



Figure 3-1 Examples of injectable dosage forms. (A) Solution. *Source:* Courtesy of Baxter Healthcare Corporation. (B) Suspension. *Source:* Courtesy of Dr. Gregory Sacha, Baxter. (C) Lyophilized powder (Gemzar®). *Source:* Courtesy of Eli Lilly and Company. (D) Emulsion. *Source:* Courtesy of Teva Pharmaceuticals

Parenteral emulsions are milky white in appearance (Fig. 3-2A) and have an average globule size of 1.0 μm to 5 μm . The United States Pharmacopoeia (USP) General Chapter <729> “Globule Size Distribution in Lipid Injectable Emulsions” specifies that “the volume-weighted, large-diameter fat globule limits of the dispersed phase, expressed as the percentage of fat residing in globules larger than 5 μm for a given lipid injectable emulsion, must be less than 0.05% (measured by light-scattering or light obscuration methods).” Emulsions are primarily used for parenteral nutrition and infused intravenously. Parenteral nutrition emulsions indeed are large volume and are terminally sterilized with the sterilization cycle designed to maintain globule size distribution. Small volume injectable emulsions are formulated with an active ingredient, the most common examples being propofol (Fig. 3-2B) and oil soluble vitamins. More coverage of emulsions is found in chapter 9.

Solids

Solids are prepared primarily by lyophilization after liquid filling with secondary preparation by sterile crystallization and powder filling. The reason most sterile solids are prepared by lyophilization is the fact that liquid filling presents less problems than powder filling and for powder filling the product needs to be crystalline in solid state character. Amorphous solids are very difficult to fill accurately because of their relative lack of density (too fluffy).