high obtained from at least three runs analyzed on at least two different days to be evaluated for the validation of the inter-day accuracy. In both intra-day and inter-day accuracy, accuracy % of QC (low, mid and high) should be within 85-115% while LLOQ should be within 85-120%, according to EMEA guidelines (EMEA 2011).

1.7.2 Precision

The precision of an analytical method describes the closeness of repeated individual measures of analyte which is usually determines the degree of repeatability under normal conditions (Shabir 2003; Taverniers *et al.* 2004) and is usually expressed as the coefficient of variation (CV %). CV% is calculated as follows:

$$\text{CV \%} = \frac{\text{Standard deviation}}{\text{Mean}} \times 100\%$$

Precision should be determined for samples of LLOQ, QC low, mid and high, within a single run and between different runs, i.e. using the same runs and data as for the demonstration of accuracy (Taverniers *et al.* 2004). Intra-day precision (within-run precision) is the minimum of five samples per concentration level of LLOQ, QC low, mid and high for each single run which will be evaluated for intra-day precision validation. Inter-day precision (between–run precision) is usually validated for all QC samples (LLOQ, QC low, mid and high) from at least three runs analyzed on at least two different days. In both intra-day and inter-day precision, CV% value should not exceed 15% for all QC samples (QC low, mid and high), except for the LLOQ which should not exceed 20% (EMEA 2011).