Available online at **www.joac.info**

ISSN: 2278-1862

Journal of Applicable Chemistry

2021, 10 (3): 291-301

(International Peer Reviewed Journal)

Development and Validation of Stability Indicating UPLC Method for the Determination of Rivaroxaban in Bulk and Finished Products and Identification of Degradation Products by LCMS

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Accepted on 14th April, 2021

ABSTRACT

The current research work reports the study on the degradation profile of Rivaroxaban, chemically known as (S)-5-chloro-N-((2-oxo-3-(4-(3-oxomorpholino) phenyl) oxazolidin-5-yl) methyl) thiophene-2-carboxamide. This work also reports the chemical stability of Rivaroxaban in different stress conditions along with the identification of degradant products by UPLC-MS. A sensitive and reproducible stability indicating ultra-performance liquid chromatography method is developed and validated for quantification of Rivaroxaban bulk drug in the presence of degradation products. The drug was subjected to various stress Conditions such as hydrolysis, oxidation, photolytic and thermal degradations. Significant degradation was observed during hydrolytic stress conditions using HCl and NaOH. It is observed that the drug is highly unstable to acidic and basic condition. Efficient chromatographic separation was achieved by using Acquity; UPLC, X-select CSH; C-18; 100 x 2.1mm; 1.7 µm column with the mobile phase consisting of 0.1% Trifluoro acetic acid in water and0.1% Trifluoro acetic acid in acetonitrilein a gradient elution mode within a short run time of 9.0minutes at a flow rate of 0.4 ml/min using PDA detector. The developed method was validated as per the current ICH guidelines with respect to specificity, precision, accuracy, linearity, robustness and solution suitability. The average recovery values of Rivaroxaban were found to be in the range of 98.10-101.92 %. The developed method was linear with the correlation coefficient value of 0.9993. The repeatability and intermediate precision were expressed by % RSD were less than 2.0% for Rivaroxaban. The test solution was found to be stable in diluent for 48 h when stored at room temperature. The developed UPLC method is superior in technology against conventional HPLC with respect to speed, resolution, solvent consumption and cost of analysis. This method is compatible to LCMS analysis which enables to identify the unknown impurities or the degradants formed in the process.

Highlights:

1. Developed a new UPLC method which is superior in technology against conventional HPLC with respect to speed, resolution, solvent consumption and cost of analysis.
2. Using this method can perform identification and quantification of Rivaroxaban drug in bulk drugs and formulation products.
3. Rivaroxaban was subjected to force degradation under acidic, basic, oxidative, photolytic and thermal conditions as per ICH guidelines. The degradant products are well resolved with main peak in this method and the method is mass compatible.

4. In hydrolytic conditions three degradant products were observed. Which is identified by LCMS and given its proposed structures.

Keywords: Rivaroxaban (RIB), UPLC, LCMS, Method Validation, stability indicating method.