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Standard Specification for User Applied Drug Labels in Anesthesiology[1]

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1. Scope

1.1 This specification covers the size, color and pattern, and type used on labels applied to unlabeled syringes filled by the users or their agents to identify the drug content. This specification is not intended to cover labels applied by the drug manufacturer.

2. Referenced Documents

2.1 *ASTM Standards:*

D 996 Terminology of Packaging and Distribution Environments[2]

2.2 *Other Standard:*

Pantone Matching System[3]

3. Terminology

3.1 *Definitions*—General definitions for packaging and distribution environments are found in Terminology D 996.

4. Size and Background Color Requirements

4.1 *Label Size*—The labels shall have a nominal length of 25 to 35 mm and a width of 10 to 13 mm.

4.2 *Label Background Color*—The colors and patterns given in Table 1 shall be used to distinguish these groups of drugs. The background color shall not interfere with the ability of the user to write information on the label.

4.2.1 *Antagonists*— To denote an antagonist, 1-mm wide diagonal stripes of the agonist color alternating with a 1-mm wide white stripe shall be used. The stripes shall run from the lower left to the upper right at an angle of approximately 45° to the long axis of the label. The name of an antagonist drug shall appear in the center of the label and the striping shall be omitted behind and below the name (see Fig. 1).

5. Significance and Use

5.1 The objective of this specification is to facilitate identification of drugs in syringes filled by the user. The use of colors is intended only as an aid in identification of drug groups and does not absolve the user from the duty to read the label to correctly identify the drug prior to use.

5.2 The user may alternatively use black and white labels rather than these colored labels. However if colors are used, the range of colors specified in this specification shall be utilized to avoid confusion.

6. Type and Color Requirements

6.1 The type should be as large as possible (minimum 10-point) using bold type. Upper and lower case letters are preferred for better legibility. All printing shall be in black with the exception of "SUCCINYLCHOLINE'' and "EPINEPHRINE'' which shall be printed against the background color as bold reverse plate letters within a black bar running from edge to edge on the upper half of the label, the rest of which shall display the colored background (see Fig. 2).

6.1.1 The established (generic) name of the drug shall be used. The use of the proprietary (trade) name of the drug is optional. The initial syllable, or initial two syllables, of the drug name may be emphasized by being printed in a bold upper case type a minimum of 2 points larger than the remainder of the drug name, which is typed in lower case (see Fig. 3).

6.1.2 Except for antagonists, the name of the drug should be printed on the upper half of the label to leave space below for entry of the dosage. In the bottom righthand corner either "mg/mL", "meg/mL" or "mcg/mL", as appropriate (except for drug mixtures such as fentanyl/droperidol) shall be printed (see Fig. 2 and Fig. 4).

6.1.3 For barbiturate induction agents the concentration of the solution (as "%'' or "mg/mL'') and the date of preparation should appear on the label, as shown in Fig. 5 and Fig. 6.

6.1.4 For antagonists the name of the drug should be printed along the center line of the label to permit a sufficient width of diagonal stripes to appear above the name for easy recognition (see Fig. 1).

7. Keywords

7.1 anesthesiology; drug labels; label requirements; prefilled syringes

[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.

[3] Available from Pantone, Inc., 55 Knickerbocker Rd., Moonachie, NJ 07074.