Figure 7-2   Typical composition of Type I borosilicate glass.

conditions with sulfur dioxide or other dealkalizers to neutralize the interior surface of the container. This surface will substantially increase the chemical resistance of the glass while the surface remains intact. However, repeated exposures to sterilization and alkaline detergents will break down this dealkalized surface and expose the underlying soda-lime compound.

The glass types are determined from the results of two USP tests: the Powdered Glass Test and the Water Attack Test (USP <660>). The Water Attack Test is used only for Type II glass and is performed on the whole container, because of the dealkalized surface; the former is performed on powdered glass, which exposes internal surfaces of the glass compound. The results are based on the amount of alkali titrated by 0.02 N sulfuric acid after an autoclaving cycle with the glass sample in contact with a high-purity distilled water. Thus, the *Powdered Glass Test* challenges the leaching potential of the interior structure of the glass while the *Water Attack Test* challenges only the intact surface of the container. Compendial references include USP <661>, European Pharmacopeia (EP) 3.2.1, and Japanese Pharmacopeia (JP) <57>. It is important to note that although the glass powder test challenges the leaching potential of the glass structure, it does not provide any information on the resistance of the inner surface of the container (22).

Selecting the appropriate glass composition and reaching agreement with the supplier on the final requirements are critical facets of determining the overall specifications for each parenteral formulation.

Physical Properties

Glass, as already described, is extremely viscous and deforms very slowly under external forces. Viscosity is temperature dependent with glass formation occurring at 10^3 to 10^8 poise. The annealing viscosity of glass is approximately 10^{13} poise.
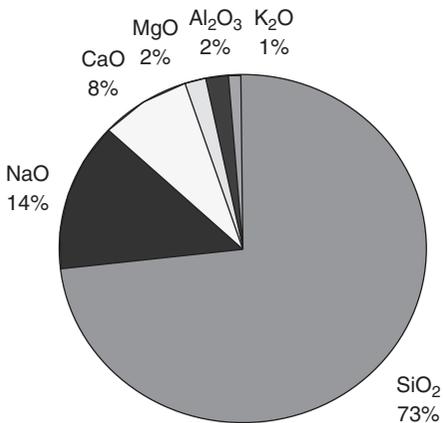

Figure 7-3   Typical composition of Type II and III soda-lime glass.