1.7.3 Linearity

The linearity of an analytical method is its ability to obtain test results (area response) that are directly proportional to the concentration of analytes in samples within the given range. It involves six calibration curves or more over the concentration range (from LLOQ to ULOQ) where the standard curves are repeated in three or more runs randomly (Huber 2007; Shabir 2003; Shah *et al.* 2000). Linearity for each calibration curve is usually evaluated by examining y-intercept and the regression factor (R^2) which is a value that is used to evaluate closeness between predicted and target data. The best linear relationship must be more than 0.99 (closer to 1) which is considered sufficient evidence to conclude that the method has a perfect linear calibration (Kazakevich and Lobrutto 2007; Shabir 2003).

1.7.4 Stability

Evaluation of stability conditions should be conducted to ensure that every step taken during sample preparation, analysis and storage conditions will not affect analyte concentration. The stability of every step in the analytical method is ensured by applying conditions to the stability tests such as sample matrix, storage, container materials and analytical conditions which should be similar to those used for the actual study samples. Analyte stability is studied using QC low and QC high samples which are analyzed immediately after preparation then after applying storage conditions to the samples to be evaluated. QC samples are analyzed against a calibration curve, obtained from freshly spiked calibration standards, and the resultant concentrations are compared to the actual