



Common SPE Method Validation Terms - **ACCURACY** and **PRECISION**

Definition: Precision and Accuracy refer to the robustness and reproducibility of an analytical method.

The **Precision** of an analytical method is the closeness of a series of individual analyte measurements applied repeatedly to multiple aliquots of the same sample. The precision is calculated as a Relative Standard Deviation.

The RSD is often tested in three different categories.

1. Repeatability (same day precision) (intra-day)
2. Intermediate precision (inter-day precision)
3. Reproducibility (between laboratories precision)

Repeatability is often tested at three different concentrations. (low, medium, high) Acceptance criteria vary according to the type of analysis. For compound analysis in Pharmaceutical QC, precision should be better than 2%. For precision studies in BioAnalytical, the precision values at the higher concentrations should be better than 15%. At the lower limit of quantitation (LLOQ) it should not exceed 20%.

Intermediate precision shows the variations affected in day-to-day analysis by different analysts, different instruments, etc.

Reproducibility, as used in these constraints, represents precision obtained between different laboratories.

The **Accuracy** of an analytical method is the degree of closeness between the 'true' value of analytes in the sample and the value determined by the method. Accuracy is often determined by measuring samples with known concentrations and comparing the measured values with the 'true' values.

The FDA mandates that accuracy be determined by a minimum of five determinations for at least three concentrations. (low, medium, high) in the range of expected concentrations.

The mean value for the higher concentrations should be within 15% from the true value. (85% - 115% of the true value)

The mean value for the LLOQ (lowest concentration with >5:1 signal to noise) should be within 20%. (80% - 120% of the true value)

