the procurement document to determine compliance with S5.2.1.

S6.7.1.2.2 *Parenterals not official in the U.S.P. or N.F.* Each lot of parenterals that are not official in the U.S.P. or N.F. shall be tested by the methods described in the procurement document or, if not described therein, the nonofficial parenterals shall be tested by suitable methods to determine compliance with S5.2.2.

S6.7.2 *Sterility and pyrogen testing.*

S6.7.2.1 *Test for sterility.* Each sterility lot shall be sterile when tested for sterility in accordance with the Sampling and Sterility Test Methods of the U.S.P. or N.F., except that each lot of parenterals manufactured under N.I.H. license shall be tested for sterility in accordance with the requirements of the N.I.H., and each lot of parenterals submitted to F.D.A. for certification shall be tested for sterility in accordance with the requirements of the F.D.A. A certificate of sterility (see S6.9.1), shall be submitted as stated in S9.1.

S6.7.2.2 *Test for freedom from pyrogens.* When test for freedom from pyrogens is required in the U.S.P., N.F., N.I.H. license, or F.D.A. certification or approved New Drug Application, or when specified in the procurement document, each lot of parenteral in the final container shall be sampled and tested in accordance with the Pyrogen Test in the U.S.P., N.F., N.I.H., or F.D.A., or procurement document, respectively. Each lot shall comply with the applicable test. A certificate of freedom from pyrogens (see S6.9.2), shall be submitted as stated in S9.1.

S6.7.2.2.1 When pyrogen testing of the parenteral in the final container is not required or specified, and Water for Injection is employed in whole or in part as the vehicle, each lot of Water for Injection used

in the parenteral shall be tested in accordance with the Pyrogen Test in the U.S.P., and shall comply with such test. The Water for Injection need not be tested for freedom from pyrogens if the parenteral in the final container is tested for freedom from pyrogens, and complies with S6.7.2.2. A certificate of freedom from pyrogens for the Water for Injection (see S6.9.2.1), or a certificate of freedom from pyrogens for the parenteral in the final container (see S6.9.2), shall be submitted as stated in S9.1.

S6.7.3 *F.D.A. certification.* For parenterals that are certified by F.D.A., a F.D.A. certification (see S6.9.3), for each lot shall be submitted as stated in S9.1.

S6.7.4 *N.I.H. release.* For parenterals that are released by N.I.H., a N.I.H. release (see S6.9.4), for each lot shall be submitted as stated in S9.1.

S6.7.5 *Test records.* Records of all tests performed shall be maintained for not less than 2 years from date of delivery of the supplies to the Government. Records shall be available to the Government for examination upon request. For inprocess testing, such test records shall include the lot number and the test findings. For parenterals that bear an expiration date, the records shall be maintained and shall be available during the full potency period and for 6 months after the expiration date.

S6.8 *Delivery schedule.*

S6.8.1 *Potency dated parenterals requiring certification by F.D.A. or manufacture under N.I.H. license.* Delivery schedule for potency dated parenterals that require certification by F.D.A. or are manufactured under N.I.H. license shall be in accordance with table I. Column No. 1 represents the specified expiration dating period (potency period), and column No. 2 represents the minimum expiration dating period remaining at the time that the material is delivered to the Government.

TABLE I. *Delivery Schedule*

Column No. 1 (months)	Column No. 2 (months)
3	2-1/2
6	5
9	8
12	10
18	16
24	21
30	27
36	33
48	44
60	56

S6.8.2 *Potency dated parenterals other than those complying with S6.8.1.* Delivery schedule for potency dated parenterals other than those complying with S6.8.1 shall be in accordance with table II. Column No. 1 represents the specified expiration dating period (potency period) and column No. 2 represents the maximum number of months that may elapse from the date of manufacture (defined in S4.7.3), of the parenteral to the date of delivery to the Government.

TABLE II. *Delivery schedule*

Column No. 1 (months)	Column No. 2 (months)
12	2
18	2
24	3
30	3
36	3
48	4
60	4

S6.8.3 *Nonpotency dated parenterals.* Unless otherwise specified, not more than 6 months shall elapse from the date of manufacture (defined in S4.7.3), of the nonpotency dated parenteral to the date of delivery to the Government.

S6.9 *Certificates, certifications and releases.* (See appendix).

S6.9.1 *Certificate of sterility.* A certificate of sterility listing all sterility lot numbers, shall state that samples from each sterility lot have been tested for sterility, as required in S6.7.2.1, and were found to be sterile. The certificate shall reference the method used in determining sterility.

S6.9.2 *Certificate of freedom from pyrogens.* A certificate of freedom from pyrogens, listing all lot numbers, shall state that final containers from each lot have been tested for pyrogens, as required in S6.7.2.2, and were found to comply with such requirements. The certificate shall reference the method used in determining freedom from pyrogens.

S6.9.2.1 A certificate of freedom from pyrogens, listing the lot number(s) of the Water for Injection and the lot number(s) of the finished parenteral, shall state that the Water for Injection used in preparing the parenteral preparation was tested for pyrogens in accordance with U.S.P. method and was found to comply with the requirements of the U.S.P.

S6.9.3 *Certification by F.D.A.* A copy of an official F.D.A. certification of the lot shall be submitted for parenterals that are certified by F.D.A.

S6.9.4 *Release by N.I.H.* A copy of an official N.I.H. release of the lot shall be submitted for parenterals that are released by N.I.H.

S6.10 *Sampling.* Unless otherwise specified in the procurement document, sampling shall be in accordance with MIL-STD-105.

S6.10.1 Examination shall be conducted in accordance with the following inspection level:

For examination	Inspection level	AQL (percent defective)	Unit of product*
Major A:			
Types I, II, and III	II	1.0	Filled bottle
Type IV	S-3	1.0	Filled bottle
Major B	S-3	1.0	Filled bottle
Major C	II	6.0	Filled bottle

* Where the unit of issue being examined is other than "bottle", substitute the terminology of the unit of issue (i.e., ampul, vial, etc.), wherever the word bottle(s) appears.

S6.10.2 *Testing.* Testing shall be conducted as follows:

For end item testing (unit of product—filled bottle*).

A composite sample shall be utilized for test (C).

Sampling shall be in accordance with the designated inspection level in table III, unless otherwise indicated.

TABLE III.

Tests	Characteristic		Requirement paragraph
(A)	Volume (types I, II, and III)		S6.3
(B)	Contents (type IV)		S6.4
(C)	Testing of finished product (Assays, identities, and other tests applicable for the item)		S6.7.1.2
	Container size	Inspection level	
	Less than 10 cc.	S-3	
	10 cc. to 100 cc. (incl.)	S-2	
	Over 100 cc.	S-1	
(D)	Sterility**		S6.7.2
(E)	Pyrogenicity** a. When required or b. Solvents containing Water for Injection		S6.7.2

* Where the unit of issue being examined is other than "bottle", substitute the terminology of the unit of issue (i.e., ampul, vial, etc.), wherever the word bottle(s) appears.

** Special sampling. U.S.P., N.F., N.I.H., F.D.A. or procurement document sample size as applicable for (D) and (E).

S6.11 *Examination.* The parenterals shall be examined to determine compliance with all requirements of this document. Nonconformance with these requirements will be permitted to the extent indicated in S6.10.

S6.11.1 *Classification of defects.* Examination shall be conducted in accordance with table IV.

TABLE IV. *Classification of defects*

	Aqueous (type I)		Nonaqueous (type II)		Emulsion (type III)	Dry solids (type IV)			
	Solution (class 1)	Suspension (class 2)	Solution (class 1)	Suspension (class 2)		Soluble (class 1)		Suspendible (class 2)	
						Aqueous (style A)	Nonaqueous (style B)	Aqueous (style A)	Nonaqueous (style B)
Major A:									
101 Material not free of extraneous color.	X	X	X	X	X	XX	XX	XX	XX
102 Solution not clear (see S.6.2.1).	X		X			XX	XX		
103 Solution not free of undissolved or particulate matter.	X		X			XX	XX		
104 Material not free of foreign matter.	X	X	X	X	X	XX	XX	XX	XX
Major B:									
151 Odor not free of oil rancidity.		X	X	X	X				
152 Suspension does not remain homogeneous (see S.6.2.2).		X		X				XX	XX
153 Emulsion does not remain homogeneous (see S.6.2.3).					X				
154 Syringability not suitable (see S.6.2.2).		X		X				XX	XX
Major C:									
171 Dry solid not free of foreign matter (see S6.2.4).						X	X	X	X

X = Inspection as supplied.
XX = Inspection when reconstituted (use level S-3).

S7. **Changes.** When a Federal agency considers that this standard does not provide for its essential needs, written request for changing or adding to the standard, supported by adequate justification, shall be sent to the Administration. This justification shall explain wherein the standard does not provide for essential needs. The request shall be sent in duplicate to the General Services Administration, Federal Supply Service, Standardization Division, Washington, D. C., 20406. The Administration will determine the appropriate action to be taken and will notify the agency.

S8. **Conflict with referenced specifications.** Where the requirements stated in this standard conflict with any requirement in a referenced specification, the requirements of the standard shall apply. Nature of conflict between the standard and the referenced specification shall be submitted in duplicate to the General Services Administration, Federal Supply Service, Standardization Division, Washington, D. C., 20406.

S9. **Appendix.** It is mandatory that certificates, certifications, and releases be forwarded as indicated.

S9.1 *Submission of certificates, certifications, and releases.*

S9.1.1 *Procurement by Defense Personnel Support Center.* Certificates, certifications and releases that are required in this standard, or required in the procurement document of the Defense Personnel Support Center, shall be submitted as follows:

(a) *For inspection at origin.* The contractor shall furnish required document(s) to the quality assurance representative for forwarding to the Technical Operations Division, Directorate of Medical Materiel, Defense Personnel Support Center, 2800 South 20th Street, Philadelphia, Pa. 19101, Attention: Quality Control Branch.

(b) *For inspection at destination.* The contractor shall forward required document(s) directly to the above (a) address. One copy of document(s) shall be forwarded with shipment to the consignee.

S9.1.2 *Procurement by other activities.* Certificates, certifications, and releases that are required in this standard, or in the procurement document of any other procuring activity, shall be forwarded as indicated by that activity.

In the use of this standard, the procuring activity shall designate, as a minimum, the type, class, and style as applicable, of parenteral (see S.2), the expiration dating period (potency period), when applicable (see S4.8), the labeling, packaging, and packing required (see S5.7), and the submission of certificates, certifications, and releases, when applicable (see S9.1.2).

Copies of this standard required by contractor in connection with specific procurement functions should be obtained from the procuring activity or as directed by the contracting officer.

CUSTODIANS:
Army—MD
Navy—BuMed
Air Force—03

Review activities:
Army—MD
Navy—BuMed
Air Force—03

Preparing activity:

Defense Supply Agency—DM

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