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RP-HPLC Method Development and Validation forthe Determination of Canagliflozin in Human Plasma

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Abstract : A simple, specific, sensitive, precise, selective and accurate reverse phase high performance liquid chromatographic method was developed for the determination of canagliflozin in human plasma as per US-FDA guidelines. Plasma samples were extracted by protein precipitation method using methanol as extracting solvent. The chromatographic separation was performed with WATERS EA874 (250 × 4.6 mm, 5 µm) column and mobile phase composed of 36.46 mM Acetate buffer: acetonitrile: methanol (30:50:20, v/v), pH 4.5 adjusted with acetic acid at a flow rate of 1.0 ml/min. Canagliflozin was detected at 290 nm with retention time of 5.1 min. Linearity was found to be 0.9929 over the range of 33.33 – 233.33 ng/ml and percentage recoveries were found to be 94.68 - 103.76 %. The validation was successfully performed by means of accuracy and precision, selectivity and specificity, linearity, recovery and stability under various conditions. This developed method can be successfully employed for the determination of Canagliflozin in human plasma.

Keywords: Canagliflozin, bioanalytical method, protein precipitation, RP-HPLC, US-FDA guidelines, stability studies.

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