

1.6.4 Intermediate Precision (Ruggedness)

It is the degree of reproducibility of test results obtained by the analysis of the same sample under a variety of conditions such as different laboratories, analysts, Instruments and days. It is calculated by measuring the standard deviation.

1.6.5 Linearity and Range

The linearity of an analytical procedure is its ability to elicit test results that are directly, or by a well-defined mathematical transformation, proportional to the concentration of analyte in samples within a given range. It should be established initially by visual examination of a plot of signals as a function of analyte concentration of content. If there appears to be a linear relationship, test results should be established by appropriate statistical methods (e.g., by calculation of a regression line by the method of least squares).

Linearity is usually expressed in terms of variance around the slope of the regression line calculated according to an established mathematical relationship from test results obtained by the analysis of samples with varying concentrations of analyte.

The range of an analytical method is the interval between the upper and lower levels of analyte in which it is found to be accurate, precise and linear.

1.6.6 Accuracy

It is the closeness of agreement between the value, which is accepted either as a conventional true value or an accepted reference value and the measured value.

1.6.7 Stability of Analytical Solutions

The standard solution is stored under conditions that ensure stability, the stability of the standard is analyzed over a specified period, using a freshly prepared standard solution at each time interval for comparison, the sample solution is typically stored at room