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October 19-20, 2018 | Tokyo, Japan
Asian J Biomed Pharmaceut Sci 2018, Volume 8 | DOI: 10.4066/2249-622X-C3-009

BIO-ANALYTICAL METHODS FOR QUANTITATIVE DETERMINATION (BIO-EQUIVALENCE AND BIO-AVAILABILITY) OF DRUG PRESENT IN THE BLOOD MATRIX

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Bio-analytical methods utilized for the quantitative determination of drugs and their metabolite in biological matrix such as, plasma, urine, saliva and serum in order to find their significant role in evaluation of interpretation of bioavailability and bio-equivalence for Pharmacokinetic data. The evaluations for linearity, precisions, accuracy and sensitivity were performed on three batches of spiked plasma samples. Each batch of spiked plasma sample included one complete set of calibration standards (blank, blank plus internal standard etc). Each different blank matrix batches were screened for interference at the retention time (RT). Bulk spiking of the samples were prepared by several dilution with analyte free plasma to obtain eight different concentration level. The closeness of the mean test results obtained by method to the true value (concentration) of the analyte showed the precision of the analytical method. Accuracy was determined by replicate analysis of samples. Large set of low, middle and high quality control (QC) samples were processed and analyzed against a single calibration curve. The following pharmacokinetic parameters were calculated for analyte using software- AUC0-t, AUC0-24, AUC-∞, AUC%, Cmax, Tmax and T1/2.