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DEVELOPMENT AND VALIDATION OF STABILITY INDICATING METHOD FORESTIMATION OF RIOCIGUAT IN BULK AND PHARMACEUTICAL DOSAGE FORM

Pamil Desai & Ankita Bhavsar

Research Scholar, Department of Pharmaceutical Quality Assurance, Sat Kaival College of Pharmacy, Sarsa, Gujarat, India

ABSTRACT

Stability indicating high performance liquid chromatography method for the analysis of Riociguat was developed and validated. The column used was Hypersil BDS C_{18} (250 X 4.6 mm 5.0 µ) with a flow rate of 1.0 ml/min using UV detector at 233 nm. The chromatograms were developed using (0.05M potassium dihydrogen orthophosphate, ph-5.0) Buffer: Methanol (10:90% V/V) as a mobile phase. The described method was linear over a concentration range of 25-75 µg/ml for the assay of Riociguat. The retention times of Riociguat was found to be 4.403 min. The % recovery of Riociguat was found to be 101.55%. The limit of detection and limit of quantification were found to be 1.95 µg/ml and 5.90 µg/ml respectively. The % RSD of Riociguat was found to be 0.73 %. The method developed is robust. The drug was exposed to acidic, basic, oxidative, photolytic and thermal degradation. The peaks of degradation products were well-resolved from the peak of the standard drug with significantly different values. Results showed that the developed method is simple, specific, accurate and robust for the determination of Riociguat in its formulation. The method can effectively separate the drug from its degradation products and it can be considered as a stability-indicating assay.

***KEYWORDS**: Riociguat, Methanol, Method Development, Validation, Stability Study*

Article History

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