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RP-UPLC Method for Simultaneous Estimation of Sacubitril and Valsartan in Its Bulk and Tablet Dosage Form with Force Degadation Studies

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Abstract:A simple, precise and accurate RP-UPLC method for simultaneous quantification of Sacubitril and Valsartan in bulk and tablet dosage form was developed and validated. Sacubitril and Valsartan were separated and estimated using waters UPLC with Inertsil ODS (1.7 x 150mm, 3 m size) column. The mobile phase used was phosphate buffer: acetonitrile (50:50%v/v). The elution of analytes was achieved with a flow rate of 0.4 ml/min and UV detection at a wavelength of 271 nm. The detector response was linear in the concentration range of 12-60 µg/mL and 13-65 µg/ml. The limits of detection, limit of quantification were 0.0626 µg/ml, 0.1897µg/ml and 0.0678µg/ml,0.2055µg/ml for sacubitril and valsartan respectively. The method was validated following ICH guidelines. All parameters of validation were found to be in the acceptance range.
Keywords: Sacubitril, Valsartan, Reversed-phase ultra-performance liquid, chromatography. Validation.

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