

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.

Comparing with the accepted criteria which is 85-115% for all concentration except for LLOQ which is 80-120%, the accuracy obtained is within the required criteria in terms of accuracy.

Measurement error

The mean measurement error at the first day assessment ranged between 1.169 ng/ml lower than the target concentration at the QC low concentration 30ng/ml of target to 26.549ng/ml higher than the target concentration) at the High concentration of target 500 ng/ml. The overall all mean measurement error at the first day was an overestimate of 7.74 ng/ml, table 11.

The mean measurement error at the second day of assessment ranged between 44.145 ng/ml (lower than the target concentration) at the high concentration 800ng/ml of