Abstract:

Reverse phase high-performance liquid chromatography method are used for the accurate, fast, simple and precise. Method development and validation for the mixture of empagliflozin and metformin HCL simultaneously in dosage form. The chromatographic separation carried out by C_{18}, 250 × 4.6mm 5µ or equivalent and UV PDA detector used for monitoring. Wavelength of 233nm used with Acetonitrile buffer (40:60 v/v) as mobile phase and injection volume was 20 µl for reverse phase isocratic mobile phase. 6.8gm potassium dihydrogen phosphate in one liter of deionized water adjust pH up to 4.0 using orthophosphate for buffer preparation. The temperature maintained at 30°C system suitability linearity, precision, accuracy specificity, (LOD), (LOQ) are the validation parameters and stability of sample and stock solution and robustness were studied as following the ICH guidelines. The limit of detection is 7.07ppm and limit of quantification is 21.44ppm.The RSD is 0.65 and 1.65 for empagliflozin and metformin HCl respectively. %age RSD of area and retention time of each concentration level is below 2.0 and 1.0 respectively. The percentage recovery is 100.17 and 100.40 for metformin HCl and empagliflozin respectively. This method is accurate, fast, precise, and simple that can be used for simultaneous estimation of drug containing empagliflozin and metformin HCl in quality control labs as well as in pharmaceutical companies.