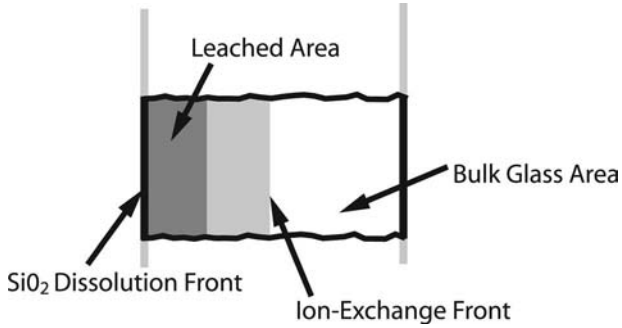
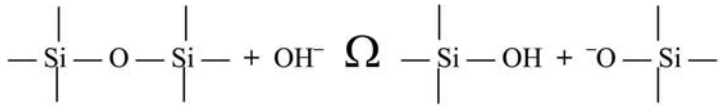



**FIGURE 2** Schematic illustration of the leaching process.




or $H_2O$

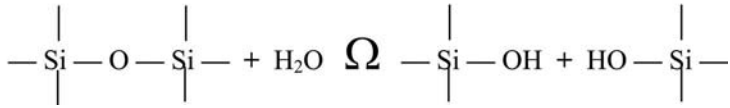



**FIGURE 3** Dissolution schematic.

Glass leaching is a selective process. It is primarily an ion exchange process for glass modifiers such as $Li^+$, $Na^+$, $K^+$, $Mg^{2+}$, $Ca^{2+}$, and $Mg^{3+}$ (4):

$Na^+$ (glass) + $H^+$(solution) → $H^+$ (Glass) + $Na^+$ (solution) (5)

A schematic view of the general glass leaching process is given in Figure 2.

There is an exchange of metal ions with hydrogen ions from water. This is typical of an acidic solution (6).

The other predominant reaction of water with glass is dissolution. This typically occurs with basic solutions. Glass dissolution reactions result in the release of metal ions and other inorganic materials (5) (Fig. 3).

## ELASTOMERIC CLOSURES FOR LYOPHILIZATION

### Composition and Manufacturing Process

Elastomeric closures for lyophilization are composed primarily of proprietary rubber formulations based on butyl polymer. Rubber is used because of its capacity to seal well against the surface of a glass vial. Nonhalogenated and halogenated butyl rubbers have been used for years in these types of applications for two primary reasons: low moisture vapor transmission (MVT) rate and low extractability. Each of these characteristics will be covered in detail in this chapter.

There are many considerations in developing and choosing a closure for freeze-drying. These are identified in Table 1.