

The precision (CV %) is not exceed 20% for LLOQ, and 15% for the other concentrations which prove the closeness of the measurements.

3.1.2 Accuracy

At the first day validation, the accuracy of mean predicted value compared to target concentration ranged between a minimum of 96.103% at the QC Low concentration of target 30 ng/ml to a maximum accuracy of 103.319% at the QC high concentration for target 800 ng/ml. The overall all average accuracy at the first day was 100.55 %, table 11. Accuracy range for six replicates of LLOQ, QC low, QC mid, QC high samples was (97.01%-107.13%), (90.89%-102.56%), (106.42%-93.34%), (107.14%-99.37%) respectively, table 14 to 17.

At the second day of validation, the accuracy of mean predicted value compared to target concentration ranged between a minimum of 94.482% at the high concentration of target 800 ng/ml to a maximum accuracy of 105.302% at the LLOQ target concentration of 10 ng/ml. The overall all average accuracy at the second day was 98.78%, table 12. Accuracy range for six replicates of LLOQ, QC low, QC mid, QC high samples was (98.70%-109.52%), (93.90%-109.07%), (92.90%-97.80%), (91.87%-96.91%) respectively, table 18 to 21.

At the third day validation, the accuracy of mean predicted value compared to target concentration ranged between a minimum of 95.691% at the Mid concentration of target 500 ng/ml to a maximum accuracy of 101.529% at the LLOQ target concentration of 10 ng/ml. The overall all average accuracy at the third day was 99.78%, table 13. Accuracy range for six replicates of LLOQ, QC low, QC mid, QC high samples was (93.68%-108.88%), (94.46%-109.59%), (90.30%-99.81%), (96.38%-105.07%) respectively, table 22 to 26.