

evaluated, and the "worst acceptable" (akin to the lower acceptable quality limit in release philosophy) agreed to. The investigator now can do a rotation test on this in the fashion described by Moore and Lemberger (1963), and state e.g. that after 20 controlled rotations, an assay of the supernatant must not be less than  $L$  mg/mL. This type of test can then be carried out at various storage times at room temperature;  $L$  can be plotted versus time, and a usual statistical test performed on this number. In other words, for physical testing that has no number associated with it, it is important to attempt to find such a number.

In some cases this is not possible. A case in point is the particle size of an intravenous oil emulsion. Coalescence and formation of free oil will result in toxic manifestations, but it is next to impossible to determine an acceptable upper limit for droplet size (Davis, 1987).

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