RP-HPLC Method for Simultaneous Estimation of Amlodipine and Valsartan in Tablet Formulation and Validation as per ICH Guidelines

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SUMMARY. **A simple, specific, sensitive and validated RP-HPLC method for the simultaneous estimation of amlodipine (AMB) and valsartan (VAL) in marketed tablet formulation was developed. The analysis was carried out on a phenomenex C18 (250 x 4.6 mm, 5 *μ*m) column using a mobile phase of 0.1% ortho phosphoric acid solution: acetonitrile (35:65 v/v, pH 3.0). The flow rate of the mobile phase was adjusted to 1.0 ml/min and was detected at 238 nm. The retention time obtained from the analysis was 1.995 min and 4.910 min for AMB and VAL respectively. The developed method was validated as per ICH guidelines. In order to find out the linearity, the concentrations ranging 2-10 *μ*g/ml for AMB and 64-320 *μ*g/ml for VAL was used. The squared correlation co-efficient (r^2 value) derived from the equation for AMB and VAL was 0.9979 and 0.9994, respectively. The percentage recoveries calculated for AMB and VAL ranges from 96.93 to 99.63 %. The estimated drug in the tablet formulation was 100.13 % and 99.99 % for AMB and VAL respectively. The results of analysis shows that method can be used for the estimation of AMB and VAL in the tablet dosage form without further separation in the quality control laboratories.**

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