Designation: D 4775 – 94 (Reapproved 1999)

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; 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.

2. Referenced Documents

2.1 *ASTM Standards:*

D 996 Terminology of Packaging and Distribution Environments[2]

D 4267 Specification for Labels for Small-Volume (Less than 100 mL) Parenteral Drug Containers[2]

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3.2.3 *syringe*—an instrument by means of which drugs in solution or other liquids are injected into or withdrawn from any vessel or cavity.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

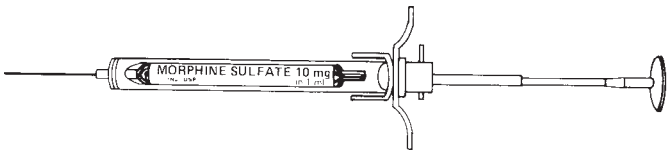

FIG. 1 Label on TUBEX Type Syringe
("TUBEX" is a registered trademark of Wyeth Laboratories.)

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 and Fig. 2, 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. 3, 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.*

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

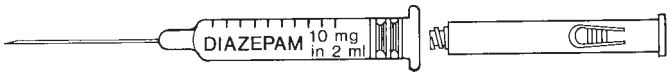

FIG. 2 Label on Tel-E-Ject Type Syringe
("Tel-E-Ject" is a registered trademark of Roche Products-Hoffman-La Roche, Inc.)

[1] This specification is under the jurisdiction of ASTM Committee D-10 on Packaging and is the direct responsibility of Subcommittee D10.32 on Consumer Packages.

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[2] *Annual Book of ASTM Standards*, Vol 15.09.