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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 D 4775/D 4775M; 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]

D 996 Terminology of Packaging and Distribution Environments

D 4267 ~~Specification for Labels for Small-Volume (Less than 100 mL) Parenteral Drug Containers~~ Specification for Labels for Small-Volume (100 mL or Less) Parenteral Drug Containers

D 7298 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 D 996.

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3.2.3 *syringe*—an instrument by means of which drugs in solution or other liquids are injected into or withdrawn from any vessel or cavity.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 D 4267 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

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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.