



Designation: D5022 – 07

Standard Specification for Identification of Vials and Ampoules Containing Concentrated Solutions of Drugs to be Diluted Before Use¹

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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*:³

D996 Terminology of Packaging and Distribution Environments

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

D4775 Specification for Identification and Configuration of Prefilled Syringes and Delivery Systems for Drugs (Excluding Pharmacy Bulk Packages)

D7298 Test Method for Measurement of Comparative Legibility by Means of Polarizing Filter Instrumentation

2.2 *Other Standards*:

Pantone Matching Systems Current Edition⁴

3. Terminology

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

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

¹ This specification 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 “Flip-Off” is a registered trademark of the West Pharmaceutical Services, 101 Gordon Dr., Lionville, PA 19341.

³ 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.

⁴ Available from Pantone Inc., World Headquarters, 590 Commerce Blvd., Carlstadt, NJ 07072–3098.

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

3.4 *Description of Terms 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 constriction on an ampul shall only be used for Potassium Chloride for Injection Concentrate.

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