

**Table 2-2** United States Pharmacopeia General Chapter <1> Recommended Excess Volume in Containers Containing Injectable Solutions

Label size	Recommended Excess Volume	
	For mobile liquids	For viscous liquids
0.5 mL	0.10 mL	0.12 mL
1.0 mL	0.10 mL	0.15 mL
2.0 mL	0.15 mL	0.25 mL
5.0 mL	0.30 mL	0.50 mL
10.0 mL	0.50 mL	0.70 mL
20.0 mL	0.60 mL	0.90 mL
30.0 mL	0.80 mL	1.20 mL
50.0 mL or more	2%	3%

or a black band at the neck of a glass ampul can only be used for potassium chloride for injection concentrate containers. All injectable preparations of neuromuscular blocking agents and paralyzing agents must be packaged in vials with a cautionary statement printed on the ferrules or cap overseals that warn what product is in the containers.

#### *Containers for Sterile Solids*

Containers and closures for sterile dry solids also must not interact physically or chemically with the product. Such containers will permit the addition of a suitable solvent and withdrawal of parts of the resulting solution of suspension without compromising the sterility of the product.

#### *Volume in Container*

Each container of an injection must be filled with sufficient excess to allow the labeled amount of volume of product to be withdrawn from the container. General chapter <1151 Pharmaceutical Dosage Forms> is referenced where under "Injections" in that chapter, there is a table that provide the recommended excess volume for injectables labels of various volume sizes to be withdrawn (Table 2-2).

#### *Determination of Volume of Injection in Containers*

This section of the USP contains a procedure of how to determine product volume in a container.

1. The labeled volume of the container will determine how many containers are to be used in the test. If the container volume is  $\geq 10$  mL, three or more containers are used. If the container volume is  $\leq 3$  mL, five or more containers are used.
2. Individually take up the contents of each container into a dry hypodermic syringe of a rated capacity not exceeding three times the volume to be measured and fitted with a 21-gauge needle not less than 2.5 cm (one inch) in length.
3. Expel any air bubbles from the syringe and needle and then discharge the contents of the syringe, without emptying the needle, into a standardized, dry cylinder (graduated to contain rather than to deliver the designated volumes) of such size that the volume to be measured occupies at least 40% of the cylinder's rated volume.
  - a. Alternatively, the contents of the syringe may be discharged into a dry, tared beaker, the volume, in mL, being calculated as the weight, in grams, of injection taken divided by its density.
4. The contents of up to five 1- or 2-mL containers may be pooled for the measurement using a separate dry syringe for each container.
5. The content of containers holding 10 mL or more may be determined by opening them and emptying the contents directly into the graduated cylinder or tared beaker.
6. The volume is not less than the labeled volume in the case of containers examined individually or, in the case of the 1- and 2-mL containers, is not less than the sum of the labeled volumes of the containers taken collectively.