



Fig. 2 Arrhenius plot of FDC Blue Dye #2 in a syrup. (Graph constructed from data by Scott et al., 1960.)

3.1 Suspensions

It would be desirable to have a suspension that did not settle (and there are such suspensions), but the general rule is that a suspension will settle, and therefore there are two parameters that are followed in this respect, namely sedimentation rate and sedimentation volume. When the sedimentation volumes are small, then there is a tendency for the suspension to cake, and hence various types of shaking tests are carried out.

Tests can be purely subjective, in that a tester notes that e.g. the suspension after three months' storage at 25°C was "difficult to resuspend, leaving some cake at the bottom." Such subjective tests should always be included in a program, but more quantitative means are desirable also. A typical quantitative test is to rotate the bottle under reproducible conditions. The type of setup used for solubility determinations is a good type apparatus for this purpose. The bottle is rotated x rotations, a sample of the supernatant is taken, and it is assayed. (This assay need not be stability indicating.) This is then repeated for twice the number of rotations, four times the number of rotations, and eight times the number of rotations. The time-relation of the assays is similar to that of a dissolution curve (although the phenomenon is redispersion), and it can often be represented by

$$Y = Y_{\infty}[1 - \exp(-kt)] \quad (10.9)$$

Y_{∞} , the asymptote value (found by iteration), should equal the dose, if caking has not occurred. The value of k is best found from the logarithmic presentation mode:

$$\ln\left[1 - \frac{Y}{Y_{\infty}}\right] = -kt \quad (10.10)$$