



there are some important factors that should be considered as part of any stability study trial.

(a) Ideally the test materials used within the stability study should be typical of those routinely sampled/analysed. If more than one type of test material is analysed, then separate studies for each matrix type should be undertaken. Alternatively, where justified, stability studies can be undertaken on the most challenging type and applied generally as a 'worst-case scenario'. Use of a synthetic matrix should be avoided where possible. Testing should be conducted on test materials with the analyte in its native ('incurred') species and close to the concentration of interest. Tests at other concentrations may be informative but are not sufficient. Tests involving fortification with the analyte (spiking) should be avoided, wherever possible.

(b) The stability should be assessed in the container, with the preservatives, and under the storage conditions typical for the analysis in question. If these factors are unknown then stability may need to be assessed under various conditions. It may also be expedient to check stability at additional temperatures to allow for variations in conditions of transportation.

(c) The design of the stability study should provide sufficient statistical power. It is usually advisable to employ a method of the highest precision available to achieve this. Routine precision may not be sufficient. The precision then determines the number and timing of points in the time series and the number of replicate measurements at each point. The number and spacing of time points should be sufficient to determine and confirm the stability time. It is unlikely that stability will be established and confirmed in less than three time points.

(d) The experimental design should be such as to avoid any ambiguity between changes in the test material and changes in the performance of the analytical method, for example, by using an isochronous design or including a quality control sample of known stability.

Conclusion

Stability or holding time of samples before analysis is an important aspect of any chemical or biological procedure and should be defined for each analyte and matrix type so that the integrity of the sample is maintained. Holding times can sometimes be obtained from the published literature but care should be taken to ensure that they are appropriate for the matrix type and that the conditions quoted are followed exactly.