

Figure 7-9 Examples of Teflon® (Teflon® is a registered trademark of E.I. du Pont de Nemours and Company) coated rubber closure. *Source:* © 2010 by West Pharmaceutical Services, Inc.

Extractables and Interactions with Drugs and Excipients Including Testing Methods

Leaching of the ingredients dispersed throughout the rubber formulation may occur when the product contacts the rubber closure. These ingredients pose potential compatibility interactions with product ingredients if leached into the product solution, and these effects must be evaluated. Further, some ingredients must be evaluated for potential toxicity. To reduce the problem of leachables, laminates have been applied to the product contact surfaces of closures, with various polymers, the most successful being Teflon® [DuPont polytetrafluoroethylene (PTFE)] (Fig. 7-9) and FluroTec® (West/Daikyo fluorinated ethylene propylene film) (Fig. 7-10). Recently, polymeric coatings have been developed that are claimed to have more integral binding with the rubber matrix, but details of their function are trade secrets.

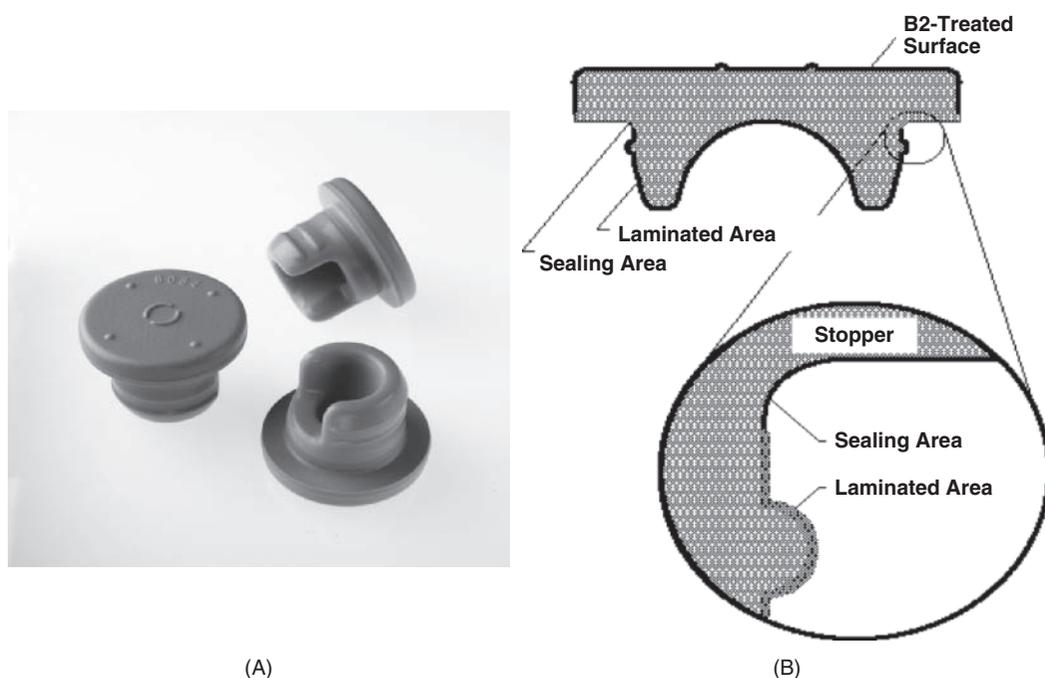


Figure 7-10 Daikyo FluroTec® closures. (A) Single vent lyophilization stopper. (B) FluroTec® (FluroTec® is a registered trademark of Daikyo Seiko Ltd) laminated plug with B2-treated top surface. *Source:* © 2010 by Daikyo/West Pharmaceutical Services, Inc.