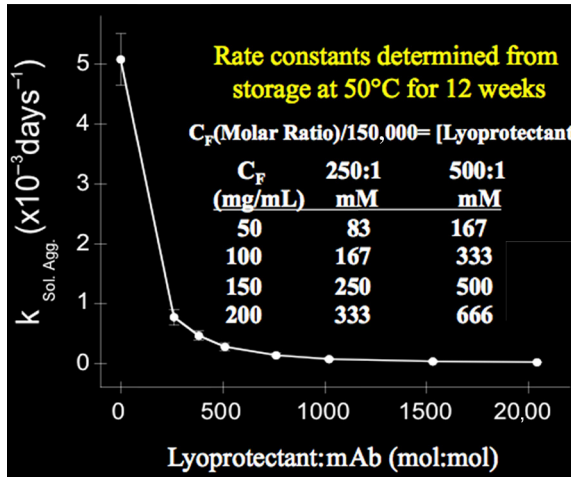

Figure 7.3 Stability and final tonicity after reconstitution as a function of lyoprotectant:mAb molar ratio.

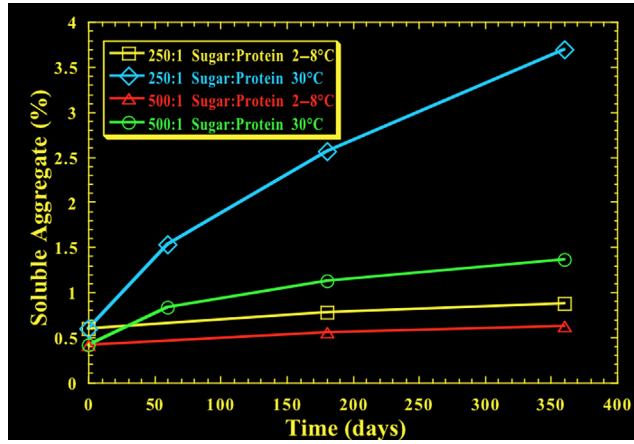

Figure 7.4 Stability of an IgG1 mAb as a function of lyoprotectant:mAb molar ratio and temperature of storage.

from a dense solid to a more loosely packed structure as protein-loading concentration was decreased (Figure 7.6). Thus, the ease of wetting of the cake and the impact on reconstitution time are very likely related to the differences in this morphology.

In the example discussed, the high-concentration formulation is created when adding sterile water for injection into the vial. Thus, the end user actually prepares the high concentration for SC delivery by reconstituting the lyophilized cake with a lower volume than used for the loading of the mAb prior to freeze-drying. This method can also be scaled up using bulk freeze-drying in trays, which after reconstitution and filtration can be filled into vials.

Different drying technologies can also be used to manufacture suspensions of mAbs at high concentrations, where the dried solute is added to a suspension vehicle that