Designation: D 5022 – 95

Standard Specification for Identification of Vials and Ampoules Containing Concentrated Solutions of Drugs to be Diluted Before Use[1]

This standard is issued under the fixed designation D 5022; 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.

1. Scope

1.1 This specification deals with identification of small volume containers of drugs intended to be diluted before parenteral administration, as follows:

1.1.1 Container shape,

1.1.2 Labeling statements.

1.1.3 Vial closures and Flip-Off,[2] type caps, and

1.1.4 Ampoule marking.

2. Referenced Documents

2.1 *ASTM Standards:*

D 996 Terminology of Packaging and Distribution Environments[3]

D 4267 Specification for Labels for Small Volume (Less than 100 mL) Parenteral Drug Containers[3]

D 4775 Specification for Identification and Configuration of Prefilled Syringes and Delivery Systems for Drugs (Excluding Pharmacy Bulk Packages)[3]

2.2 *Other Standards:*

Pantone Matching Systems Current Edition[4]

3. Terminology

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

3.2 *ampoule*—a hermetically sealed, small bulbous glass or plastic vessel; opening is achieved by breaking the stem (also ampule or ampul).

3.3 *vial*—a small, usually cylindrical, vessel capable of closure, such as for medications, perfumes, essences, and samples.

3.4 *Description of Term Specific to This Standard:*

3.4.1 *Flip-Off type cap*—a plastic cap which must be removed to expose the injection port in the elastomeric and metal vial closure.

4. Requirements

4.1 Drugs in liquid form requiring dilution before parenteral administration shall not be packaged in containers that resemble a normal syringe. The design of such containers shall preclude direct intravenous line injection of the solution.

4.2 The labels on such containers (for example, vials and ampoules) shall bear the words “Dilute Before Use”, or similar warning, in type with initial capitals at least 2.5 mm in vertical height (10 point or larger) in bold font in contrasting ink, whenever space permits, preferably with a box printed in red (such as Pantone 805 or Warm Red). When copy space is not sufficient for 10 point type, the warning shall be at least equal in size to the name and strength designation of the drug.

4.3 Additional requirements specific for Potassium Chloride for Injection Concentrate as Mandated by the *United States Pharmacopeia*,[5] are as follows:

4.3.1 Immediately following the name, the label for Potassium Chloride for Injection Concentrate shall bear the boxed warning as shown in Fig. 1.

4.3.2 Vials containing potassium Chloride for Injection Concentrate shall be provided with a black metal closure (overseal) with a black cap. Both shall bear the words “Must be diluted” in legible type, in a color that stands out from its background (see Fig. 2).

4.3.3 Ampoules containing Potassium Chloride for Injection Concentrate shall be identified by a black band or series of black bands above the constriction (see Fig. 3).

4.3.4 Such black metal closures and black Flip-Off type caps and use of a black band or series of bands above the constricture on an ampul shall only be used for Potassium Chloride for Injection Concentrate.

5. Significance and Use

5.1 Accidents continue to occur due to the user’s inability to easily identify vials and ampoules containing concentrated solutions of drugs which must be diluted before parenteral administration. The objective of this specification is to facilitate easy identification of such vials and ampoules.

6. Legibility Test

6.1 The copy for the proprietary name or established name

[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] “Flip-Off” is a registered trademark of the West Company.

[3] *Annual Book of ASTM Standards*, Vol 15.09.

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

[5] USP 23/NF18 1995, pp. 1254, 1651, Available from USPC, Inc, Order Processing Dept., 12601 Twinbrook Parkway, Rockville, MD 20852.