Designation: D 4267 – 95

Standard Specification for Labels for Small-Volume (100 mL or Less) Parenteral Drug Containers[1]

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1. Scope

1.1 This specification covers the orientation, the size of type used, and the contrast of the copy with the label background on immediate drug containers having a volume of 100 mL or less.

1.2 The values stated in SI units are to be regarded as the standard. The values given in parentheses are for information only.

2. Terminology

2.1 *Definitions:*

2.1.1 *established name*—the designated name or official name (commonly referred to as *generic* name).

2.1.2 *immediate container*—that which is in direct contact with the article at all times.[2]

2.1.3 *label*—a display of written, printed, or graphic matter upon the immediate container of any article.[3]

2.1.4 *labeling*—all labels and other written, printed, or graphic matter (*1*) upon any article or any of its containers or wrappers, or (*2*) accompanying such article[4]

2.1.5 *proprietary name*—manufacturer's trade or brand name.

3. Label Requirements

3.1 *Contents of Label*—The label shall consist of the following:

3.1.1 Proprietary name of drug (optional).

3.1.2 Established name of drug (required). Printing the active moiety of the established name in accordance with 5.1 shall suffice, example, GENTAMICIN Sulfate Inj).

3.1.3 Amount of drug per unit (for example, milligrams per millilitre (mg per mL) or quantity of drug per container as appropriate).

3.1.4 For liquids, the total volume of the contents shall be marked in a legible manner.

3.1.5 Other information as required by regulation and the manufacturer.

3.2 *General*—Manufacturers are encouraged to use acceptable abbreviations (for example, *HCl* for *hydrochloride*) and minimize the use or size of other copy (for example, *brand of*, *USP* solution, injection) or unrequired punctuation (such as *mg.* versus *mg*) where label space is critical.

4. Significance and Use

4.1 Medication errors by users sometimes occur due to difficulty in reading or understanding drug container labels. The objective of this specification is to facilitate correct drug product identification. *It does not absolve the user from the duty to read the label and correctly identify the drug product prior to use.*

5. Type Size Requirements

5.1 The type size of the print used for the proprietary name or established name of the drug and the numerals indicating the amount of drug per unit shall be as large as possible.

5.1.1 On containers larger than 2 mL, the vertical height of capitals and numerals used for these items should be at least 2.5-mm (10-point or larger) type.

5.1.2 On containers of 2 mL or less, the vertical height of capitals and numerals for these items should be at least 1.5-mm (6-point or larger) type.

5.2 *Legibility*—In all cases the type used for these items shall be bold enough to satisfy the legibility test (see 8.1).

6. Orientation Requirements

6.1 The copy required for proprietary name, or established name of drug, and amount of drug per unit (3.1.1, 3.1.2, and 3.1.3) shall be printed parallel to the long axis of the container. The left-hand margin of the copy shall start from the base end of the container so that it can be read while the top is held in the right hand (see Fig. 1). In prefilled syringes, the copy shall start flush with, and read from, the needle end (see Fig. 2).

6.2 Alternatively, if the proprietary name and established name of drug, and amount of drug per unit (3.1.1, 3.1.2, and 3.1.3) can be printed within 180° around the circumference of the container, the copy may be printed at right angles (perpendicular) to the long axis of the container (see Fig. 3).

[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] *United States Pharmacopeia*, U.S. Pharmaceutical Convention, Inc. (USPC), Order Processing Dept., 12601 Twinbrook Parkway, Rockville, MD, 20852, USP 23/NF 18, 1995, p. 10.

[3] Federal Food, Drug, and Cosmetic Act, Section 201(k); and USP 23/NF 18, 1995, p. 11. Available from U.S. Government Printing Office, Washington, DC 20402.

[4] Federal Food, Drug, and Cosmetic Act, Section 201(m); and USP 23/NF 18, 1995, p. 11.