

In the current study, HPLC/MS/MS method is used to separate, identify and determine the concentration of candesartan in plasma. Moreover, this method is very fast, reproducible and easy to operate (Pharmacopoeial Forum, 2004). The developed method was validated to meet the requirements for a global regulatory filing. The validation parameters such as precision, linearity, specificity, accuracy, limit of quantitation were carried out in accordance with ICH and US Pharmacopoeia guidelines.

Linearity

The linearity of candesartan response is evaluated from the range of 10–1000 ng/mL and showed a good correlation coefficient (r^2) of more than 0.997. To validate linearity, the standard curve of candesartan was constructed by plotting concentration (ng/mL) versus area response (mAU) which is shown in Figure 3 to 5. The linear regression and slope were calculated and are shown in Tables 28, 30, 32 and 36.

4.2.3. Precision

The precision of an analytical procedure expresses the closeness of the agreement (degree of scatter) between a series of measurements obtained from the multiple samples of the same homogeneous sample under the prescribed conditions. Repeatability is a measure of the precision under the same operating conditions over a short interval of time and it is also known as intra assay precision. A minimum six determinations at 100% of the standard concentration were tested to find out the average, standard deviation and relative standard deviation, and all the calculated