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Standard Practice to Enhance Identification of Drug Names on Labels[1]

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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 standard. The values given in parentheses are for information only.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D996 Terminology of Packaging and Distribution Environments

D4267 Specification for Labels for Small-Volume (100 mL or Less) Parenteral Drug Containers

D4774 Specification for User Applied Drug Labels in Anesthesiology

D7298 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 Insulin[3]

21 CFR 201.66 Format and Content Requirements for Over-the-Counter (OTC) Drug Product Labeling[3]

ISO 3864 Safety Colors and Safety Signs[4]

3. Terminology

3.1 General definitions for packaging and distribution environments are in accordance with Terminology D996.

3.2 *Definitions of Terms Specific to This Standard:*

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. 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.

[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, Medical, and Child Resistant Packaging.

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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.

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

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

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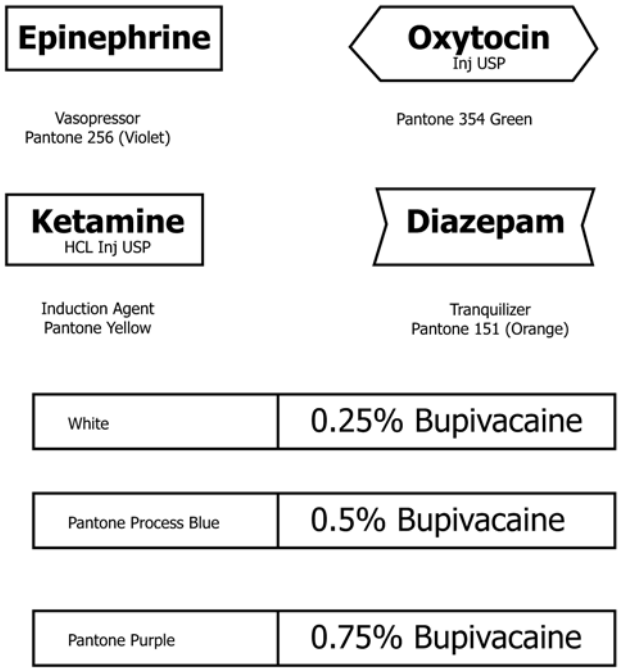

FIG. 1 Labels to Distinguish Three Different Concentrations of a Local Anesthetic

6. Color

6.1 If applicable, manufacturers should use the colors specified for the specific drug groups in accordance with Specification D4774 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
Black	White
Blue	Yellow
White	Blue
Blue	White

7. Copy Legibility

7.1 Label copy shall be measured in accordance with Test Method D7298.

7.1.1 If the instrumentation called for in Test Method D7298 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:*

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

7.2.2 The initial capital letter of the drug name may be given added emphasis in bold type.

7.2.3 To facilitate legibility, extra space should be provided around the drug name to separate the name from the rest of the label copy.

7.3 Where different strengths of the same compound are available, the concentration per unit should be prominently marked in large figures (see 21 CFR 201.66 for examples).

7.4 Where groups of drugs have names with similar endings that may cause confusion, the initial syllable of the name may be printed in 2 or 4-point larger-sized capital letters (see Fig. 2).

8. Barcoding

8.1 Critical information, for example, name of drug, dosage, concentration per unit, or total contents shall be encoded in an appropriate location on each item of labeling.

8.2 Adequate space may be needed to allow for the addition of a bar code by the pharmacist or user.

8.3 Human readable characters shall be printed above, below, or adjacent to the barcoding to allow for confirming inspections.

Pancuronium	PANcuronium
Vecuronium	VECuronium
Pipecuronium	PIPEcuronium
Atracurium	ATRAcurium
Doxacurium	DOXAcurium
Mivacurium	MIVAcurium

FIG. 2 Labels to Show Initial Syllable of Name in Larger Capital Letters

9. Rationale

9.1 Experiments in accordance with Professor A. Treisman and colleagues, Department of Psychology, UC Berkeley (**1, 2**)[5] showed that the visual processing towards identification of an object passes throughout several phases. Initially, the entire visual field is taken in simultaneously, and than an object is separated from its surroundings for subsequent detailed examination. The ease with which key information is separated, and therefore quickly identified, depends in part upon contrast in color and brightness. Also, the contrast between the outline shape of the boundary of the object and its surroundings is important. Thus, a curved outline stands out from regularly striped surroundings or an outline at a 45° diagonal will similarly stand out from vertical or horizontal stripes. These features will help an object to "snap out" from its surroundings, greatly facilitating and speeding up the process of identification.

9.2 Attneave (**3**) found that people do better in identification when different colors are combined with different shapes. Therefore, a red square, green triangle, or blue circle would be easier to identify than red, blue, green, purple, orange, or black squares or red squares, triangles, circles, stars, ellipses, and rectangles.

9.3 Kosslyn (**4**) has pointed out that mental imagery may occur in which the brain recalls an image, without sensory input, so that the subject "sees with the mind's eye." This may be responsible for the "expectancy effect" in which the brain records the object that it anticipates it will see rather than the actual object visible.

9.4 Chang (**5**) states that the most common abnormality of color vision is X-linked red-green "color blindness" which is present in approximately 8 % of males and is due to an X-linked congenital deficiency of one specific retinal photoreceptor. For more detail, consult Ref (**6**).

10. Keywords

10.1 color contrasts; labeling; labels; legibility

[5] The boldface numbers in parentheses refer to a list of references at the end of this standard.

REFERENCES

(1) Treisman, A., "Feature and Objects in Visual Processing," *Scientific American*, November 1986, pp. 114–125.
(2) Treisman, A., "Features and Objects," *Quarterly Journal of Experimental Psychology*, Vol 2, No. 40A, 1988, pp. 201–237.
(3) Attneave, F., *Applications of Information Theory to Psychology*, Hold, Rinehart, and Winston, New York, NY, 1959.
(4) Kosslyn, S. M., "Aspects of a Cognitive Neuroscience of Mental Imagery," *Science* , Vol 240, 1988, pp. 1621–1626.
(5) Chang, D. F., "Ophthalmologic Examination," in *General Ophthalmology*, 12th ed., edited by D. Vaughan, T. Asbury, and K. F. Tabbara, Appleton & Lange, Norwalk, CT, 1989, p. 40.
(6) "Genes and Pigments in Color Defective Vision," in *The Perception of Color: Vision and Visual Dysfunction* , edited by P. Gouras, CRC Press, Boston, MA, 1991, p. 98.

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