Fed. Std. No. 140A
Amendment - 1
March 25, 1970

FEDERAL STANDARD

TABLETS (FOR MEDICINAL PURPOSES)

This amendment, which forms a part of Federal Standard Fed. Std. No. 140A, dated October 30, 1966, was approved by the Commissioner, Federal Supply Service, General Services Administration, for the use of all Federal agencies.

PAGE 2

S4.1.4 Type IV, ophthalmic. At the end of the first sentence delete the period (.) and substitute "and are placed directly on the eye."

PAGE 3

S4.3.1 At the end of this paragraph add the following new sentence, "This certification shall be not later than 6 months after the date of tableting."

PAGE 4

Under "S4.4 Expiration dating period", add the following new sub-paragraph:

S4.4.1 For those tablets that are submitted to F.D.A. for certification prior to release, the expiration dating period (potency period) shall be based upon the first or original F.D.A. certification. This certification shall be not later than 6 months after the date of tableting."

S4.4.2 For those tablets that are manufactured under N.I.H. license, the expiration dating period (potency period) shall be as established by the N.I.H., and shall be as specified in the procurement document.

S5.1 After the first sentence add the following new sentence: "The 'Descriptions' included in U. S. P. and N. F. 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." At the end of this paragraph add the following new sentence: "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 ingredients, Purified Water, U. S. P. shall be required."

S5.2 After the first sentence add the following new sentence: "Notwithstanding deletion from U. S. P. and N. F. monographs, the Weight Variation requirement of S6.4.10 is applicable to monographed tablets."

PAGE 5

S6.4.1.2 Coated tablets. Line 7, after "splitting," add the following "local erosion of coating,".

S6.4.1.3 Film coated tablets. Line 8, after the word "stickiness," insert "flaking, local erosion of coating".

PAGE 6

S6.4.6 Hardness. Delete the second sentence in its entirety and substitute: "If not specified in the procurement document the hardness of the tablets shall be in accordance with manufacturer's specified internal requirements and shall be such as to prevent breakage, crumbling, or powdering of the tablets in the course of ordinary handling and storage. Sampling shall be as specified in S6.8.2".

PAGE 8

Add the following new subparagraph:

S6.4.14.2 For tablets packaged in blister packets the number of tablets in each immediate container shall be 100.0 percent of the number of tablets specified in the procurement document. No tolerances shall be allowed.

Add new paragraph:

S6.4.17 Foreign material inside the tablet. Tablets shall be free of foreign material inside the tablet and not visible from the surface when examined, using either method described below, without accessory magnification (except for such optical correction as may be required to establish normal vision). The tablets shall comply with the limits permitted in the classification of defects (S6.9.1), and the applicable AQL.

(a) Method I. Place one (1) tablet on a clean surface and place a clean metal spatula on the tablet (horizontal surfaces parallel and touching). Using a suitable instrument (e.g. mallet), hit the spatula with sufficient force to fragment the tablet into two or more pieces. Do not powder. Examine the fragments for foreign material, and record the number of tablets found to contain such material.

(b) Method II. Place one (1) tablet in each depression of a clean, white, glazed porcelain spot plate.* Cover the tablets with a clean sheet of white paper to prevent dispersion of fragments. Gently tap each tablet with a suitable device (e. g. small pestle) until each tablet is fragmented into two or more pieces. Examine each tablet for foreign material and record the number of tablets found to contain such material.

*Spot plates are avilable with up to 30 depressions per plate.

NOTE: Method(s) other than the two 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 tablets to determine foreign material inside the tablet(s).

S6. 6. 2 Inprocess testing. Line 5, after the first sentence, insert the following: "Samples shall be obtained from each platform of multistage machines. In addition, the weight test shall be performed immediately following any machine adjustment which will affect tablet weight."

Insert the following new subparagraph:

S6. 6. 2. 2 All coated tablets shall be subjected to 100 percent visual inspection for defects prior to packaging in the immediate container."

S6. 8. 1 Examination. At top of page, in the table, under "Inspection Level" - for "Major A" add "*" after "II."

In paragraph "Note" - Line 10, after "5 bottles" - Delete the period (.) and insert", except where the immediate container is a transparent blister packet. The sample size shall then be based on the lot size of the tablets. After the tablets are placed in the packets, only a visual (physical) examination of the tablets (without destruction of the blister) shall be required, using three (3) times the sample size of each lot of tablets."

At bottom of page, add the following:

*Except 109 (table IV); 107 (table V); and 109 (table VI) where inspection level S-4 shall be used.

Change the paragraph with one asterisk (*) to two asterisks (**).

S6. 8. 2 Testing. Under the table, preceding subparagraph "(c)" insert the following: "Note: Unless otherwise specified 20 tablets shall be tested for hardness."

PAGE 11

Table IV.

In column "Type X," "Class 1", delete the "X" for Major A, defect 102. Delete Major A defect 103 in its entirety. No substitution is necessary. Preceding defect 109, delete the "#". Delete Major B defect 153 in its entirety and substitute: "#153 Immediate container not free of extraneous material." At the bottom of the page add the following:

Note: Tablets 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 tablets need be selected.

PAGE 12

Table V.

After Major A defect 108 add the following "#109 Coating not free from local erosion". Delete Major B defect 153 in its entirety and substitute:

#153 Immediate container not free from extraneous material." Under Table V add the following Note:

Note: Tablets 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 tablets need be selected.

Table VI.

Under Major A, delete defect "#107" in its entirety and substitute:

#107 Coated tablet not free of flaking.

After Major A defect 110 add the following:

#111 Coating not free from local erosion.

Delete Major B defect 153 in its entirety and substitute: #153
Immediate container not free from extraneous material.

At the bottom of the page, under Table VI add the following note:

Note: Tablets 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 tablets need be selected.

PAGE 13

S6.9.1.1 Add the following definitions:

Terminology	Definition	Unit of Product
Flaking	A peeling or separation of coating from any area of the tablet	Tablet
Erosion	Stripping away or dissolving of the film coating or layers of the sugar coating resulting in a loss of the coating integrity.	Tablet