



Figure 4-3 Plastic Vials—Daikyo Crystal Zenith Cyclic Polyolefin (Daikyo Crystal Zenith® is a registered trademark of Daikyo Seiko, Ltd). *Source:* © 2010 by West Pharmaceutical Services.

some time before being commonplace in the injectable market. Plastic vials are made of cyclic olefin polymer (COP) or cyclic olefin copolymer (COC). The appearance of a plastic vial looks identical to a glass vial (Fig. 4-3).

The main reason why plastic vials have not become as commonplace as glass vials is associated with the ease of introducing the container into a classified (ISO 5) aseptic environment. Glass vials are sterilized and depyrogenated in dry heat tunnels that convey the vials directly into the aseptic environment without the need for manual transfer. Plastic vials are presterilized (typically irradiation) at the vial manufacturer and the finished product manufacturer needs to figure out how to aseptically transfer plastic vials into the aseptic environment. This is not an easy solution, especially compared to the convenient way glass vials are introduced via the dry heat tunnels.

Two other potential disadvantages of plastic vials are: (1) challenges in handling and movement of much lighter weight containers compared with glass along conveyer systems on high-speed filling lines, with smaller vials (1–5 mL) especially difficult to process; and (2) concerns about potential interactions with the drug product (absorption, adsorption, migration, leachables) especially over a two to three year shelf-life.

Manufacture of glass vials, either tubing vials or blow-molded vials, is covered in chapter 7. Vial openings are 13, 20, or 28 mm.

Syringes

Syringes are very popular delivery systems and growing in market share more than any other injectable primary packaging system (1–5). They are used either as empty sterile container systems where solutions are withdrawn from vials into the empty syringe prior to injection or as prefilled syringes (Fig. 4-4). Prefilled syringes can be presterilized by the empty syringe manufacturer or can be cleaned and sterilized by the finished product manufacture. Other options regarding syringe size, components, formats, treatment of rubber materials, and manufacturing methods are summarized in Table 4-1. Most of the world's vaccines are packaged and delivered in syringes. The growth rate for products filled and packaged in prefilled syringes increases about 13% per year (6). This growth is related to the top factors that influence a physician's choice of a drug delivery type, including the ease of use by patients, convenience, and comfort.