concentrations where accuracy % of QC (low and high) should be within 85-115% according to EMEA guidelines (EMEA 2011).

Stability tests should be evaluated as follow:

1.7.4.1 Freeze and thaw stability test

QC samples are stored and frozen in the freezer at the intended temperature and thereafter thawed at room processing temperature (room temperature) where freezing and thawing of stability samples should be similar to sample handling conditions. Stability should be assessed for a minimum of three freeze-thaw cycles (EMEA 2011; FDA 2013).

1.7.4.2 Sample stability after preparation at room temperature (bench-top stability)

Bench-top stability is the short term stability of the analyte in the matrix at room temperature or laboratory handling conditions which are expected for study samples and under storage conditions used during the study (EMEA 2011; FDA 2013).

1.7.4.3 Autosampler stability

On-instrument/ autosampler stability of the processed sample at injector or autosampler temperature (EMEA 2011; FDA 2013).

1.7.5 Recovery

Recovery is not considered among the validation parameters regarded as essential for method validation. Recovery describes method ability to detect the sample to be tested in the presence of internal standard and drug in order to obtain results with less error or bias (Peters *et al.* 2007). Recovery is the extraction efficiency of an analytical process,