1.9.6 Limit of Detection

This is the lowest concentration of a sample that can be detected, but not necessarily quantitated, under the stated experimental conditions. The limit of detection is important for impurity testing and the assay of drugs containing low active ingredient level and placebo (USP 36, Lawson GM, *et al.*. 1994).

1.9.7 Limit of Quantitation

This is the lowest concentration of analyte in a sample that can be determined with acceptable precision and accuracy (Bansal and DeStefano 2007; USP 36 , ICH guidelines), lt is quoted as the concentration yielding a signal-to-noise ratio of 10:1 and is confirmed by analyzing a number of samples near this value (USP 36).

1.9.8 Selectivity

Selectivity is the ability to measure accurately and specifically the analyte in the presence of components that may be expected to be present in the sample matrix (USP 36; Kazakevich and Lobrutto 2007).

1.9.9 Specificity

Specificity for an assay ensures that the measured signal comes from the substance of interest, and that there is no interference coming from excipients and/or degradation products and/or impurities (USP 36 ; ICH guidelines; Kazakevich and Lobrutto 2007).

1.9.10 Stability

Stability of the analyte in the studied matrix is evaluated using low and high QC samples (blank matrix spiked with analyte at a concentration of a maximum of 3 times the LLOQ and close to the ULOQ) which are analysed immediately after preparation