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SUPERSEDING
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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.

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Shapes of capsules.

Shape a. Conventional.

Shape b. Bullet-like.

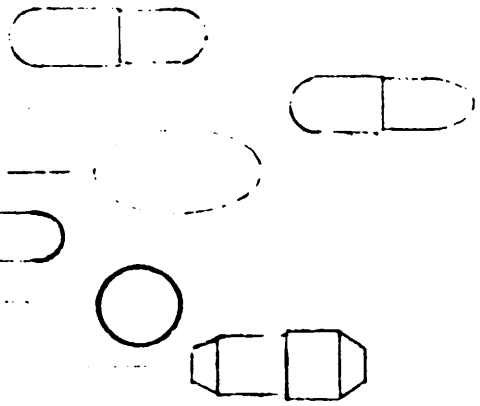
Shape c. Elliptical (oval).

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.

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