

and after the applied storage condition that are to be evaluated. The QC samples are analysed against a calibration curve, obtained from freshly spiked calibration standards, and the obtained concentration are compared to the nominal concentrations. The mean concentration at each level should be within  $\pm 15\%$  of the nominal concentration. Stability should be ensured for every step in the analytical method, meaning that the conditions applied to the stability tests, should be similar to those used for the actual study samples. (USP 36; ICH guidelines; Armbruster DA *et al.*. 1994).

The following stability tests should be evaluated:

- Stability of the stock solution and working solutions of the analyte and internal standard.
- Short term stability of the analyte in matrix at room temperature or sample processing temperature.
- Freeze and thaw stability of the analyte in the matrix from freezer storage conditions to room temperature or sample processing temperature.
- Long term stability of the analyte in matrix stored in the freezer.( Armbruster DA *et al.*. 1994).

### **1.10. Internal standard**

An internal standard is a chemical substance that is added in a constant amount to samples, the blank and calibration standards in the analysis. then the internal standard be used for calibration by plotting the ratio of the analyte signal to the internal standard signal as a function of the analyte concentration of the standards. This is done to correct for the loss of analyte during sample preparation or sample inlet. The internal standard used needs to provide a signal that is similar to the analyte signal in