

GLOSSARY

Accuracy: Expresses the closeness of agreement between the value that is accepted either as a conventional true or an accepted reference value and the value found.

Detection limit: The lowest amount of analyte in a sample that can be detected but not necessarily quantitated, as an exact value.

Identification Tests: Those tests are intended to ensure the identity of an analyte in a sample. This is normally achieved by comparison of a property of the sample to that of a reference standard.

Impurity tests: Those tests that are intended to accurately reflect the purity characteristics of the sample. These tests can be either quantitative or limit based.

Microbiological tests: those tests that demonstrate the presence, quantity, or character of microbes.

Potency/Bioassay/Binding tests: Those tests that demonstrate some biological attributes of an analyte. These tests may include animal cell or biochemical-based determinations.

Precision: The closeness of agreement among a series of measurements obtained from multiple sampling of the same homogeneous sample under prescribed conditions.

Quantitation Limit: The lowest amount of analyte in a sample that can be quantitatively determined with suitable precision and accuracy.

Quantitation tests: Those tests that are intended to accurately measure the amount of analyte in a sample.

Range: The interval between the upper and lower concentration of analyte in the sample for which it has been demonstrated that the analytical procedure has a suitable level of precision, accuracy, and linearity.

Robustness: The measure of an analytical procedure's capacity to remain unaffected by small, but deliberate, variations in method parameters and provides an indication of its reliability during normal usage.

Specificity: The ability to assess the analyte in the presence of components that may be expected to be present.

Stability: The ability to assess the analyte in the presence of components that may be expected to be present.

Stability-Indicating properties: The ability of a test procedure to discern changes in an analyte over time at the recommended storage conditions and to discern changes in an analyte that has been subjected to stress conditions.