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Assay of Valsartan and Sacubitril in Combined Dosage Form by RP-HPLC (Method Development and Validation)

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ABSTRACT

A new, sensitive, precise, and accurate reversed-phase-high performance liquid chromatographic assay method for Valsartan and Sacubitril in combined tablet dosage form was developed and validated. Chromatographic separation was optimized by gradient HPLC on a C18 column [Inertsil ODS, 250 x 4.6 mm, 5µ] utilizing a mobile phase consisting of mixture of buffer (pH-2.7), acetonitrile and methanol in the ratio of 25:60:15 % v/v/v in the ratio of 30:50:20 %v/v at a flow rate of 1.0mL/min with UV detection at 245nm. The retention time of sacubitril and valsartan was 3.407 and 4.280 min respectively. The developed reversed-phase-high performance liquid chromatographic (RP-HPLC) method was validated as per International Conference on Harmonization (ICH) guidelines with respect to specificity, limit of detection, limit of quantification, precision, linearity, accuracy, robustness and system suitability. Good linearity obtained over the range of 50µg mL^{-1} to 150µg mL^{-1} for valsartan and sacubitril. The correlation coefficient was found to be 0.9987 and 0.9988 for valsartan and sacubitril respectively. The % RSD of precision was found to be 0.0478 and 0.158% for valsartan and 0.0355 and 0.154% for sacubitril respectively. The % mean recovery was found to be 99.92 to 99.84 % for valsartan and 101.14 % to 101.28 % for sacubitril respectively. The results obtained for accuracy, precision, LOD, LOQ and ruggedness were within limits.

Keywords: Valsartan, Sacubitril, Reversed-phase-high performance liquid chromatographic method.