It is determined by applying the method to samples to which known amounts of analyte have been added. These should be analyzed against standard and blank solutions to ensure that no interference exists. Percentage of the analyte is recovered by the assay (USP 36).

1.9.3 Linearity

Linearity of an analytical procedure as its ability (within a given range) to obtain test results that are directly proportional to the concentration (amount) of analyte in the sample (USP 36 , ICH guidelines).

Linearity is determined by calculating the regression line using a mathematical treatment of the results (i.e. least mean squares) vs analyte concentration (USP 36).

1.9.4 Range

The range of the method is the interval between the upper and lower levels of an analyte that have been determined with acceptable precision, accuracy and linearity, (USP 36).

It is determined on either a linear or nonlinear response curve (where more than one range is involved), and is normally expressed in the same units as the test results (USP 36 , ICH guidelines).

1.9.5 Ruggedness

Ruggedness is the degree of reproducibility of results obtained by the analysis of the same sample under different test conditions (different analysts, laboratories, instruments, reagents,days….etc).(USP 36 , ICH guidelines, Y. Vander Heyden, 2006).