

used by different individuals using the same equipment in the same or different laboratories.( ISO/IEC, 2005; USP 36).

### **Validation Analytical Tools Include:**

Precision, Accuracy, Linearity, Range, Ruggedness, Limit of detection, Limit of quantitation, Selectivity and stability .(USP 36, ICH) Evaluation of stability should be carried out to ensure that every step taken during sample preparation, sample analysis and storage conditions used.(USP 36 , ICH guidelines, S. Seno *et al.*. 1997).

#### **1.9.1 Precision**

The precision of an analytical method is the degree of agreement among individual test results obtained when the method is applied to multiple sampling of a homogenous sample (USP 36 , ICH guidelines).

Precision is a measure of the reproducibility of the whole analytical method (including sampling, sample preparation and analysis) under normal operating circumstances.

Precision is determined by using the method to assay a sample for a sufficient number of times to obtain statistically valid results (ie between 6 - 10). The precision is then expressed as the relative standard deviation  $\%RSD = \frac{SD}{\text{mean}} \times 100 \%$ , (USP 36).

#### **1.9.2 Accuracy**

Accuracy is a measure of the closeness of test results obtained by a method to the true value. Accuracy indicates the deviation between the mean value found and the true value ( USP 36 , ICH guidelines, JCGM 200:2008)