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Reverse Phase Stability Indicating HPLC Method for Determination of Sacubitril and Valsartan in the Presence of its Stress Degradation Products

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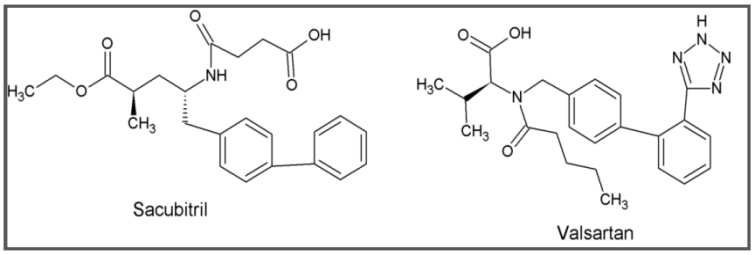
ABSTRACT

A rapid, sensitive reversed phase stability indicating high performance liquid chromatographic method was developed and validated for the simultaneous assay of sacubitril and valsartan in bulk and tablet dosage forms. The method was developed using the Sunsil C18 analytical column using isocratic elution with mobile phase consisting of 0.1M dipotassium hydrogen phosphate and methanol in the ratio of 65:35 (v v^{-1}) at a flow rate of 1.0 mL min^{-1}. Sacubitril and valsartan were monitored at 254 nm. These were subjected to various stress conditions of acid, base, oxidative, thermal and photolytic degradations. The method is efficient for the estimation of sacubitril and valsartan in the presence of stress degradation products. The method performance was validated according to the ICH guidelines for selectivity, specificity, limit of detection, limit of quantification, linearity, accuracy, precision and robustness. The results of validation parameters are found to be within the recommended limits. Therefore, the method is appropriate for stability study and quantification of sacubitril and valsartan in tablet samples.

Graphical Abstract



Keywords: Sacubitril, Valsartan, Heart Failure, Stability Indicating, Assay.