ABSTRACT

Rivaroxaban is an anticoagulant which is used to prevent blood clotting leads to thromboembolism. The objective of present study was to develop a new, economic, less time consuming, simple and efficient UV spectrophotometry and reverse phase HPLC-PDA method for the Rivaroxaban determination in pharmaceutical formulations and in blood plasma of humans. The determination was made at 253 nm in acetonitrile as solvent for UV Spectroscopy and mixture of ACN and H_2O in ratio 70:30 (%v/v) for RP-HPLC. The separation through RP-HPLC was carried out at room temperature by column from Thermo Scientific ODS Hypersil C_{18} (250 × 4.6 mm, 5 µm) with 1.2 ml/min flow rate of M.P. The proposed methods were validated as per ICH-guidelines. Both methods were linear, precise, robust and showed specificity in all applied stress conditions i.e., photolytic (200–800 nm, 3 h) thermal (70 °C, 2 h), oxidative (3% H_2O_2, 70°C, 1 h), acidic (0.1 N, 70°C, 1 h), and basic (0.1 N, 70 °C, 1 h). The plasma samples were pre-cleaned before analysis by protein precipitation method to avoid the matrix interference. The validated methods were successfully applied for the Rivaroxaban quantitative determination in pharmaceutical dosages and human blood plasma.

Keywords: Rivaroxaban, Validation, ICH, UV spectrophotometry, HPLC-UV, Acetonitrile, Stability Indicating, Solid dosage form, Quantitative determination, human blood plasma, Protein precipitation.