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Analytical Method Development and Validation for the Simultaneous Estimation of Evinacumab Injection Formulation by RP-HPLC

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Abstract: *This paper describes in detail the RP-HPLC method used to evaluate the content of evinacumab (EVC) in combination with evkeeza injections. The mobile phase used in the assay is a mixture of potassium dihydrogen phosphate and methanol in an isocratic ratio of 70:30 (v/v) on a column Shimpac solar C18, 150*4.6, 5µm column. The flow rate was 1.0 ml/min, isocratic. At 226 nm, the quantification and detection of EVC were done concurrently. It was discovered that the response obtained was linear over the concentration range of 75-225 µg/ml, and the estimated RT in minutes for EVC was 4.063. 1.805 µg/ml was the LOD and 6.017 µg/ml was the LOQ. For the EVC assay, precision was 0.3% RSD and accuracy was 100%.*

Keywords: Evinacumab, Simultaneous estimation, ICH guidelines.