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http://www.usamma.army.mil/dlar/appm6.txt

This document describes procedures which may be prescribed for performing physical examination for selected pharmaceutical products. For more detailed description and apparent discrepancies please refer to the original document.

1-6 Training

To accomplish storage inspection for medical materiel, it is necessary to assign qualified personnel. These inspectors must have a basic understanding of the packaging, packing, labeling, storage functional requirements and the ability to perform visual and other simple test procedures for medical materiel.

2-2 Facilities

A. Recommended Inspection Facilities and Equipment. Quality evaluation is determined by examination for appearance, taste, order, texture, and other qualities involving sensory perception, and certain tests involving weighing, measuring, counting, and the application of certain physical procedures. To effectively accomplish the Quality Assurance mission, certain facilities and equipment are essential. The following is a recommended list of facilities that the depots should provide the inspection and quality audit elements.

4-4 General Inspection Information

A. Metric Equivalents. In conversion from the English to metric system, the metric equivalent used by some manufacturers may be slightly different from that shown in the item identification. The metric equivalents listed in the Federal Supply Catalog should be considered as nominal quantity of contents.

B. Commercial Packaging and Packing. Since most medical items are packaged to commercial, rather than military specifications or standards, care must be exercised to ensure that unit and intermediate quantities are properly marked on containers; also that issue document quantities correspond to the package quantities. When the catalog issue quantity differs from the quantity shown on the package, the item(s) should be repackaged/remarked to correspond with the issue needs.

D. Tamper-Resistant Packaging.

1) Manufacturers are utilizing tamper-resistant packaging for certain over-the-counter (OTC) nonprescription drug products. A tamper-resistant package is one having an indicator, seal or barrier to entry, which if broken, breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. A tamper-resistant package may involve an immediate-container and closure system or secondary container or carton system or any combination of systems intended to provide a visual indication of package integrity. Further, each such package is required to bear a statement that is prominently placed so that consumers are alerted to the specific tamper-resistant feature of the package.
2) Due to the variety of tamper-resistant seals, packages, and designs being used, there is a corresponding variety in the statements being used to specify the specific tamper-resistant feature to be checked. The following are some examples of such statements illustrating specific tamper-resistant features:

    a) Sealed for your protection.
    b) If foil seal under cap is broken or missing when purchased, do not use.
    c) Protective overwrap on carton. Do not use if red stripe is missing.
    d) Do not use if safety seal broken.
    e) Each tablet sealed. Do not use if seal is torn.
    f) Safety sealed. Do not use if opened.
    g) Do not use if seal under cap is broken.
    h) Safety sealed. Do not use if film wrap is cut or torn.

4-6 Methods Of Inspection

A. Sampling Inspeciton (Statistical). A modified method of selection of samples may be used because supplies are usually warehoused in such a manner as to render true random selection of samples impractical or economically prohibitive, provided samples selected are representative of the "lot".

B. Full Inspection (100 Percent). Full inspection 100 percent inspection (screening) of the total quantity of an item in a specific lot or shipping unit. Full inspection will be limited to:

1) Requests by the contracting officer as a result of warranty action on an item.
2) Requests by DPSC-MQ
3) Instances where result of a sampling inspection indicate that full inspection is necessary and can be accomplished with facilities and personnel currently available at the storage activity.

4-11 Inspection of Parenterals/Injectables

A. Definition. Parenterals are sterile preparation administered by injection under or through the skin or mucous membrane.

B. Method of Inspection.

1) Clarity and Completeness of Solution. Solutions of parenteral preparations shall be clear and free from undissolved or particulate matter the limits permitted in applicable serviceability quality level. NOTE: For dry solid products, prior to examination, the product must be constituted as directed in the labeling supplied by the manufacturer.

a) The containers are examined without accessory magnification (except for such optical correction as may be required to establish normal vision) against a black background and against a white background with illumination from a light at a point 25.4 centimeters (10 inches) from its source provides an intensity of illumination of not less than 100 and not more than 350 foot-candles as measured by a light meter. (Some biological products need not be clear and entirely free from turbidity, provided this is characteristic of the products.)

b) A fluorescent X-ray film illuminator can be used as a light source in illumination of the ampuls, vials, or bottles under examination for clarity.

c) In examining for clarity, invert the container several times or swirl gently. Do not agitate the solution. Agitation will incorporate air into the solution. Foreign matter (solid particles) is usually irregular in shape and will tend to settle to the bottom of the container, whereas lint or thread-like particles may float in the liquid. In contrast, fine air bubbles which may be seen during handling of the container may be recognized by a spherical or oval shape and movement to the surface of the solution.

d) In examining for completeness of solutions of dry solid products, note that the solid dissolves completely, leaving no visible residue as undissolved matter. In addition, this constituted solution is not significantly less clear than an equal volume of diluent or of purified water (Purified USP) contained in a similar container and examined similarly. e. In reporting lack of clarity in parenteral preparations, indicate the type and nature of the particulate matter, its extent, and number of containers found to contain particles and number of containers without particles.

2) Clarity of Suspensions

a) Suspensions shall contain fine, evenly dispersed powder or crystalline materials in suitable vehicles. (NOTE: For dry solid products, prior to examination, the product must be constituted as directed in the labeling supplied by the manufacturer.)

b) Suspensions shall be free from foreign matter when examined, without accessory magnification, under ordinary room lighting. If separation of the suspension occurs, a uniform suspension shall be obtained after moderate shaking of the container for 20 seconds. The suspension shall remain homogeneous for at least three minutes. Suspensions in aqueous vehicles, after shaking as above, shall flow freely without binding when the contents of the final containers are aspirated through a 22-gauge, 1 inch hypodermic needle, using a suitable hypodermic syringe. Suspension in nonaqueous vehicles, after shaking as above, shall flow freely without binding

when the contents of the final containers are aspirated through an 18-gauge, 1-1/2 inch hypodermic needle using a suitable hypodermic syringe. Requirements for suspension needing special treatment will be described in the procurement document.

3) Examination of Containers. The container may be glass or plastic bottle, ampoule, multi-dose vial, tube, or bag complete with a closure which holds and is in direct contact with the medical product. Examine carefully each container sampled for evidence of physical damage such as cracks, breaks, tears, leakage, and interaction between contents and container. Those containers found defective are considered not suitable for use.

4-12 Inspection Of Tablets

A. Definition. Tablets are solid dosage forms containing one or more medicinal substances, except placebo tablets, with or without suitable diluents. Tablets are made in various shapes, colors, sizes, and weights, coated and uncoated, depending upon the amount of the medicinal substance(s) and the intended mode of administration or use. Various types of tablets are: Oral Tablets, Solution Tablets, Hypodermic Tablets, Ophthalmic Tablets, Buccal Tablets, Sublingual Tablets, Vaginal Tablets, Pellets, Impregnated or Laminated, including "delayed-action", "repeat-action", prolonged-action", and "sustained-action" tablets.

B. Characteristics of Tablets

1) Uniformity. All tablets within one contractual quantity shall be smooth and uniform in size, shape, and color. Tablets within one lot shall be of a uniform shade and hue. If one tablet bears identifying marking, all shall bear the identical marking. In addition, tablets shall show no evidence of defects as specified in subparagraph D.
2) Color. In reporting discoloration of tablets, identify the color, using the closest matching color in Federal Standard Number 595, Colors. Unless otherwise specified, any coloring materiel employed in the tablets shall be uniformly and homogeneously distributed, with the possible exception of multilayer, impregnated, or laminated tablets.

C. Method of Inspection

1) Visual Examination. Tablets shall be placed on a white sheet of paper and both sides of each tablet examined, without accessory magnification, under ordinary room lighting. Turning can be affected by means of a spatula. Handling of tablets with bare hands should be avoided by the use of surgical gloves.
2) Odor Examination. Tablets shall be odorless if they are not flavored or do not contain active ingredients which are normally characteristically odorous. Tablets shall have no foreign odor or odor resulting from decomposition or deterioration. Tablets with an inspection Code "B4" shall be examined in the freshly opened immediate container; the cotton or other filler shall be removed from the immediate container during the exposure to air. After exposure to the air at room temperature (in a room from drafts) for the period specified herein, the contents of a freshly opened immediate container shall have no odor.

3) Quantity Tablets per container Exposure to Air in minutes

Tablets Per Container	Exposure to Air in Minutes
100 or less	5
101 to 500	10
1001 or more	25

D. Classification of Defects. Examination of all tablets shall be conducted using the following classification of defects, unless otherwise noted.

1) Major Defects
   a) Tablet not uniform in color (mottle).
   b) Color of tablets in bottle not uniform.
   c) Tablet not free of foreign odor.

d) Tablet not uniform in shape or size.
e) Tablet not free of breaks.
f) Tablet not free of cracks.
g) Tablet not free of embedded surface spots or contamination.
h) Tablet not free of foreign particulate contamination.
i) Bottle not free of extraneous materiel.
j) Base tablet not fully covered (coated and film-coated tablets only).
k) Tablet not uniformly polished, if polished (coated tablets only).
l) Tablet not free of stickiness (film-coated tablets only).
m) Tablet not free of splitting (uncoated and film-coated tablets only).
n) Tablet not free of capping or cavitation (uncoated tablets only).
o) Tablet not free of foreign materiel inside the tablet (uncoated tablets only).
p) Solution not free of undissolved or particulate matter (solution, hypodermic, or tablets only).

2) Minor Defects
a) Tablet not smooth.
b) Tablet not free of surface blemishes, i.e., pits, pimples.
c) Tablet not free of adhering surface spots.
d) Tablet not free of chips.
e) Tablet not free of overturned (projected) edges (uncoated and film-coated tablets only).
f) Tablet not free of feathered edges (uncoated and filmcoated tablets only).
g) Tablet not free of die spots (uncoated and film coated tablets).
h) Tablet not free of cleavage (uncoated tablets only).
i) Tablet not free of pitting (uncoated and film coated tablets only).
j) Immediate container not internally and externally clean.
k) Void space of immediate container not filled, when required.
l) Brochure not included (or attached), when required.
m) Labeling not legible.

E. Reporting Defective Tablets. In reporting defective tablets indicate in the report the number found with defects. A qualitative statement or photograph is to be submitted that will describe the magnitude or extent of the defects. In describing defects the following definitions apply to the terminology used:

Terminology	**Definition**
Break	The separation or dislodging of more than 10 percent of the tablet.
Capping or	The separation (or tendency toward separation) of a Cavitation portion of the upper or lower surface of the 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.
Cleavage	An indentation or "weak point" on the side of the tablet which may result in breakage of the tablet.
Crack	A break in the surface of the tablet.
Die spot	The small indentation in the surface of the tablet such as that caused by sticking to or the result of a gummed punch or die.
Excess powder	That amount of powder and tablet chips which are equivalent to more than 0.5 percent of the total weight of tablets in the immediate container.
Feathered side	Similar to an overturned edge except that the ridge resembles the teeth of a saw and the ridge (at its maximum) is 10 percent or less of the vertical length.
Foreign matter	Foreign materiel contained in the tablet is not visible from the surface.
Mottling or Non-uniformity of color	The irregular coloration of tablet or non-uniformity of Color
Overturned	The excess ridge at the point where the "face" (projected) edge (convex or flat surface) meets the vertical (perpendicular) surface of the tablet. This ridge (projection) is more than 10 percent of the vertical length.
Pitting	Small indentations the surface of the tablet such as that exhibited by porous tablets.

Smooth surface	A surface that is sooth to the touch excluding the effects of scoring or trademark impressions.
Splitting	A complete separation of the tablet into two or more substantial parts.
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.
Uniformity	Self-explanatory. of shape or size

4-13 Inspection of Capsules

A. Definition. Capsules are solid dosage forms containing one or more medicinal substances, except for placebo capsules, with or without diluents, enclosed within either a hard or soft soluble container (shell). The container is prepared from a gelatin base containing glycerin or other suitable plasticizer in a proportion which may be varied to produce either a hard or soft capsule in the following shapes: conventional, bullet-like, elliptical (oval), oblong, round, tapered ends, or a special shape as specified in the procurement document. Hard capsules consist of two pieces (the base and the cap) and contain powders, granulations, or pellets. Soft capsules consist of two flexible pieces formed into a body and permanently sealed and contain liquids, powders, or semisolids.

B. Method of Inspection

1) Uniformity. Capsules within one lot and within one contractual quantity shall be of the same color, transparency, size and shape. If one capsule bears identifying markings, all capsules shall bear the identical marking. In addition, capsules shall show no evidence of defects as specified in Section C of the contract. Unless otherwise specified, any coloring materiel employed in the capsules shall be uniformly and homogeneously distributed, with the possible exception of the pellets in certain types of capsules.

2) Odor Examination. See Paragraph 4-12C to accomplish this test.

C. Classification of Defects. Examination of all capsules shall be conducted in accordance with the following classification of defects, unless otherwise noted.

1) Major Defects
   a) Capsule not as specified (i.e., hard shell or soft shell).
   b) Capsule not free of cracks, breaks, pinholes or splits where leakage of contents may occur.
   c) Capsule not uniform in appearance.
   d) Base and/or cap of capsule not as specified (hard capsules).
   e) Capsule not uniform in color(s).
   f) Capsule empty.
   g) Capsule not free of embedded surface spots or contamination.
   h) Capsule does not maintain tight closure or seal in the immediate container, or during normal handling, or dispensing.
   i) Capsule fill not free from foreign matter (not visible through capsule shell).
   j) Capsule not intact (i.e., cap separated from body).
   k) Capsule not free of foreign odor, other than characteristic odor.
   l) Immediate container not internally or externally clean.
   m) Void space of immediate container not filled.
   n) Brochure not included (or attached), when required.
   o) Labeling not legible.
   p) Immediate container not free of excess ingredient (capsule contents).
2) Minor Defects
   a) Capsule not free of pits or dents.
   b) Capsule not free of thin areas.
   c) Capsule not free of specks, spots or blemishes.
   d) Capsule not free of cap and/or body cutting into one another (hard capsules).
   e) Capsule not smooth.
   f) Capsule not free of adhering surface spots.

D. Reporting Defective Capsules. In reporting defective capsules indicate in the report the number found with defects. A qualitative statement or photograph is to be submitted that will describe the magnitude or extent of the defects. In describing defects, the following definitions apply to the terminology used:

Terminology	**Definition**
Break and Crack	A fracture in the surface of the capsule.
Dents	Small indentation in the surface of the capsule.
Excess Ingredient	That amount of fill from the capsules which is equivalent to more than 0.5 percent of the total weight of the capsules in the immediate container.
Foreign Matter	Foreign materiel contained in the capsule and not visible from the surface.
Mottling or Non-uniformity of color	The irregular coloration of the capsule. Non-uniformity of color
Splitting	A complete separation of the capsule into two or more substantial parts.
Smooth Surface	A surface that is smooth to the touch excluding effects of trademark impressions.
Surface Spots	(a) Clearly defined particles which are embedded in or on the surface of the capsules. (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 a contaminant to the capsules. Examination is conducted without accessory magnification.
Thin Area	A "weak point" on the surface of the capsule which may result in leaking from the capsule.
Uniformity	Self explanatory: of shape or size