



Designation: ~~D6398-01~~^{ε1} Designation: D 6398 – 08

Standard Practice to Enhance Identification of Drug Names on Labels¹

This standard is issued under the fixed designation D 6398; 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.

~~ε¹Note—Figure 1 was corrected editorially in August 2001.~~

1. Scope

1.1 This practice covers the shape, size, color, layout, typeface, and barcoding on drug container labels intended for prescription product packaging such as might be used in hospitals, pharmacies, and nursing centers.

1.1.1 This practice does not apply to bulk product shipping containers; in-process transfer containers; or primary, secondary, or tertiary finished goods containers.

1.2 This practice does not apply to over-the-counter drug product labeling.

1.3 This practice does not apply to retail product labeling.

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

2. Referenced Documents

2.1 ASTM Standards:²

D 996 Terminology of Packaging and Distribution Environments

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

~~D 4774 Specification for User Applied Drug Labels in Anesthesiology~~ Specification for User Applied Drug Labels in Anesthesiology

D 7298 Test Method for Measurement of Comparative Legibility by Means of Polarizing Filter Instrumentation

2.2 Other Documents:

21 CFR 429.12 Packaging and Labeling of Insulin³

21 CFR 201.66 Format and Content Requirements for Over-the-Counter (OTC) Drug Product Labeling³

ISO 3864 Safety Colors and Safety Signs⁴

3. Terminology

3.1 General definitions for packaging and distribution environments are in accordance with Terminology D 996.

3.2 *Definitions of Terms Specific to This Standard:* ~~https://standards.iteh.ai/756a1d5c-7954-458e-9749-9f220e7fe16e/astm-d6398-08~~

3.2.1 *shape of label*—shape of the label wherein is written the name of the drug, the dosage, and the total contents of the drug in its final form.

4. Significance and Use

4.1 Medication errors occur when users are confused by the similar size, shape, color, typeface, and layout of labels that are used for a range of a manufacturer's drugs with widely dissimilar actions or potencies. The human visual system uses shape, size, color, and typeface in the initial recognition of a labeled drug. (See 9.1-9.3.) The use of this human visual system has been described in 21 CFR 429.12 for the labeling of insulin. Using the similar label design, color, and typeface throughout a product line makes identifying an individual drug more difficult.

~~4.2 The objective of this practice is to provide guidance for the design of drug labels which will enable users to easily distinguish between drugs of differing action or potency.~~

¹ This practice is under the jurisdiction of ASTM Committee D10 on Packaging and is the direct responsibility of Subcommittee D10.32 on Consumer, Pharmaceutical and Medical Packaging.

~~Current edition approved April 10, 2001. Published June 2001.~~

Current edition approved Feb. 1, 2008. Published March 2008. Originally approved in 2001. Last previous edition approved in 2001 as D 6398 – 01^{ε1}.

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.

³ Available from Standardization Documents Order Desk, DODSSP, Bldg. 4, Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS:19111-5098, <http://www.dodssp.daps.mil>.

⁴ Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

⁴ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

4.2 The objective of this practice is to provide guidance for the design of drug labels which will enable users to easily distinguish between drugs of differing action or potency. See Note 1.

NOTE 1—For specific requirements for these labels and other features of labels for OTC human drugs, see 21 CFR 201.66.

5. Label Requirements—Panel Shape, Color, and Contrast

5.1 Differing combinations of label shape and color, with differing layouts and text face should be used to provide a readily recognizable combination for each group of drugs with different actions or potency within a manufacturer’s range of products. (See Fig. 1.)

5.2 High contrast between the margin of the label and its surroundings and between the drug name and background should be provided.

6. Color

6.1 If applicable, manufacturers should use the colors specified for the specific drug groups in accordance with Specification D 4774 or refer to ISO 3864 for guidance concerning safety colors.

6.2 Pastel colors should not be used for the identification of drugs, since approximately 8 % of the male population have congenital X-linked “color blindness” which diminishes their ability to distinguish between pastel shades of red, green, and beige (see 9.4).

6.3 Color contrasts with bright saturated colors contrasting with the text and the background should be used.

6.3.1 Suggested color contrasts are as follows:

Text	Background
Text	Background
Black	White
Blue	Yellow
White	Blue
Blue	White

7. Copy Legibility

7. Label copy shall be in accordance with Section 8 of Specification D4267

7.1 Label copy shall be measured in accordance with Test Method D 7298.

7.1.1 If the instrumentation called for in Test Method D 7298 is unavailable, copy legibility shall be measured in a light of 215 lx (lux) 20 fc (foot candles) at a distance of 500 mm (19.7 in.) by a person with 20/30 unaided or corrected vision. A contrasting background may be used.

7.2 *Recognition of the drug name* Recognition of the Drug Name :

7.2.1 Upper and lower case lettering for the drug name should be used.

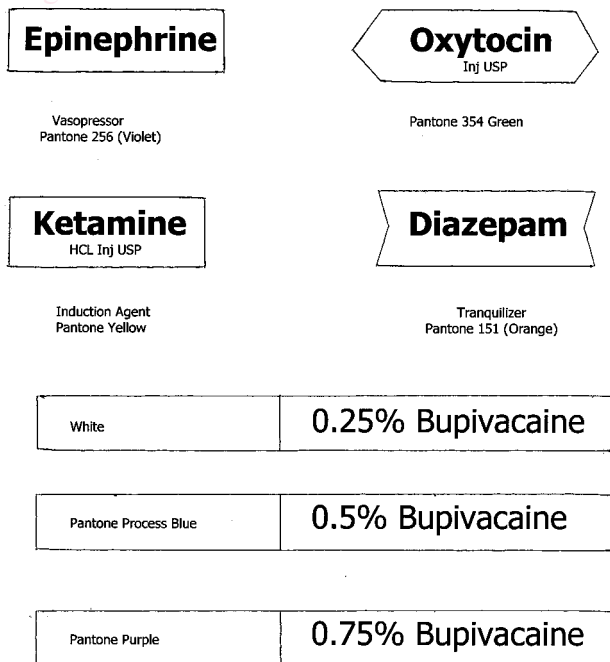


FIG. 1 Labels to Distinguish Three Different Concentrations of a Local Anesthetic