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PHARMACEUTICAL INDUSTRY STANDARD
OF THE PEOPLE'S REPUBLIC OF CHINA

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YY/T 0296-2013 / ISO 6009:1992

Replacing YY/T 0296-1997

**Hypodermic needles for single
use - Color coding for identification**

一次性使用注射针 识别色标

(ISO 6009:1992, IDT)

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Foreword

This Standard is drafted in accordance with the rules given in GB/T 1.1-2009.

This Standard replaces YY/T 0296-1997 "Hypodermic needles for single use - Color coding for identification". Main technical differences between this Standard and YY/T 0296-1997 are as follows:

- MODIFY the contact information of the organization that provides reference color samples;
- MAKE editorial modifications to the standard text.

This Standard is identical to ISO 6009:1992 "Hypodermic needles for single use - Color coding for identification" and its amendment 1:2008.

This Standard has been made editorial modifications to the format of the text of ISO 6009:1992, and modified the contact information of the organization that provides reference color samples.

Attention is drawn to the possibility that some of the elements of this Standard may be the subject of patent rights. Issuing organizations of this Standard shall not be held responsible for identifying any or all such patent rights.

This Standard is proposed by State Food and Drug Administration.

This Standard is under the jurisdiction of National Technical Committee on Medical Hypodermic Syringes (Needles) of Standardization Administration of China (SAC/TC 95).

Drafting organization of this Standard: Shanghai Medical Devices Testing Institute.

Main drafter of this Standard: Hua Songhe.

This Standard was first published in 1997.

Introduction

The intention of this Standard is to specify colors to enable rapid visual identification of the outside diameter of single-use hypodermic needles (hereinafter referred to as hypodermic needles). The presence of color coding on a needle or package does not absolve the user of the responsibility to check the marked size of the needle.

The colors used to code needles may be applied in either opaque or transparent form, and the color code is equally applicable to normal-walled, thin-walled and extra-thin-walled needles. The nominal outside diameters of needles listed in this Standard for which colors are given are those specified in GB 15811. This does not imply that hypodermic needles of all the listed nominal outside diameters are currently manufactured.

This Standard establishes a color code but does not specify that needles are to be color-coded or to what portion of the needle and/or packaging the color is to be applied. Such requirements may be given in the relevant product standards such as GB 18457.

The Technical Committee responsible for the preparation of this Standard has reviewed the use of instrumentally determined color zones (chromaticity and luminance index) as used in previous editions to specify opaque colors, and has decided that instrumental measurement is not practicable. The measurement of the color zone of an opaque color, especially of an item of the size and shape of the hub of a needle, is a complex procedure requiring apparatus and expertise that is to be found in relatively few laboratories and test houses. It may therefore be inconvenient, difficult or impossible for a manufacturer or purchaser routinely to assess compliance of a product with color zone values. Such difficulties are compounded in the case of translucent colors, which are being used increasingly by needle manufacturers to allow air bubbles inside the hub to be seen and eliminated before injection.

As a consequence, the colors in this Standard are specified by name, accepting that this inevitably introduces a certain amount of subjectivity in the assessment of compliance. This subjectivity may be minimized by viewing the hubs under controlled lighting conditions (e.g. "daylight" (D65) illumination at 1 000 lx to 1 500 lx) and by the use of assessors of medically-demonstrated correct color vision. Visual comparison of the color of a product with a reference color sample is simple and quick, and is therefore a useful routine method of product assessment. Accordingly, reference color samples have been made available. These take the form of sets of needle hubs of colors complying with this Standard. Details are given in annex B and it should be noted that only those diameters of needle currently having colored hubs are included (i.e. 0.3 mm to 1.2 mm nominal outside diameter). It is expected that the range of diameters included in the reference color samples will be extended in due course.

Annex A
(informative)
Reference color samples

The reference color samples referred to in this Standard are available by contacting:

Melab

Medizintechnik und Labor GmbH

Mollenbachstrasse 19

712299 Leonberg

Germany

info@melab.de

This information is given for the convenience of the users of this Standard and does not constitute an endorsement of the reference color samples.

Bibliography

- [1] ISO 7864:1988, *Sterile hypodermic needles for single use.*
- [2] ISO 9628:1991, *Stainless steel needle tubing for the manufacture of medical devices.*
- [3] CIE Publication No. 15.2:1986, *Colorimetry.*
- [4] Munsell Book of Color.
- [5] USA Federal Standard 595a, *Colors-Vol.1.*
- [6] German Standard RAL 840, *HR Farbbregister (Color register).*
- [7] French Standard NFX 08-002, *Collection reduite des couleurs - Designation et catalogue des couleurs CCR - Etaions secondaires (Limited collection of colors - Designation and catalogue of CCR colors - Secondary Standards).*

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