



Figure 7-4 Example of tubing (left two) and molded (right two) glass vials. *Source:* Photo courtesy of Dr. Gregory Sacha, Baxter BioPharma Solutions.

Other important glass physical properties include chemical durability (as determined by compendial alkalinity tests), thermal expansion, color, and density. Glass color is produced using different metal oxides. Amber colored glass is created using ferric oxide and is the most frequently used colored glass for parenteral products. Glass density depends somewhat on type of glass, but the range of density is 2.44 to 2.50 g/cc.

Commercially available containers vary in size from 0.5 to 1000 mL. Sizes up to 100 mL may be obtained as ampoules and vials, and larger sizes as bottles. The latter are used mostly for intravenous and irrigating solutions. Smaller sizes also are available as syringes and cartridges. Ampoules, syringes, and cartridges are formed from glass tubing. The smaller vials may be made by molding or from tubing. Larger vials and bottles are made only by molding. Containers produced from glass tubing are generally optically clearer and have a thinner wall than molded containers (Fig. 7-4). Compared with molded glass, tubing glass also has better wall and finish dimensional consistency, no seams, easier to label, weighs less, facilitates inspection, and has lower tooling costs. Tubing glass is preferable to molded glass for freeze-dried products because of more efficient heat transfer from the shelf into the product. Molded containers can be more uniform in external dimensions, stronger, and heavier.

Glass containers must be sufficiently strong to withstand the physical shocks of handling and shipping and the pressure differentials that develop, particularly during the autoclave sterilization cycle. They must be able to withstand the thermal shock resulting from large temperature changes during processing, for example, when the hot bottle and contents are exposed to room air at the end of the sterilization cycle. Therefore, a glass with a low coefficient of thermal expansion is necessary. The container also must be transparent to permit inspection of the contents.

Preparations that are light sensitive must be protected by placing them in amber glass containers or by enclosing flint glass containers in opaque cartons labeled to remain on the container during the period of use. It should be noted that the amber color of the glass is imparted by the incorporation of potentially leachable heavy metals, mostly iron and manganese, which may act as catalysts for oxidative degradation reactions. Silicone coatings, typically silicone emulsions, are sometimes applied ("baked") to the inner surfaces of vials to produce a hydrophobic surface. One example for using the application is to facilitate the drainage of injectable suspension products.

The size of single-dose containers is limited to 1000 mL by the USP and multiple-dose containers to 30 mL (23) unless stated otherwise in a particular monograph. Multiple-dose vials are limited in size to reduce the number of punctures for withdrawing doses and the accompanying risk of contamination of the contents. As the name implies, single-dose containers are opened or penetrated with aseptic care, and the contents used at one time. These may range in size from 1000-mL bottles to 1-mL or less ampoules, vials, or syringes. The integrity of