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FEDERAL STANDARD

CAPSULES (FOR MEDICINAL PURPOSES)

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

S1. Purpose and scope. This standard describes the general requirements for filled capsules in the dispensing of medicinal substance(s) for oral administration.

S2. Classification. Capsules shall be of the following types, size, numbers, shapes, grades, and classes:

Types and size numbers of capsules.

Type I - Hard.

Size No. 000
Size No. 00
Size No. 0
Size No. 1
Size No. 2
Size No. 3
Size No. 4
Size No. 5
Special, as specified.

Type II - Soft.

Dimensions for type II capsules shall be specified in the procurement document. When not specified, the dimensions shall be those which are commercially supplied for the item.

Shapes of capsules.

Shape a. Conventional.

Shape b. Bullet-like.

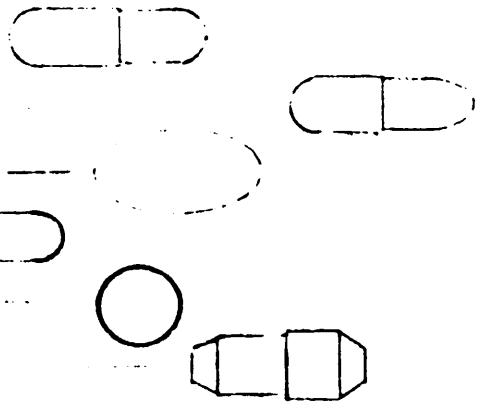
Shape c. Elliptical (oval).

Shape d. Oblong.

Shape e. Round

Shape f. Tapered ends.

Shape g. Special, as specified.



Grades of transparency.

Grade A. Opaque.
Grade B. Clear.
Grade C. Combination.
Grade D. Special, as specified.

Classes (form of fill).

Class 1. Powder.
Class 2. Liquid.
Class 3. Pellets.
Class 4. Special, as specified.

S3. Referenced documents.

S3.1 Standard. The following document, of the issue in effect on date of invitation for bids, or request for proposals, form a part of this standard:

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 or request for proposals shall apply.

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, DC 20204.)

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 Drug Enforcement Administration, Department of Justice, P.O. Box 28083, Central Station, Washington, DC 20005.)

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.)

S4. Definitions.

S4.1 Capsules. Capsules are solid dosage forms containing one or more medicinal substance(s), except for placebo capsules, with or without diluents, enclosed in either a hard or a soft, soluble container (shell) prepared from a gelatin base which may contain glycerin or other suitable plasticizer in a proportion which may be varied in order to produce either the hard capsule or the soft capsule.

S4.1.1 Type I, hard. Type I, hard capsules consist of 2 pieces (i.e., the base and the cap). Hard capsules are those which contain powder(s), granulation(s), or pellets.

S4.1.2 Type II, soft. Type II capsules consist of two flexible pieces formed into a body and permanently sealed. Soft capsules are those which contain liquids, powder(s), or semi-solid ingredient(s).

S4.1.3 Sizes of hard capsules. Hard capsules are manufactured under standard size numbers ranging from Size No. 000 to Size No. 5. When special size capsules are required, the size shall be specified in the procurement document.

S4.1.4 Sizes of soft capsules. Soft capsules are manufactured in various sizes (dimensions). When not specified, the dimensions shall be those which are commercially supplied for the item.

S4.1.5 Shapes of capsules.

S4.1.5.1 Conventional, bullet-like, elliptical (oval), oblong, round, and tapered ends. (See appropriate illustration in S2.)

S4.1.5.2 Special capsules. Special capsules shall be of the capsule shape specified in the procurement document.

S4.1.6 Grades of transparency.

S4.1.6.1 Grade A, opaque capsules. Grade A, opaque capsules are those which protect contents from light rays.

S4.1.6.2 Grade B, clear capsules. Grade B, clear capsules are those in which the contained ingredient(s) may be seen through the capsule. Such capsules may be colored or uncolored.

S4.1.6.3 Grade C, combination. Grade C, combination capsules are those in which the shells of the capsule are of different grades of transparency, i.e., one shell clear (colored or uncolored) and the other shell, of the same capsule, opaque. Grade C capsules shall be in accordance with manufacturer's commercial practice, when such is not specified in the procurement document.

S4.1.6.4 Grade D, special. Grade D, special capsules shall be of the grade specified in the procurement document.

S4.1.7 Classes (forms of fill).

S4.1.7.1 Class 1. Class 1 shall be dry powder(s), including granulation(s).

S4.1.7.2 Class 2. Class 2 shall be liquid(s) encapsulated as a suspension or solution.

S4.1.7.3 Class 3. Class 3 shall be pellets which release sustained action (timed) substance(s).

S4.1.7.4 Class 4. Class 4, special fill capsules, shall be as specified in the procurement document. These capsules may contain a paste (semi-solid) or other form of fill not specified above.

S4.2 Lot. For purposes of this document, a lot, batch, or control is that single, uniform, and homogeneous quantity of filled capsules produced from one compounding formulation, in one manufacturing and filling operation, and which quantity has received entirely the same processing and treatment.

S4.2.1 Lot, batch, or control number. Lot, batch, or control number is a series of numbers and/or letters that identify the lot.

S4.3 Date of manufacture. The date of manufacture is defined as follows:

S4.3.1 For those capsules that are submitted to Federal Food and Drug Administration (FDA) for certification prior to release, the date of manufacture is the date of the official certification notice. This certification shall be not later than 6 months after the date of filling the capsules.

S4.3.2 For those capsules that are manufactured under Bureau of Biologics, FDA, (B of B), license, the date of manufacture conforms to the definition established by the B of B.

S4.3.3 For other capsules not covered by S4.3.1 and S4.3.2, the date of manufacture is the date of filling of the capsules, or the date of manufacturer's or contractor's final quality approval, which shall be not later than one month after the date of filling the capsule.

S4.4 Expiration dating period. The expiration dating period shall be designated by the procuring activity and represents the period beyond which the capsules cannot be expected, beyond reasonable doubt, to yield their specific results, or retain their required potency.

S4.4.1 For those capsules that are submitted to FDA for certification prior to release, the expiration dating period shall be based upon the first or original FDA certification. This certification shall be not later than 6 months after the date of encapsulation.

S4.4.2 For those capsules that are manufactured under B of B license, the expiration dating period shall be as established by the B of B, and shall be as specified in the procurement document.

S4.5 Expiration date. The expiration date is the date of termination of the expiration dating period.

S5. General requirements.

S5.1 Unfilled capsules. The unfilled hard capsules and the gelatin mix for soft capsules shall be manufactured from type A or type B gelatin, or a suitable mixture of both, and shall be in accordance with the requirements of the USP for gelatin used in the manufacture of capsules.

S5.2 The ingredients entering into the preparation or manufacture of the filled capsules shall comply with the tests, standards, and requirements of the USP or NF, and the procurement document. The descriptions included in the USP and NF monographs that pertain to appearance or other attributes which can be specifically determined, by organoleptic examination or simple manipulations, shall be considered part of the requirements for the item. If the ingredients are not monographed in the USP or NF, and the standards for the ingredients are not included in the procurement document, the ingredients shall be of high quality and purity suitable for use in capsules (See S6.4.1). Whenever water is required to be used in a step of the manufacturing process, either as part of the formulation or as a vehicle for adding other ingredient(s), Purified Water, USP, shall be required.

S5.3 Capsules that are official articles in the USP or NF shall comply with the tests, standards, and requirements of the USP or NF, and the procurement document. The capsules shall also comply with all specifications of the USP or NF, 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 S6.4.3).

S5.4 Capsules that are not official articles in the USP or NF shall comply with all requirements of the procurement document (see S6.4.3).

S5.5 Capsules that require from FDA either a Certification or an Approved New Drug Application shall comply with the applicable requirements of the FDA and the procurement document.

S5.6 Sealing. The base and cap segments of the hard capsule shall so fit that a tight friction closure is maintained. Capsules may be sealed by a band or a spot seal.

S5.7 Workmanship. Workmanship shall be first class throughout. The materials shall be free from any defects which detract from their appearance or may impair their usefulness.

S5.8 Labeling, packaging, and packing of capsules. Labeling, packaging, and packing of capsules shall be as specified in the procurement document.

S6. Detail requirements.

Note: Attention is directed to paragraphs S6.4, S6.6, and S6.7 for inprocess and final product testing and examination.

S6.1 Ingredients entering into the preparation or manufacture of capsules.

S6.1.1 All ingredients shall conform to the requirements of S5.2. Each ingredient, and all ingredients combined, shall be nontoxic in the amounts administered. The gelatin used in the capsules shall comply with S5.1.

S6.1.2 Diluents, coloring, and other materials. Diluents (including excipients, bulking agents, absorbents, disintegrants, binders, adhesives, and lubricants), coloring, and other materials used in the medicament in the capsules shall be therapeutically innocuous in the amounts used, and shall not in any way adversely affect the stability nor the therapeutic efficacy of the capsules. The diluents, coloring, and other materials shall not interfere with the applicable tests and assays.

S6.1.2.1 Coloring material. For capsules that are required to have added color(s), the coloring agent(s) used in the formula shall be a color additive certified or listed as harmless and suitable for coloring drugs under the terms of the Federal Food, Drug, and Cosmetic Act and Color Additive Regulations.

S6.2 Characteristics of capsules.

S6.2.1 Appearance. Capsules within one lot, and within one contractual quantity, shall be of the same color, transparency, size, and shape. If one capsule bears identifying marking, all capsules shall bear the identical marking.

S6.2.1.1 Capsules. Capsules shall be smooth and uniform in size, shape, and color. Capsules shall show no evidence of spots, breaks, excess powder in the containers, mottling, cracks, splitting, foreign particulate contamination (foreign matter) and embedded or adhering surface spots, or foreign material contained in the capsule not visible through the capsule shell, exceeding the limits permitted in the classification of defects (see S6.7.1), within the applicable acceptable quality level (AQL). Unless otherwise specified, any coloring material employed in the capsules shall be uniformly and homogeneously distributed, with the possible exception of the pellets in capsules and special capsules.

S6.2.2 Color. Color of the capsules and of the fill shall be specified in the procurement document. If the color is not specified, capsules and fill shall be the same as that which is commercially supplied for the item.

S6.2.3 Size. Capsules shall be of the size number specified in the procurement document. If the specific size for capsules is not specified in the procurement document, the size shall be the same as that which is commercially supplied for the item. When special size capsules are supplied, the size shall be of sufficient capacity to contain the prescribed amount of medicinal substance(s).

S6.2.4 Shape. The shape of the capsule shall be specified in the procurement document. When the shape of the capsule is not specified, the shape shall conform to that commercially accepted as standard in the pharmaceutical industry for the capsules being supplied.

S6.2.5 Odor. Upon opening a sealed bottle, the filled capsules shall be odorless if they (a) are not flavored, or (b) do not contain ingredient(s) which normally have a characteristic odor. Capsules shall have no foreign odor or odor resulting from decomposition or deterioration. The term "odorless" applies to examination of capsules in the freshly-opened immediate container, with the cotton or other filler removed. After exposure to the air at room temperature (in room free from drafts) for the period specified herein, the contents of a freshly-opened immediate container shall have no odor. For containers labeled to contain 100 capsules, or less, exposure to air shall be 5 minutes; for containers labeled to contain between 101 and 500 capsules, exposure to air shall be 10 minutes; for containers labeled to contain between 501 and 1000 capsules, exposure to air shall be 15 minutes; and for containers labeled to contain more than 1000 capsules, exposure to air shall be 25 minutes. The cotton or other filler shall be removed from the immediate container during the exposure to air.

S6.2.6 Disintegration and solubility. When a disintegration and solubility time is required (other than specified in S6.2.15), it shall be as specified in the procurement document.

S6.2.7 Moisture content. The limit of moisture content shall be specified in the procurement document. When the limit of moisture content is not specified, the medication in the capsules shall contain a minimum amount of moisture, so as to insure maximum stability of the capsules. The moisture content of the capsule (hard or soft gelatin) itself, shall be such as to prevent brittleness and cracking.

S6.2.8 Marking on capsules. Capsules may bear a trademark or other designation distinctive of the manufacturer's item.

S6.2.9 Weight variation.

S6.2.9.1 Type I and Type II. Unless otherwise specified, filled capsules shall conform to the USP Weight Variation Test for Capsules. Hard and soft capsules shall be tested in accordance with the applicable procedure.

S6.2.10 Uniformity of pellets. The pellets in each capsule shall be of uniform size(s) and not less than 95 percent of the pellets in each capsule shall fall within the numbered mesh range specified in the procurement document, when tested in accordance with the USP, using U.S. Standard Mesh Sieves.

S6.2.11 Stability. Capsules shall be so compounded as to provide physical stability of capsules and chemical stability of the ingredients. Capsules that are designated as having an expiration dating period shall comply with all applicable requirements for the full expiration dating period under normal storage and handling, or storage as specified in the procurement document.

S6.2.12 Net contents and variations in count. The number (count) of capsules in the immediate containers shall average not less than that quantity specified in the item identification of the procurement document. The figure (number) representing the average count shall be adjusted to the nearest whole number. In addition, the following shall apply:

(a) No immediate container shall contain less than 97 percent of the required amount of capsules when the specified number of capsules per immediate container is 100 or more.

(b) No immediate container shall be more than two (2) capsules short of the required amount when the specified number of capsules per immediate container is between 50 and 99.

(c) No immediate container shall be more than one (1) capsule short of the required amount when the specified number of capsules per immediate container is less than 50.

S6.2.12.1 For capsules containing narcotics or barbiturates, and capsules subject to the Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act, the number of capsules in the immediate container shall comply with the preceding, except that the average count shall be not less than 99.8 percent and not more than 100.5 percent of the number of capsules specified in the item identification of the procurement document.

S6.2.12.2 For capsules packaged in blister packets, the number of capsules in each immediate container shall be 100.0 percent of the number of capsules specified in the procurement document. No tolerances shall be allowed.

S6.2.13 Volume occupied by capsules. When specified, the capsules shall meet the test requirements in the procurement document for volume occupied by capsules.

S6.2.14 Water resistance. Unless otherwise specified, the capsule shell shall show no signs of disintegration when tested as follows:

The capsules shall be immersed in purified water at 25°C. ± 1°C. for 15 minutes. A sample of 20 capsules shall be tested for compliance with this test.

S6.2.15 Acid solubility. Unless otherwise specified, the Type I capsule shell shall completely fall apart, dissolve, or disintegrate, when tested as follows:

The capsules shall be immersed in 0.5 percent, by weight, aqueous hydrochloric acid solution at 36°C. to 38°C. and allowed to remain at this temperature for 15 minutes. A sample of 20 capsules shell shall be tested for compliance with this test.

Unless otherwise specified, the Type II capsule shell shall dissolve within 15 minutes in artificial gastric fluid, using the USP Disintegration Test Method for Tablets.

S6.2.16 Foreign material inside filled capsules. Capsules shall be free of foreign material inside the capsule, when examined using either method (a) or method (b) without accessory magnification (except for such optional correction as may be required to establish normal vision). The capsules shall comply with the limits permitted in the classification of defects (see table IV and table V), and the applicable AQL.

Method (a). Type I capsules. Take one (1) capsule and open carefully. Empty the contents of the capsule onto a clean, dry surface. Examine the contents (powder, granulations, or pellets) for foreign material. Record the number of capsules found to contain foreign material.

(cc.) hypodermic or implantation syringe. Only, unless otherwise specified.

Method (b). Type II capsules. Place one (1) capsule in a depression of a clean, porcelain spotplate. Using a sharp cutting instrument (scalpel, etc.) slit or cut the capsule into two or more pieces. Examine the contents (liquid, powder, semi-solids, etc.), for foreign material. Record the number of capsules found to contain foreign material.

NOTE: Method(s), other than Method (a) or Method (b), as specified, shall be submitted for approval and acceptance by the Government, prior to use. If the method(s) are approved by the Government, such method(s) shall be employed in testing of the capsules to determine foreign material inside the capsules.

S6.3 Delivery.

S6.3.1 Expiration dated capsules requiring certification by FDA or manufacture under B of B license. Delivery for expiration dated capsules that required certification by **FDA** or are manufactured under B of B license, shall be in accordance with table I. Column no. 1 represents the specified expiration dating period, and column no. 2 represents the allowable minimum expiration dating period remaining at the time that the material is delivered to the Government.

TABLE I. Delivery

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

S6.3.2 Expiration dated capsules other than those complying with S6.3.1. Delivery schedule for expiration dated capsules, other than those complying with S6.3.1, shall be in accordance with table II. Column no. 1 represents the specified expiration dating period and column no. 2 represents the maximum number of months that may elapse from the date of manufacture (defined in S4.3) of the capsules to the date that the material is delivered to the Government.

TABLE II. Delivery

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

S6.3.3 Non-expiration dated capsules. Unless otherwise specified, not more than 6 months shall elapse from the date of manufacture (defined in S4.3) of non-expiration dated capsules, to the date of delivery to the Government.

S6.4 Tests.

S6.4.1 Testing of ingredients. Ingredients that are official in the USP or NF shall be tested by the methods described in the USP or NF and the procurement document, and the ingredients shall comply with S5.2. Ingredients that are not official in the USP or NF shall be tested by the 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 S5.2.

S6.4.2 Inprocess testing. During the encapsulating operation of hard gelatin capsules, not less than 10 capsules from each lot shall be drawn from each capsulating machine, at regular intervals of 30 minutes or less, and tested for weight. For soft gelatin capsules, not less than 10 capsules shall be drawn from each lot at the beginning of the filling operation and tested for fill weight. If filling pumps are adjusted or changed, the fill weight test shall be repeated. In addition, for soft gelatin capsules, the seal thickness shall be verified at the beginning and during the encapsulating (filling) operation. The seal thickness shall be within required limits. The inprocess testing shall be applicable to capsules from each capsulating machine. The test results shall be recorded for each capsulating machine used for each lot to confirm uniformity of weight.

S6.4.3 Testing of finished capsules.

S6.4.3.1 Capsules official in the USP or NF. Each lot of capsules that are official in the USP or NF shall be tested by the methods described in the USP or NF and the procurement document to determine compliance with S5.3.

S6.4.3.2 Capsules not official in the USP or NF. Each lot of capsules that are not official in the USP or NF shall be tested by the methods described in the procurement document.

S6.5 Test records. Records of all tests performed shall be maintained for not less than 3 years from date of delivery of the supplies to the Government. Upon request, records shall be available to the Government for examination. For inprocess testing, such test records shall include the capsulating machine number or the permanent capsulating station number, lot number, and test findings. For capsules that bear an expiration date, the records shall be maintained and shall be available during the full expiration dating period and for 6 months after the expiration date.

S6.6 Sampling. Unless otherwise specified in the procurement document, sampling shall be in accordance with MIL-STD-105.

S6.6.1 Examination. Examination shall be conducted in accordance with the following inspection level:

TABLE III. Examination. 1/

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

1/ When the examination of major A and minor characteristics is not performed prior to filling of final (immediate) containers, and such examination is necessary on the filled, final (immediate) containers, the sample size for capsules shall remain the same. The required number of capsules for examination shall then be selected at random from filled, final (immediate) containers sampled in accordance with MIL-STD-105, level S-2, minimum sample of 5 immediate containers except where the immediate container is a transparent blister packet. The sample size shall then be based on the lot size of the capsules. Whenever the capsules are placed in the packets, only a visual (physical) examination of the capsules

(without destruction of the blister) shall be required, using three (3) times the sample size of each lot of capsules. If the number of immediate containers selected does not give the required number of capsules for examination, randomly select additional immediate containers to give the required number of capsules. Those defects that are annotated "#" in the classification of defects must be determined on capsules from filled, final (immediate) containers. Results of examination for those defects obtained prior to filling of final (immediate) containers shall not be acceptable.

S6.6.2 Testing. Shall be conducted as follows: For end item testing (unit of product - filled immediate container) 1/

(a) Sampling of each lot for the tests required in table IV shall be in accordance with level S-1, except as indicated by 2/. Minimum sample size is three (3) immediate containers. The acceptance number for each test shall be zero (0).

(b) As an alternate to the above procedure, each lot shall be tested, as required in table IV, on capsules taken from bulk stock (prior to packaging of capsules). A minimum of 300 capsules shall be utilized. The acceptance number shall be zero (0). In addition, a minimum of one (1) identification test shall be performed on each lot of filled immediate containers. The identity test shall be specific for the products. For products containing more than one active ingredient, a minimum of two ingredients shall be identified by specific tests.

TABLE IV. Testing.

Characteristic	Requirement paragraph
Testing of finished capsules (assays, identities, and other tests applicable for the item)	S6.4.3
Color	S6.2.2
Disintegration and solubility (when specified)	S6.2.6
Weight variation	S6.2.9
Moisture	S6.2.7
Capsule size	S6.2.3
Shape	S6.2.4
Volume (when specified)	S6.2.13
Water resistance 2/	S6.2.14
Acid solubility 2/	S6.2.15

1/ Where the unit of issue being examined is other than "immediate container" substitute the terminology of the unit of issue (i.e., package, can, tube, etc.), wherever the words "immediate container" appear.

2/ Use sample size in S6.2.14 and S6.2.15, as applicable.

(c) The net content and variation in count (S6.2.12 and S6.2.12.1) shall be sampled in accordance with inspection level S-2. Acceptance number shall be zero (0).

S6.7 Examination. The capsules shall be examined to determine compliance with all requirements of this document. Nonconformance with these requirements will be permitted to the extent indicated in S6.6.

S6.7.1 Classification of defects. Examination shall be conducted in accordance with the following classification of defects:

TABLE V. Hard Capsules.

Categories	Defects 1/
#Major A	
101	Capsule not type-specified (i.e., hard shell).
#102	Capsule not free of cracks, breaks, pinholes, or splits where leakage of contents may occur.
103	Capsules not uniform in appearance.
104	Base and/or cap of capsule not as specified.
105	Capsule not uniform in color(s).
#106	Capsule empty.
#107	Capsule not free of embedded surface spots and contamination (definition (a), S6.7.1.1).
108 2/	Capsule fill not free from foreign matter.
Major B 3/	
#151	Capsule does not maintain tight closure or seal in the immediate container, or during normal handling, or dispensing.
#152	Immediate container not free from extraneous matter.
#153	Capsule not intact (i.e., cap separated from body).
#154	Capsule not free of foreign odor, other than characteristic odor.
#155	Immediate container not internally and externally clean.
#156	Void space of immediate container not filled, when required.
#157	Immediate container not free of excess ingredient (capsule contents).

TABLE V. Hard capsules (cont'd)

Categories	Defects 1/
Minor	
201	Capsule not free of pits or dents.
202	Capsule not free of thin areas.
203	Capsule not free of specks, spots, or blemishes.
#204	Capsule not free of cap and/or body cutting into one another.
205	Capsule not smooth.
#206	Capsule not free of adhering surface spots (definition (b), S6.7.1.1).

1/ Inspection is not restricted to classified possible defects listed above.
2/ For opaque capsules use a sample size of 20 capsules to examine contents. No capsule shall show evidence of foreign matter.
3/ Capsules obtained from the bottles used for examination of Major B defects may be used for examination of Major A and Minor defects annotated "#". Thus, no additional capsules need be selected. # Applies to examination of capsules in filled, final (immediate) containers.

TABLE VI. Soft Capsules.

Categories	Defects 1/
Major A	
101	Capsule not type specified (i.e., soft shell).
#102	Capsule not free of cracks, breaks, pinholes, or splits where leakage of contents may occur.
103	Capsules not uniform in appearance.
104	Capsule not uniform in color(s).
#105	Capsule empty.
#106	Capsule not free of embedded surface spots and contamination (definition (a), S6.7.1.1).
107 2/	Capsule fill not free from foreign matter.
Major B 3/	
#151	Capsule does not maintain tight closure or seal in the immediate container, or during normal handling, or dispensing.
#152	Immediate container not free from extraneous matter.
#153	Capsule not intact.
#154	Capsule not free of foreign odor other than characteristic odor.

TABLE VI. Soft Capsules (cont'd)

Categories	Defects 1/
Major B 3/	
#155	Immediate container not internally and externally clean.
#156	Void space of immediate container not filled, when required.
#157	Immediate container not free of excess ingredient (capsule contents).
Minor	
201	Capsule not free of pits or dents.
202	Capsule not free of thin areas.
203	Capsule not free of specks, spots, or blemishes.
204	Capsule not smooth.
#205	Capsule not free of adhering surface spots (definition (b), S6.7.1.1).

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

2/ For opaque capsules use a sample size of 20 capsules to examine contents. No capsule shall show evidence of foreign matter.

3/ Capsules obtained from the immediate containers used for examination of Major B defects may be used for examination of Major A and Minor defects annotated "#". Thus, no additional capsules need be selected. # Applies to examination of capsules in filled, final (immediate) containers.

S6.7.1.1 Definitions of terms for classification of defects.

TABLE VII. Definitions of terms

Terminology	Definition	Unit of product
Uniformity of shape	Self-explanatory	Capsule
Uniformity of size	Self-explanatory	Capsule
Surface spots	(a) Clearly defined particles which are embedded in or on the surface of the capsules.	Capsule

TABLE VII. Definition of terms (cont'd)

Terminology	Definition	Unit of product
	(b) Clearly defined particles which adhere to the surface, but can be wiped or blown off the surface. The particles (spots) are foreign, extraneous, or a contaminant to the capsules. Examination is conducted without accessory magnification.	
Pits or dents	Small indentation in the surface of the capsule.	Capsule
Excess ingredient	That amount of fill from the capsules which is equivalent to more than 0.5 percent of the total weight of capsules in the immediate container.	Immediate Container
Foreign matter	Foreign material contained in the capsule fill and not visible from the surface.	Capsule
Mottling or non-uniformity of color	The irregular coloration of the capsule.	Capsule
Thin area	A section on the surface of the capsule which may result in leaking from the capsule.	Capsule
Smooth surface	A surface that is smooth to the touch and is not intended to include effects of trademark impressions.	Capsule
Break and crack	A break in the surface of the capsule.	Capsule
Splitting	A complete separation of the capsule into two or more substantial parts by cap and/or body cutting into one another.	Capsule

S7. Changes. Whan 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, Washington, DC 20406. The administration will determine the appropriate action to be taken and will notify the agency.

S8. Conflict with referenced specifications. When 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 Servie, Washington, DC 20406.

In the use of this standard, the procuring activity shall designate, as a minimum, the type and class of capsule required (see S2), the expiration dating period when applicable (see S4.4), and the labeling, packaging, and packing required (see S5.8).

MILITARY CUSTODIANS:

Army - MD
Navy - MS
Air Force - 03

CIVIL AGENCY COORDINATING ACTIVITIES:

GSA - FSS
HEW - FDA, NIH
VA - DMS

PREPARING ACTIVITY: DSA - DM

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