



**FIGURE 7** Arrhenius plot illustrating the temperature dependence of the benzyl alcohol sorption to the CAVERJECT IMPULSE dual chamber syringe package.

### Siliconization of Components

Syringe barrels and elastomer components are siliconized for machineability, functionality, reduced sorptive loss to the glass walls, and to assure maximal volume delivery. Medical-grade silicone oil (polydimethylsiloxane) is applied to the barrel by wiping, spraying, or spraying followed by baking (i.e., spray-baking). The application method impacts the amount of residual silicone left on the barrel that may be extracted/leached into the drug product solution. The wiping application method usually leaves the highest level of residual silicone, followed by spraying and finally spray-baking. Because of the need to produce lower levels of residual silicone, siliconization of most syringes is achieved by spraying or spray-baking. The spray nozzle used during silicone application may be either static or moving (i.e., the nozzle actually enters the barrel and sprays a uniform layer of silicone as it is removed at a controlled rate). A moving spray nozzle normally delivers a more uniform layer of silicone on the entire length of the barrel than a static nozzle.

Spray-baking is specifically used for dual chamber packaging because it gives a lower total content of silicone in the barrel and a more homogenous/reproducible layer of silicone on the glass surface compared to the other siliconization methods. Another key advantage with spray-baking is that the break-loose and glide force of the plungers have less variability and are more stable during long-term storage. Therefore, spray-baking is the most reliable option for DCCs in pen injectors. This siliconization technique involves spraying a diluted medical-grade silicone oil emulsion (e.g., a 1–3% solution of Dow 365™ medical-grade silicone emulsion) into the barrel of the syringe and then heat-curing the silicone to the glass surface at approximately 300°C. Heat-curing leaves two layers of silicone on the glass as illustrated in Figure 8. The first layer is a