present in the sample matrix (Araujo 2009; EMEA 2011; Huber 2007; Shah *et al.* 2000). Selectivity may also investigate interference from degradation products formed during sample preparation, interferences caused by metabolites of the drug(s) and interference from possible co-administered medications (EMEA 2011).

1.7.9 Sensitivity

The sensitivity of an analytical method is defined as the method capability to discriminate small differences in concentration or mass of the test analyte and is dependent on the signal-to-noise ratio in a given detector (Huber 2007; Kupiec 2004).

1.7.10 Limit of detection

It is the lowest amount of analyte in a sample that can be detected but not necessarily quantitated as an exact value (Huber 2007), the limit of detection is expressed as the concentration of analyte in the sample based on a signal-to-noise (S/N) ratio (3:1) (Bliesner 2006). At each concentration level six to ten independent replicates will be measured randomly at the various level (Armbruster and Pry 2008).

1.7.11 Lower limit of quantification

The LLOQ of an analytical procedure is the lowest concentration of analyte in a sample that can be quantitatively determined with acceptable accuracy and precision and is considered the lowest calibration standards (Bliesner 2006; EMEA 2011). The analyte signal of the LLOQ sample should be at least five times the signal of a blank sample. The LLOQ should be suitable with the desired concentrations required for the aim of the study (EMEA 2011).