parameters were well within the prescribed limit. Intra-day precision and intermediate precision were done for ensuring the robustness of the method. The standard deviation (SD) of both the tests was well within the desirable limit. which is clearly indicated that the developed method is robust. Intraday and intermediate precision results are shown in Table 26.

Accuracy

The accuracy of an analytical procedure is the closeness of agreement between the values that are accepted either as conventional true values or an accepted reference value. Accuracy is usually reported as percent recovery by an assay using the proposed analytical procedure of known amount of analyte added to the sample. The ICH also recommended assessing a minimum of three determinations over a minimum of three concentration levels covering the specified range. The common method of determining accuracy is to apply the analytical procedure to the drug substance and to be quantitated against the reference standard of known purity.

At the first day validation, the accuracy of mean predicted value compared to target concentration ranged between a minimum of 96.103% at the QC Low concentration of target 30 ng/ml to a maximum accuracy of 103.319% at the QC high concentration for target 800 ng/ml. The overall all average accuracy at the first day was 100.55 %, table 11. Accuracy range for six replicates of LLOQ, QC low, QC mid, QC high samples was (97.01%-107.13%), (90.89%-102.56%), (106.42%-93.34%), (107.14%-99.37%) respectively, table 14 to 17.

At the second day of validation, the accuracy of mean predicted value compared to target concentration ranged between a minimum of 94.482% at the high concentration of target 800 ng/ml to a maximum accuracy of 105.302% at the LLOQ target