

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.

Stability

From the table's data, we find the autosampler stability test is passed according to the ICH accepted range where the accuracy % doesn't exceed 15%. Table 27 and 28 shows data for short term stability indicated by two QC concentrations (low, high) for candesartan after preparation procedure (auto-sampler stability), T=4°C.

Regarding short term stability at room temperature or processing temperature, freshly prepared 0 hour two QC's concentrations were taken as a reference upon calculating stability of candesartan at room temperature. All the results are within the accepted criteria which are in the range 85%-115%, as shown in table 31 and 32.

Regarding the freeze and thaw stability: the QC samples are stored and frozen in the freezer at the intended temperature and thereafter thawed at room or processing temperature. After complete thawing, samples are refrozen again applying the same