

Guidance Number: 007

Figure: Parameters that can be used for test method robustness:

Parameters that can be used to test method robustness:

Suggested changes in parameters to prove robustness are given in the following table.

Attribute/Technique	Robustness Considerations
General	Different Analysts Test location environment (air conditioned lab vs non temperature controlled manufacturing area) Crude and purified products
Standard Solution Stability	Storage time Storage conditions (room temp, refrigerated, direct sunlight)
Sample Solution Stability	Storage time Storage conditions (room temp, refrigerated, direct sunlight), sample quenching (effect on stability)
HPLC	pH of mobile phase Mobile phase composition (e.g. % Organic) Different columns (lots or suppliers) Detection wavelength (typically +/- 5 nm) Temperature Flow rate
GC	Different columns (different lots or suppliers) Temperature (injector, oven, detector) Flow rate (carrier, inlet, split)
AA (Atomic Absorption)	Gas flow Nebulization rate Slit width
TLC (Thin Layer Chromatography)	Evaluation of plates (different brands, lots) Variation of solution (eluent conditions) Chamber saturation effects time vs. chromatography Elution time (separation, degradation of sample) Development time (e.g. spray with reagent then heat for "x" minutes) Degradation of sample (2d spots)
LOD (instrumental e.g. Denver or Computrac or oven)	Time vs. result (optimize required drying time) Result vs. temp (lack of temp. degradation)
UV	Detection wavelength Solution stability
IR	Effects of possible relevant variations, e.g. temperature (environment and sample), humidity, different position of the sample in the optical window, different sample presentation devices, probe depth. Effects of sample quantity (e.g. in a pellet).

Attribute/Technique	Robustness Considerations
	Effects of particle size between standards and samples.
Titration Methods or KF	Different electrodes Varying amounts of sample Temperature and Humidity of test environment