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Standard Specification for Identification and Configuration of Prefilled Syringes and Delivery Systems for Drugs (Excluding Pharmacy Bulk Packages)[1]

This standard is issued under the fixed designation D4775/D4775M; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers the identification of:

1.1.1 The drug contained in the prefilled syringe or delivery system.

1.1.2 The concentration, volume, and total amount of the drug, and whether it is to be diluted prior to administration.

1.2 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

NOTE 1—The values in SI units are the recommended values.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D996 Terminology of Packaging and Distribution Environments

D4267 Specification for Labels for Small-Volume (100 mL or Less) Parenteral Drug Containers

D7298 Test Method for Measurement of Comparative Legibility by Means of Polarizing Filter Instrumentation

3. Terminology

3.1 General definitions for packaging and distribution environments are found in Terminology D996.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *delivery system—as used in this specification*, a closed system consisting of a container of concentrated solution or powder which facilitates the transfer of the contents into a diluent prior to administration or use.

3.2.2 *pharmacy bulk package*—drug supplied in a stock container to be held in the pharmacy and used for multiple dispensing.

3.2.3 *syringe*—an instrument by means of which drugs in solution or other liquids are injected into or withdrawn from any vessel or cavity.

4. Significance and Use

4.1 Difficulties have occurred in the correct identification of syringes containing significantly different medications once they have been removed from their cartons. The objective of this specification is to facilitate identification of the drug, its concentration, volume, and total amount.

4.2 Difficulties have also occurred in distinguishing between syringes containing drugs ready for intravenous injection and similar syringes containing solutions which must be diluted before use. An objective of this specification is to minimize the chance for such errors.

5. Label Requirements

5.1 Label copy shall comply with Specification D4267 and shall include the information required by regulation and by the manufacturer. In addition, the requirements of the following sections shall apply.

5.2 In syringes of the type shown in Fig. 1, 10-point or larger type is preferred for the drug name and the amount of drug per millilitre, or total amount as appropriate. This type shall satisfy the test for legibility in 7.1, but at a distance of 500 mm [19.7 in.]. This information shall be legible with minimal rotation of the immediate drug container.

5.3 In syringes of the type in Fig. 2, where the immediate drug container is fitted into the syringe barrel, the drug name, concentration, and total volume shall appear as close to the extreme right hand end of the drug container—that is, the opposite end to the needle—as possible, in bold type, in height at least equal to one ninth of the external circumference of the container up to a maximum of 10 mm.

[1] This specification is under the jurisdiction of ASTM Committee D10 on Packaging and is the direct responsibility of Subcommittee D10.32 on Consumer, Pharmaceutical, Medical, and Child Resistant Packaging.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

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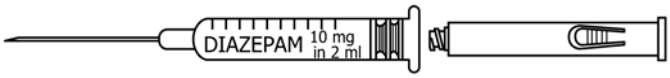

FIG. 1 Label on Syringe Type Shown

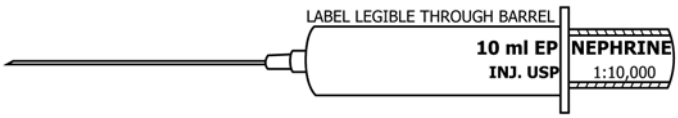

FIG. 2 Label on Syringe Type Shown

5.3.1 The opaque background of these two lines of text shall not exceed one third of the circumference of the container. There shall be good contrast between the type used for the drug name, concentration, and total volume, and either the drug container or an added opaque label background sufficient to conform with Section 7. The name of the drug on the container shall be legible through the barrel during preparation and use sufficient to conform with Section 7.

5.4 Distinctive labels or other means of distinguishing syringes and containers filled with medications which can only be given safely by specific routes (such as anti-cancer drugs) shall be employed.

5.5 Syringes and containers of medications intended only for regional anesthesia shall be clearly marked as such.

6. Delivery Systems

6.1 Delivery systems, for drugs which must be diluted before administration, shall not resemble a normal syringe and shall be unsuitable for direct intravenous line injection (see Fig. 3). Such drugs shall preferably be supplied as a powder in a delivery system designed to facilitate the addition of the powder to the container of parenteral solution. If supplied as a concentrated solution, the immediate container shall not allow the use of a standard syringe to transfer the concentrated solution to a container of parenteral solution.

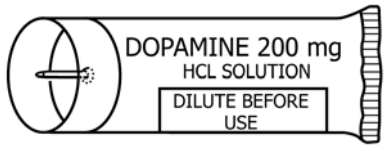

FIG. 3 Label on Delivery System with Spike

6.2 The drug container shall be labelled "Dilute Before Use" or other appropriate warning, in at least 10-point bold type in dark ink, whenever space permits, preferably within a red fluorescent box, such as Pantone 805 (see Fig. 3).

6.3 When copy space is not sufficient for 10-point type size, the warning shall be at least equal in size to the name and strength designations of the drug. In addition to the label on the container, "Dilute Before Use" or other appropriate warning shall be prominently displayed on the box and in accompanying instructions.

7. Legibility Test

7.1 Copy legibility of the proprietary name or established name of the drug and the amount of drug per unit and total volume shall be evaluated using the preferred method for determining legibility as specified by Test Method D7298.

7.2 The alternative test for copy legibility of the proprietary name or established name of the drug and the amount of drug per unit and total volume may be determined using the Legibility Test outlined in Specification D4267 whereby the copy for the proprietary name or established name of the drug and the amount of drug per unit and total volume shall be legible in a light of 215 lx [20 fc] at a distance of 155 cm [5 ft] (see 5.3) by a person with 20:20 unaided or corrected vision.

8. Keywords

8.1 delivery systems; label requirements; legibility; prefilled syringes

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