

reported as a percentage of the known amount of an analyte carried through the sample extraction and processing steps of the method (Huber 2007; Shah *et al.* 2000). Recovery depends on sample processing procedure, sample matrix and analyte concentration (Huber 2007). Recovery is calculated as follows:

$$\text{Absolute recovery of the drug or internal standard} = \left(\frac{\text{AUC mean of serum/krebs buffer}}{\text{AUC mean of the mobile phase}} \right) \times 100\%$$

1.7.6 Range

Range is defined as the range of concentration between the upper and lower levels (ULOQ and LLOQ) that can be reproducibly and reliably quantified with accuracy, precision and linearity using concentration-response relationship since the range is derived from linearity (FDA 2013 ; Huber 2007).

1.7.7 Reproducibility

Reproducibility is the degree of reproducibility of results obtained under different conditions, such as different laboratories, environmental conditions, analysts, operators, instruments, and materials. It is also considered a measurement of test results reproducibility under normal, expected operational conditions from laboratory to laboratory and from analyst to analyst (Huber 2007).

2.3.8 Selectivity

Selectivity of an analytical method is defined as the ability of a method to measure the analyte of interest accurately in the presence of interference, such as synthetic precursors, excipients, enantiomers, or degradation products that may be expected to be