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Bioanalytical Method Development and Validation for Estimation of Amlodipine Besylate in Human Plasma using RP-HPLC

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Abstract : A simple, sensitive, rapid and precise bioanalytical RP-HPLC method was developed for estimation of Amlodipine besylate in human plasma. The work carried out on Shimadzu LC-2010 CHT HPLC system equipped with Waters C18 (150×4.6 mm, 5µ) column with mobile phase containing 10 mM potassium dihydrogen phosphate buffer, pH 6.4: Acetonitrile: Methanol in the ratio 20:70:10 v/v/v (1ml/min.) and detection wavelength 360 nm. The retention time of Amlodipine besylate was found to be 4.1 min. The developed bioanalytical method was found to be linear in concentration range of 35.71-71.42 µg/ml ($R^2 = 0.9835$). The precision study revealed that the percentage cumulative variation was within acceptable limit and accuracy study showed the value of mean percent recovery between 89.69-100.65 %. The Amlodipine besylate was stable in human plasma at different storage conditions. The validation parameters of the method met the acceptance criteria. Sufficient stability of both LQC and HQC was shown to allow for completion of sample analysis in clinical trials. From the results, we can conclude that developed bioanalytical method can be used for routine analysis of Amlodipine besylate.

Keywords : Bioanalytical method, Amlodipine besylate, Human plasma, RP-HPLC method, Validation.

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