



Figure 4-1 Glass-sealed ampoules.

weakened at the neck by scoring or applying a ceramic paint with a different coefficient of thermal expansion, that permit the user to break off the tip at the neck constriction without the use of a file. Nevertheless, it is the glass particle problem and the need for use of a filter to withdraw product from the ampoule that caused the American Society of Hospital Pharmacists (now called American Society of Health-System Pharmacists) in the late 1980s to appeal to the pharmaceutical industry not to use ampoules for any new sterile product. Glass-sealed ampoules still exist, but they are not the choice for new products in America. Elsewhere in the world, ampoule products are still widely used and still a popular package of choice for new sterile product solutions.

Glass ampoules are Type I tubing glass (see chap. 7 for further elaboration of Type I and tubing glass) in sizes ranging from 1 to 50 mL. After solution is filled into the top opening of the ampoule, the glass is heat sealed by one of two techniques—tip sealing or pull sealing. Tip sealing has the open flame directed toward the top of the ampoule that melts and seals itself while the ampoule is rotating on the sealing machine. Pull sealing has the open flame directed at the middle of the portion of the ampoule above the neck where the glass is melted while rotating and the top portion is physically removed during rotation. Thus the tip-sealed ampoule has a longer section above the neck while the pull-sealed ampoule has a more blunt, ‘fatter” top.

Modifications of ampoules are available, for example, wide-mouth ampoules with flat or rounded bottoms to facilitate filling with dry materials or suspensions.

Vials

The most common packaging for liquid and freeze-dried injectables is the glass vial (Fig. 4-2). Plastic vials have made some ingress as marketed packages for cancer drugs, but may require



Figure 4-2 Glass vials with rubber closures and aluminum seal.