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FEDERAL STANDARD

TABLETS (FOR MEDICINAL PURPOSES)

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FEDERAL STANDARD

TABLETS (FOR MEDICINAL PURPOSES)

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

S1. Purpose and scope. This standard covers the general requirements for tablets for medicinal purposes.

S2. Classification. Tablets shall be of the following types and classes, with styles of coated tablets and grades of coverings for coated tablets:

Types and classes of tablets.

Type I—Oral.
- Class 1—Uncoated.
- Class 2—Coated.

Type II—Solution.
- Class 1—Noneffervescent.
- Class 2—Effervescent.

Type III—Hypodermic.

Type IV—Ophthalmic.

Type V—Buccal.

Type VI—Sublingual.

Type VII—Vaginal.
- Class 1—Uncoated.
- Class 2—Coated.

Type VIII—Pellets or implantation.

Type IX—Dispensing.

Type X—Multilayer.
- Class 1—Uncoated.
- Class 2—Coated.

Type XI—Tablet triturate.

Type XII—Impregnated or laminated.
- Class 1—Uncoated.
- Class 2—Coated.

Type XIII—Special, as specified.
- Class 1—Uncoated.
- Class 2—Coated.

Styles of coated tablets.

Style A—Plain (Nonenteric).
Style B—Enteric.
Style C—Special.

Grades of coverings for coated tablets.

Grade 1—Sugar.
Grade 2—Gelatin mixture.
Grade 3—Plastic (film).
Grade 4—Special.

S3. Referenced documents.

S3.1 *Standard.* The following document, of the issue in effect on date of invitation for bids, forms 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 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 *Tablets.* Tablets are solid dosage forms containing one or more medicinal substances except for placebo tablets, with or without diluents. Tablets are made in various shapes, colors, sizes, and weights, depending upon the amount of the medicinal substance(s) and the intended mode of administration or use.

S4.1.1 *Type I, oral.* Type I, oral tablets are uncoated (class 1) or coated (class 2), as specified, and are the conventional compressed tablets that are taken by mouth and swallowed. Tablets that should be chewed prior to swallowing shall be so indicated in the procurement document.

S4.1.2 *Type II, solution.* Type II, solution tablets are noneffervescent (class 1) or effervescent (class 2), as specified. Noneffervescent solution tablets are uncoated tablets that are dissolved in water or aqueous solutions prior to use. Effervescent solution tablets are uncoated tablets that are added to water or aqueous solutions for administration or application after effervescence has ceased.

S4.1.3 *Type III, hypodermic.* Type III, hypodermic tablets are uncoated tablets that are intended for hypodermic injection after the tablet is dissolved in sterile water for injection, using aseptic technique. Special care shall be taken in the manufacture and packaging of hypodermic tablets to prevent contamination that would give adverse effects when the tablets are dissolved and the solutions are injected.

S4.1.4 *Type IV, ophthalmic.* Type IV, ophthalmic tablets are small, thin, wafer-like, uncoated tablets intended for ophthalmological use. Special care must be taken in the manufacture and packaging of ophthalmic tablets to prevent contamination that would give adverse effects when the tablets are used for the eye.

S4.1.5 *Type V, buccal.* Type V, buccal tablets are uncoated tablets that are inserted in the buccal pouch where the active ingredient(s) enters the circulation through the oral mucosa.

S4.1.6 *Type VI, sublingual.* Type VI, sublingual tablets are uncoated tablets that are placed beneath the tongue where the active ingredient(s) enters the circulation through the sublingual mucosa.

S4.1.7 *Type VII, vaginal.* Type VII, vaginal tablets are uncoated (class 1) or coated (class 2), as specified, and are inserted in the vagina where the active ingredient(s) is released.

S4.1.8 *Type VIII, pellets or implantation.* Type VIII, pellets or implantation tablets are uncoated tablets that are intended for implantation in body tissue for slow release of medicament over an extended period of time. Special care must be taken in the manufacture and packaging of pellets or implantation tablets to prevent contamination that would give adverse effects when the pellets or implantation tablets are implanted in body tissue. The pellets or implantation tablets are sterile and are packaged individually in sterile vials.

S4.1.9 *Type IX, dispensing.* Type IX, dispensing tablets are uncoated tablets that contain relatively large amounts of drugs

and are not intended for use as a dosage form. They are employed by the dispensing pharmacist for obtaining quantities of certain potent substances in tablet form for accurate compounding.

S4.1.10 *Type X, multilayer.* Type X, multilayer tablets are uncoated (class 1) or coated (class 2), as specified, and are manufactured by more than one compression cycle thereby resulting in two or more layers within the tablet.

S4.1.11 *Type XI, tablet triturate.* Type XI, tablets triturate are small, uncoated tablets that contain small amounts of potent drugs in diluents usually consisting of dextrose, or a mixture of lactose and powdered sucrose, and a moistening agent such as diluted alcohol or suitable lubricant(s) depending on whether the tablets are to be molded or machine compressed.

S4.1.12 *Type XII, impregnated or laminated.* Type XII, impregnated or laminated, including "delayed-action", "repeat-action", "prolonged-action", and "sustained-action" tablets, are uncoated (class 1) or coated (class 2), as specified, and disintegrate or release the active ingredient(s) slowly, over an extended period of time as indicated in the procurement document.

S4.1.13 *Type XIII, special, as specified.* Type XIII, special tablets are uncoated (class 1) or coated (class 2) as described in the procurement document.

S4.1.14 *Styles of coated tablets.*

S4.1.14.1 *Style A, plain (nonenteric).* Style A, plain (nonenteric) coated tablets are those in which the base tablets start to dissolve or disintegrate in the gastric juice of the stomach. Plain coated tablets are composed of a base tablet which is coated with a grade of covering as designated in the procurement document (see S2).

S4.1.14.2 *Style B, enteric.* Style B, enteric coated tablets are those in which the base tablets are protected from the gastric juice of the stomach and therefore do not dissolve or disintegrate until they reach the intestine. An enteric coated tablet is composed of a base tablet which is coated with an enteric coating and further coated with a grade of covering as designated in the procurement document (see S2.).

S4.1.14.3 *Style C, special.* Style C, special coated tablets are styles as described in the procurement document.

S4.1.15 *Grades of coverings for coated tablets.* Coverings for coated tablets are of the following grades as specified:

Grade 1—Sugar.
Grade 2—Gelatin mixture.
Grade 3—Plastic (film).
Grade 4—Special, as described in the procurement document.

(The coverings may be finished with a wax coating.)

S4.2 *Lot.* For purposes of this document, a lot, batch, or control is that single, uniform, and homogeneous quantity of tablets produced from one compounding formulation, in one manufacturing and tableting 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 identifies the lot.

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

S4.3.1 For those tablets that are submitted to F.D.A. for certification prior to release, the date of manufacture is the date of the official certification notice.

S4.3.2 For those tablets that are manufactured under N.I.H. license, the date of manufacture conforms to the definition established by the N.I.H.

S4.3.3 For those tablets that are not subject to S4.3.1 or S4.3.2.

S4.3.3.1 *Uncoated tablets.* The date of manufacture is the date of compressing the

tablets or the date of manufacturer's or contractor's final quality approval which shall be not later than one (1) month after the date of compressing the tablets.

S4.3.3.2 *Coated tablets.* The date of manufacture is the date of compressing the tablets or the date of manufacturer's or contractor's final quality approval which shall be not later than two (2) months after the date of compressing the tablets.

S4.4 *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 tablets cannot be expected, beyond reasonable doubt, to yield its specific results, or retain its required potency.

S4.5 *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 tablets 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 tablets (see S6.6.1).

S5.2 Tablets 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 tablets 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 S6.6.3).

S5.3 Tablets that are not official articles in the U.S.P. or N.F. shall comply with all requirements of the procurement document (see S6.6.3).

S5.4 Tablets 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.

S5.5 Tablets manufactured under N.I.H. license shall comply with all requirements of the N.I.H. and the procurement document.

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 tablets.* Labeling, packaging, and packing of tablets shall be as specified in the procurement document.

S6. Detail requirements.

Note: Attention is directed to paragraphs under S6.6, S6.8, and S6.9 for inprocess and final product testing and examination.

S6.1 *Ingredients entering into the preparation or manufacture of tablets.*

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 *Diluents, coloring, flavoring, coating, covering, and other materials.* Diluents (including excipients, bulking agents, absorbents, disintegrators, binders, adhesives, and lubricants), coloring, flavoring, coating, covering, and other materials used in tablets shall be therapeutically innocuous in the amounts used, and shall not in any way adversely affect the stability nor the therapeutic efficacy of the tablets. The diluents, coloring, flavoring, coating, covering, and other materials shall not interfere with the applicable tests and assays.

S6.1.2.1 *Coloring material.* For tablets 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 the Color Additive Regulations.

S6.2 *Styles of coated tablets.* The styles of coated tablets shall be specified in the procurement document. The use of subcoatings(s) is permitted for coated tablets.

Style A, plain (nonenteric). The base tablets shall be coated with a covering that is smooth, uniform, and homogeneously distributed.

Style B, enteric. The base tablets shall be coated with an enteric coating which is further coated with a covering that is smooth, uniform, and homogeneously distributed.

Style C, special. The base tablets shall be coated with a special coating as specified in the procurement document.

S6.3 *Coverings for coated tablets.* The grades of coverings for coated tablets shall be specified in the procurement document (see S2). If the specific covering for tablets is not specified in the procurement document, the covering shall be the same as that which is generally commercially supplied for the item. The covering of the tablets shall be such that the finished tablets comply with S6.4.1.2.

S6.4 *Characteristics of tablets.*

S6.4.1 *Appearance.* Tablets within one contractual quantity shall be smooth, and of the same size, shape, and color. In addition, tablets within one lot shall be of a uniform shade and hue. If one tablet is scored or bears identifying marking, all tablets shall be similarly scored and shall bear the identical marking.

S6.4.1.1 *Uncoated tablets.* Uncoated tablets shall be smooth and uniform in size, shape, and color. Uncoated tablets shall show no evidence of spots, pitting, capping or cavitation, chips, breaks, excess powder, overturned (projected) edges, die spots, mottling, cleavage, feathered edge, cracks, splitting, foreign particulate contamination (foreign matter) and embedded or adhering surface spots, or foreign material contained in the tablet not visible from the surface, exceeding the limits permitted in the classification of defects (see S6.9.1, table IV), within the applicable acceptable quality level (AQL). Unless otherwise specified, any coloring material employed in the tablets shall be uniformly and homogeneously distributed, with the possible exception of multilayer tablets (type X), impregnated or laminated tablets (type XII), and special tablets (type XIII).

S6.4.1.2 *Coated tablets.* Coated tablets shall be smooth, and uniform in size, shape, and color. The base tablet shall be fully and evenly covered with the coating. Coated tablets shall show no evidence of spots, chips, breaks, mottling, cracks, surface blemishes (pits, pimples, etc.), splitting, or foreign particulate contamination (foreign matter), and embedded or adhering surface spots exceeding the limits permitted in the classification of defects (S6.9.1, table V), and the applicable AQL. If the coated tablets are polished, all such tablets shall be uniformly polished.

S6.4.1.2.1 *Base tablet prior to coating.* The base tablets, prior to coating, shall comply with the requirements for uncoated tablets, using the sampling and applicable AQL as specified in S6.8.3.

S6.4.1.3 *Film coated tablets.* Film coated tablets shall be smooth, and uniform in shape, size, and color. The base tablets shall be fully covered with an even coating. The film coated tablets shall show no evidence of chips, breaks, overturned (projected edge), feathered edge, die spots, cracks, stickiness, mottling, surface blemishes (pits, pimples, etc.), splitting, or foreign particulate contamination (foreign matter) and embedded or adhering surface spots exceeding the limits permitted in the classification of defects (S6.9.1, table VI), and the applicable AQL. If the film coated tablets are polished, such tablets shall be entirely and uniformly polished.

S6.4.1.3.1 *Base tablet prior to coating.* The base tablets, prior to coating, shall comply with the requirements for uncoated tablets, using the sampling and applicable AQL as specified in S6.8.3.

S6.4.2 *Color.* Color of the tablets shall be specified in the procurement document. If the color is not specified, the tablets shall be the same as that which is generally commercially supplied for the item.

S6.4.3 *Flavored tablets.* Unless otherwise specified in the procurement document, tablets shall not be flavored. Tablets that are intended to be chewed prior to swallowing shall be sufficiently flavored to render them palatable in taste.

S6.4.4 *Size.* Tablets shall be of a minimum size, depending on the amount of active ingredient(s), and consistent with good manufacturing practice. Tablets containing minute amounts of active ingredient(s) shall be built-up to a practical size for the usage intended. Unless otherwise specified, the size of type III tablets shall be such that 20 tablets could be packaged in a tube having overall dimensions of 0.24 inch in diameter and 2-7 8 inches in length. Type VIII tablets shall be of a size no larger than that which could be readily dropped in the barrel of an appropriate 1 cubic centimeter (cc.) hypodermic or implantation syringe.

S6.4.5 *Shape.* Tablets are generally manufactured in discoid shape, but other shapes are used, such as elliptical, triangular, hexagonal, rod-shaped, round, oblong, square, tear-shaped, diamond-shaped, etc. Tablets for the types indicated shall be as follows:

Types I, II, III, IV, X, XI, and XII shall be essentially discoid in shape.
Type V, buccal tablets shall be elliptical in shape.
Type VI, sublingual tablets shall be elliptical or discoid in shape, as specified.
Type VII, vaginal tablets shall be diamond or tea shaped.
Type VIII, pellets or implantation tablets shall be small, rod, discoid, or elliptical in shape.
Type IX, dispensing tablets shall be diamond shaped.
Type XIII, special tablets shall be as specified in the procurement document.

When the above shapes are deleted in the procurement document, the shape of tablets shall conform to that generally accepted as standard in the pharmaceutical industry for the tablets being supplied. When the above shapes are modified by the procurement document, the shape of the tablets shall conform to the procurement document. Tablets containing a potentially lethal human dose per tablet shall have an angular or irregular shape; not discoid. Mercury bichloride tablets shall be coffin-shaped and blue in color.

S6.4.6 *Hardness.* When a hardness range or value is required for the tablets, it shall be specified in the procurement document, along with the method to be used in determining such hardness. The hardness of tablets shall be such as to prevent breakage, crumbling, or powdering of the tablets in the course of ordinary handling and storage.

S6.4.7 *Scoring.* Unless otherwise specified, scored tablets are acceptable when such tablets are generally commercially supplied for the item. The score shall be of a single score on one side of the tablet only, unless otherwise specified.

S6.4.8 *Odor.* Upon opening a sealed bottle, the tablets shall be odorless if they (a) are not flavored, or (b) do not contain active ingredients which are normally characteristically odorous. Tablets shall have no foreign odor or odor resulting from decomposition or deterioration. The term "odorless" applies to examination of tablets in the freshly-opened immediate container, with the cotton or other filler removed. After exposure to the air at room temperature (in a 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 tablets or less, exposure to air shall be 5 minutes; for containers labeled to contain between 101 and 500 tablets, exposure to air shall be 10 minutes; containers labeled to contain between 501 and 1000 tablets, exposure to air shall be 15 minutes; and containers labeled to contain more than 1000 tablets, exposure to air shall be 25 minutes. The cotton or other filler shall be removed from the immediate container during the exposure to air.

S6.4.9 *Disintegration and solubility.*

S6.4.9.1 *Type I, and Types V through XI.* Unless otherwise specified, disintegration of tablets that are classified as type I and types V through XI shall be determined by U.S.P. or N.F. method. Disintegration time for such tablets shall be in accordance with the U.S.P., N.F., or the procurement document. Tablets that are intended to be chewed prior to swallowing shall be of appropriate hardness. Types XII and XIII shall be tested for disintegration, as specified in the procurement document.

S6.4.9.2 *Types II, III, and IV.* Solubility of tablets of types II, III, and IV shall comply with the following requirements, unless otherwise specified in the procurement document.

Type II, class 1, tablets shall completely dissolve in the ratio 1 tablet to 10 cc. of distilled water at 25 C. within 5 minutes to form a clear solution, free from sediment. The solution shall be colorless, unless otherwise specified. Moderate agitation or shaking may be employed to facilitate solution.

Type II, class 2 tablets shall effervesce and shall completely dissolve within the period designated in the procurement document when tested as stated therein.

Type III tablets shall completely dissolve in the ratio of 1 tablet to 1 cc. of distilled water at 25 C. within 2 minutes, unless otherwise specified. Moderate agitation or shaking may be employed to facilitate solution. No effervescence shall occur during or after solution. The resulting solution shall be clear and free of undissolved or particulate matter when examined without accessory magnification.

Type IV tablets shall completely dissolve in the ratio of 1 tablet to 0.5 cc. of distilled water at 25 C. within 15 seconds. Moderate agitation or shaking may be employed to facilitate solution. No effervescence shall occur during or after solution. The resulting solution shall be clear and free of undissolved or particulate matter when examined without accessory magnification.

For types II, III, and IV tablets. Tablets shall be free of undissolved or particulate matter when examined without accessory magnification, within the limits permitted in the classification of defects, and the applicable AQL. No tolerance on the solubility time shall be permitted (see S6.8.2).

S6.4.10 *Weight variation.*

S6.4.10.1 *Uncoated tablets.* The weight variation of uncoated tablets shall fall within the limits allowed in the U.S.P. or N.F., or as specified in the procurement document.

S6.4.10.2 *Coated tablets.* The requirement of weight variation for coated tablets shall be the same as that described in S6.4.10.1, except that the weight variation shall be determined on the uncoated or base tablets.

S6.4.11 *Moisture content.* The moisture (water) content shall not exceed that which is specified in the procurement document. If the moisture content is not specified, the tablets shall contain a minimum amount of moisture so as to insure maximum stability of the tablets.

S6.4.12 *Markings on tablets.* Tablets may bear a trademark or other designation distinctive of the item or of the manufacturer.

S6.4.13 *Stability.* Tablets shall be so com-

pounded as to provide physical stability of tablets and chemical stability of the ingredients. Tablets that are designated as having a potency period shall comply with all applicable requirements for the full potency period under normal storage and handling.

S6.4.14 *Net content and variation in count.* The number of tablets (count) 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 tablets when the specified number of tablets per immediate container is 100 or more.

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

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

S6.4.14.1 For tablets containing narcotics or barbiturates, and tablets subject to the Drug Abuse Control Amendments, the number of tablets 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 tablets specified in the item identification of the procurement document.

S6.4.15 *Volume occupied by tablets.* When specified, the tablets shall meet the test requirement in the procurement document for volume occupied by tablets.

S6.4.16 *Dimensions of tablets.* When dimensional requirements for tablets are specified in the procurement document, the tablets shall comply with the specified dimensions.

S6.5 *Delivery schedule.*

S6.5.1 *Potency dated tablets requiring certification by F.D.A. or manufacture under N.I.H. license.* Delivery schedule for potency dated tablets 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 allowable 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

S6.5.2 *Potency dated tablets other than those complying with S6.5.1.* Delivery schedule for potency dated tablets, other than those complying with S6.5.1 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 S4.3) of the tablets to the date that the material is delivered to the Government.

TABLE II. *Delivery schedule*

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

S6.5.3 *Nonpotency dated tablets.* Unless otherwise specified, not more than 6 months shall elapse from the date of manufacture (defined in S4.3) of nonpotency dated tablets to the date of delivery to the Government.

S6.6 *Tests.*

S6.6.1 *Testing of 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 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 S5.1.

S6.6.2 *Inprocess testing.* During the tableting operation, not less than 10 tablets from each lot shall be drawn from each tableting machine at regular intervals of 30 minutes, or less, and tested for weight. The disintegration time shall be verified at least during the beginning of the tableting (compression) operation. For soluble tablets (types II, III, and IV), the solubility time shall be verified at least during the beginning, middle, and end of the tableting operation. The hardness of tablets shall be determined at least during the beginning, middle, and end of the compression of the lot, using 6 tablets each time. The disintegration time, solubility time, and hardness shall be within the required limits. The inprocess testing shall be applicable to tablets from each tableting machine. The test results shall be recorded for each tableting machine used for each lot to confirm uniformity of compression.

S6.6.2.1 Tablets which are to be coated in subsequent manufacturing operation shall be subject to the inprocess testing required by S6.6.2, prior to coating.

S6.6.3 *Testing of finished tablets.*

S6.6.3.1 *Tablets official in the U.S.P. or N.F.* Each lot of tablets 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 to determine compliance with S5.2.

S6.6.3.2 *Tablets not official in the U.S.P. or N.F.* Each lot of tablets 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 tablets shall be tested by suitable methods, to determine compliance with S5.3.

S6.7 *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 tablet machine number or the permanent tableting station number, lot number, and test findings. For tablets 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 *Sampling.* Unless otherwise specified in the procurement document, sampling shall be in accordance with MIL-STD-105.

S6.8.1 *Examination.* Examination shall be conducted in accordance with the following inspection level:

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

Note. 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 tablets shall remain the same. The required number of tablets 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 bottles. If the number of bottles selected does not give the required number of tablets for examination, at random, select additional bottles to give the required number of tablets. Those defects that are annotated "#" in the classification of defects, must be determined on tablets from filled, final (immediate) containers. Results of examination for those defects, obtained prior to filling of final (immediate) containers, shall not be acceptable.

S6.8.2 *Testing.* Shall be conducted as follows:

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

(a) Sampling of each lot for the tests required in table III shall be in accordance with level S-1. Minimum sample size is three (3) bottles. 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 III, on tablets taken from bulk stock (prior to packaging of tablets). A minimum of 300 tablets 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 bottles. The identity test shall be specific for the product. For products containing more than one active ingredient, a minimum of two of the ingredients shall be identified by specific tests.

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

TABLE III.

Characteristic	Requirement paragraph
Testing of finished tablets (assays, identities, and other tests applicable for the item).	S6.6.3
Flavor	S6.4.3
Hardness	S6.4.6
Scoring	S6.4.7
Disintegration (types I, and V through XI)	S6.4.9.1
Solubility (types II, III, and IV)	S6.4.9.2
Weight variation	S6.4.10
Moisture	S6.4.11
Volume occupied by tablets (when specified)	S6.4.15
Dimensions of tablets (when specified)	S6.4.16

(c) The net content and variation in count (S6.4.14 and S6.4.14.1) shall be sampled in accordance with inspection level S-2. Acceptance number shall be zero (0).

S6.8.3 Base tablets prior to coating shall be sampled in accordance with MIL-STD-105, level I, unit of product—tablet, with an AQL (percent defective) of 1.5 for major defects and 4.0 for minor defects. All major A categories under "Uncoated Tablets," except numbers 106 and 111, shall apply. Minor categories numbers 203 and 205 shall also apply. Notwithstanding the omission of examination for certain minor defects for the tablets prior to coating, final coated tablets shall comply with all requirements.

S6.9 *Examination.* The tablets shall be examined to determine compliance with all requirements of this document. Nonconformance with these requirements will be permitted to the extent indicated in S6.8.

S6.9.1 *Classification of defects.* Examination shall be conducted in accordance with the following classification of defects:

Table IV—Uncoated tablets.
Table V—Coated tablets.
Table VI—Film coated tablets.

TAB IV. *Uncoated tablets classification of tablets****

Type	I	II	II	III	IV	V	VI	VII	VIII	IX	X	XI	XII	XIII
Class	1	1	2	—	—	—	—	1	--	—	1	—	1	1
Major A:														
101 Tablet not uniform in size and shape	X	X	X	X	X	X	X	X	X	X	X	X	X	X
102 Tablet not uniform in color (mottled).	X	X	X	X	X	X	X	X	X	X	X	X		X
103 Tablet not free of foreign particulate contamination (foreign matter).	X	X	X	X	X	X	X	X	X	X	X	X	X	X
#104 Tablet not free of embedded surface spots and contamination (definition a, S6.9.1.1).	X	X	X	X	X	X	X	X	X	X	X	X	X	X
#105 Tablet not free of breaks.	X	X	X	X	X	X	X	X	X	X	X	X	X	X
106 Tablet not suitable size.				X					X					
107 Tablet not free from splitting.	X	X	X	X	X	X	X	X	X	X	X	X	X	X
108 Tablet not free of capping or cavitation.	X	X	X	X	X	X	X	X	X	X	X	X	X	X
#109 Tablet not free from foreign material inside the tablet (not visible from the surface).	X	X	X	X	X	X	X	X	X	X	X	X	X	X
#110 Tablet not free of cracks.	X	X	X	X	X	X	X	X	X	X	X	X	X	X
111 Solution not free of undissolved or particulate matter.		X	X	X	X									
Major B:														
#151 Tablets not free of foreign odor.	X	X	X	X	X	X	X	X	X	X	X	X	X	X
= 152 Bottle not free of excess powder.	X	X	X	X	X	X	X	X	X	X	X	X	X	X
= 153 Bottle not free of extraneous material.	X	X	X	X	X	X	X	X	X	X	X	X	X	X
= 154 Color of tablets in bottle not uniform.	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Minor:														
201 Tablet not free of overturned (projected edge).	X	X	X	X	X	X	X	X	X	X	X	X	X	X
202 Tablet not free of feathered edge.	X	X	X	X	X	X	X	X	X	X	X	X	X	X
203 Tablet not free of die spots.	X	X	X	X	X	X	X	X	X	X	X	X	X	X
= 204 Tablet not free of adhering surface spots (definition b, S6.9.1.1).	X	X	X	X	X	X	X	X	X	X	X	X	X	X
205 Tablet not free of pitting.	X	X	X	X	X	X	X	X	X	X	X	X	X	X
206 Tablet not free of cleavage.	X	X	X	X	X	X	X	X	X	X	X	X	X	X
= 207 Tablet not free of chips.	X	X	X	X	X	X	X	X	X	X	X	X	X	X
= 208 Tablet not smooth.	X	X	X	X	X	X	X	X	X	X	X	X	X	X

** Examination is not restricted to the classification given above.

= Applies to examination of tablets in filled, final (immediate) containers.

TABLE V. *Coated tablets classification of defects***

Type	I	VII	X	XII	XIII
Class	2	2	2	2	2
Major A:					
101 Base tablet not fully covered.	X	X	X	X	X
102 Coating not uniform in color (mottled).	X	X	X	X	X
#103 Tablet not free of breaks.	X	X	X	X	X
104 Tablet not uniform in shape and size.	X	X	X	X	X
#105 Tablet not free of cracks.	X	X	X	X	X
#106 Tablet not free of embedded surface spots and contamination (definition a, S6.9.1.1).	X	X	X	X	X
107 Tablet not free of foreign particulate contamination (foreign matter).	X	X	X	X	X
108 Tablets not uniformly polished (if polished).	X	X	X	X	X
Major B:					
#151 Tablets not free of foreign odor.	X	X	X	X	X
#152 Color of tablets in bottle not uniform.	X	X	X	X	X
#153 Bottle not free of extraneous material.	X	X	X	X	X
Minor:					
#201 Coated tablet not smooth.	X	X	X	X	X
#202 Coating not free of surface blemishes (i.e., pits, pimples, etc.).	X	X	X	X	X
#203 Coated tablet not free of adhering surface spots (definition b, S6.9.1.1).	X	X	X	X	X
204 Coated tablets not free of chips.	X	X	X	X	X

** Examination is not restricted to the classification given above.
# Applies to examination of tablets in filled, final (immediate) containers.

TABLE VI. *Film coated tablets classification of defects***

Major A:
101 Base tablet not fully covered.
102 Coating not uniform in color (mottled).
#103 Tablet not free of breaks.
104 Tablet not uniform in shape and size.
#105 Tablet not free of cracks.
106 Tablet not free of embedded surface spots and contamination (definition a, S6.9.1.1).
#107 Coated tablet not free of cracks.
108 Tablet not free from splitting.
109 Coated tablet not free of foreign particulate contamination (foreign matter).
#110 Tablets not free of stickiness.
Major B:
#151 Tablets not free of foreign odor.
#152 Color of tablets in bottle not uniform.
#153 Bottle not free of extraneous material.
Minor:
201 Coated tablet not free of overturned (projected) edge.
202 Coated tablet not free of feathered edge.
203 Coated tablet not free of die spots.
#204 Coated tablet not free of adhering surface spots (definition b, S6.9.1.1).
205 Coated tablet not free of pitting.
#206 Coated tablet not free of chips.
#207 Coated tablet not smooth.
#208 Coating not free of surface blemishes (i.e., pits, "pimples," etc.).

** Examination is not restricted to the classification given above.
# Applies to examination of tablets in filled, final (immediate) containers.

S6.9.1.1 Definition of terms for classification of defects:

Terminology	Definition	Unit of product
Uniformity of shape	Self-explanatory.	Tablet
Uniformity of size	Self-explanatory.	Tablet
Surface spots	(a) Clearly defined particles which are embedded in or on the surface of the tablets. (b) Clearly defined particles which adhere to the surface but can be wiped or blown off of the surface. The particles (spots) are foreign, extraneous, or contaminant to the tablets. Examination is conducted without accessory magnification.	Tablet
Pitting	Small identations in the surface of the tablet such as that exhibited by porous tablets.	Tablet
Capping or cavitation	The separation (or tendency toward separation) of a portion of the upper or lower surface of the tablet.	Tablet
Chip	An indentation on the edge of the tablet. The cross section (largest dimension) of the chip in the tablet is more than 10 percent of the diameter of the tablet, but less than 10 percent of the tablet weight.	Tablet
Break	The separation or dislodging of more than 10 percent of the tablet.	Tablet
Excess powder	That amount of powder and tablet chips which is equivalent to more than 0.5 percent of the total weight of tablets in the immediate container.	Bottle
Foreign matter	Foreign material contained in the tablet not visible from the surface.	Tablet
Die spot	The small indentation in the surface of the tablet such as that caused by a sticking to the punch or die, or the result of a gummed punch or die.	Tablet
Mottling or nonuniformity of color	The irregular coloration of the tablet.	Tablet
Cleavage	An indentation or "weak point" on the vertical (perpendicular) surface of the tablet which may result in breakage of the tablet. 	Tablet
Smooth surface	A surface that is smooth to the touch and is not intended to include effects of scoring or trademark impressions.	Tablet
Crack	A break in the surface of the tablet.	Tablet
Overturned (projected) edge	The excess ridge at the point where the "face" (convex or flat surface) meets the vertical (perpendicular) surface of the tablet. This ridge (projection) is more than 10 percent of the vertical length.	
Feathered edge	Similar to an overturned edge except that the ridge resembles somewhat the teeth of a saw and the ridge (at its maximum) is not 10 percent of the vertical length.	Tablet
Splitting	A completed separation of the tablet into two or more substantial parts.	Tablet

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.

In the use of this standard, the procuring activity shall designate, as a minimum, the type and class of tablet required (see S.2), the expiration dating period (potency period), when applicable (see S4.4), and the labeling, packaging, and packing required (see S5.7).

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.

STANDARDIZATION DOCUMENT IMPROVEMENT PROPOSAL

OMB Approval
No. 22-R255

INSTRUCTIONS: The purpose of this form is to solicit beneficial comments which will help achieve procurement of suitable products at reasonable cost and minimum delay, or will otherwise enhance use of the document. DoD contractors, government activities, or manufacturers/vendors who are prospective suppliers of the product are invited to submit comments to the government. Fold on lines on reverse side, staple in corner, and send to preparing activity. Comments submitted on this form do not constitute or imply authorization to waive any portion of the referenced document(s) or to amend contractual requirements. Attach any pertinent data which may be of use in improving this document. If there are additional papers, attach to form and place both in an envelope addressed to preparing activity.

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A. GIVE PARAGRAPH NUMBER AND WORDING.

B. RECOMMENDATIONS FOR CORRECTING THE DEFICIENCIES

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