3. Results

3.1 Validation

A full method validation were performed accourding to ICH and EMA guidelines for any analytical method to demonstrate the reliability of a particular method for the determination of an analyte concentration in a specific biological matrix.

3.1.1 Precision

At the first day of validation, the variability of errors (precision) in predicted concentration ranged between as low as 2.645% observed with the High target concentration of 800 ng/ml to a maximum coefficient of variation of (CV%) of 5.963% at the mid target concentration, table 11. The precision for low and mid concentrations of target was 5.778%, 5.963% respectively, table 15 and 16.

At the second day of validation, the variability of errors (precision) in predicted concentration ranged between as low as 1.839% observed with the mid target concentration of 500 ng/ml to a maximum coefficient of variation of (CV%) of 5.677% at the low QC target concentration of 30 ng/ml, table 12. The precision for low and high concentrations of target was 5.677%, 1.916% respectively, table 20 and 21.

At the third day of validation, the precision of predicted concentration ranged between as low as 2.833% observed with the High QC concentration of target of 800 ng/ml to a maximum coefficient of variation of (CV %) of 5.030% at the QC low target concentration of 30 ng/ml, table 13. The precision for LLOQ and mid concentration of target was 4.816%, 3.681% respectively, table 22 and 28