

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.

3.1.3 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 target to 0.530 ng/ml higher than the target concentration at the LLOQ concentration of target of 10 ng/ml. The overall all mean measurement error at the second day was an underestimate of 17.91 ng/ml, table 12.

The mean measurement error at the third day of assessment ranged between 21.545 ng/ml lower than the target concentration at the mid concentration 500ng/ml of target to 2.033 ng/ml higher than the target concentration at the high concentration of target of 800 ng/ml. The overall all mean measurement error at the third day was an underestimate of 6.07 ng/ml, table 13.

Looking at all the 3 days of validation one would conclude an overall mean measurement error of 10.3 ng/ml (underestimate on average) for the validation experiments of candesartan.