

Day 3 validation: table 31, which represents the standard calibration curve and intra-day accuracy data, shows an accuracy range of (94.95-107.56).

Since the accepted criteria according to USFDA are 85%-115% except for the LLOQ is 80%-120%, the results of three days of validation passed the required criteria in terms of accuracy.

Table 27: Standard Calibration Curve of Day One Validation, intraday accuracy data for candesartan.

Theoretical conc.ng/ml	Drug Area	IS Area	Ratio	Measured Conc.	Accuracy%
10.00	3073	51659	0.059	9.098	90.98
25.00	5765	55295	0.104	24.217	96.87
75.00	14499	56771	0.255	75.269	100.36
250.00	42754	53723	0.796	257.830	103.13
400.00	80846	59901	1.350	444.913	111.23
600.00	102389	53257	1.923	638.432	106.41
1000.00	152936	56078	2.727	910.240	91.02

$$\text{Ratio} = \text{drug area} / \text{IS area}$$

$$\text{Measured conc.} = (\text{ratio} / 0.00296) - (+ 0.0326)$$

$$\text{Function is } Y = 0.00296X + 0.0326 \text{ (R} = 0.9962 \text{)}$$

$$P < 0.05$$

Table 28: Raw data of the standard curve with regards to correlation, slope, R², and intercept for day one for candesartan.

Correlation (R)	Slope	R ²	Intercept
0.9962	0.00296	0.9924	+0.0326