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Development and validation of a new analytical rp-hplc method for the quantitative estimation of finerenone in api form and marketed pharmaceutical dosage form

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ABSTRACT

A new, simple, rapid, precise, accurate and reproducible RP-HPLC method for estimation of Finerenone in bulk form and marketed formulation. Separation of Finerenone was successfully achieved on a Symmetry ODS C18 (4.6 x 250mm, 5µm) column in an isocratic mode of separation utilizing Acetonitrile: Methanol in the ratio of 80:20% v/v at a flow rate of 1.0 mL/min and the detection was carried out at 272nm. The method was validated according to ICH guidelines for linearity, sensitivity, accuracy, precision, specificity and robustness. The response was found to be linear in the drug concentration range of 10-50mcg/mL for Finerenone. The correlation coefficient was found to be 0.999 for Finerenone. The LOD and LOQ for Finerenone were found to be 1.1µg/mL and 3.2µg/mL respectively. The proposed method was found to be good percentage recovery for Finerenone, which indicates that the proposed method is highly accurate. The specificity of the method shows good correlation between retention times of standard solution with the sample solution. Therefore, the proposed method specifically determines the analyte in the sample without interference from excipients of pharmaceutical dosage forms.

Keywords: Finerenone, RP-HPLC, Accuracy, ICH Guidelines.