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RP-HPLC Method for Estimation of Dapagliflozin from its Tablet

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Abstract: Rapid, precise and accurate RP-HPLC method for estimation of Dapagliflozin from its tablet dosage form was developed and validated as per ICH guidelines. The chromatographic separation was achieved by isocratic mode with a mixture of Acetonitrile: 0.1% Triethylamine (pH-5.0) in the ratio of 50:50v/v as mobile phase using Princeton C_{18}column at flow rate of 1mL/min and detection wavelength of 224nm. Using optimized chromatographic conditions, retention time of drug was found to be 5.163min. The proposedmethod obeyed Beer's-lambert's law in the concentration range of 10-70µg/mL, with correlation coefficient value 0.999.The mean percent amount of drug estimated was 100.57%, found to be good in agreement with label claim of marketed tablet formulation. The validation parameters like accuracy, precision, ruggedness, robustness, linearity and range were studied for proposed method and were found to be within limits. Stress testing under various conditions such as pH (acid/base), oxidation,temperature, light,humidity, etc. was also carried out.

Keywords: Dapagliflozin, HPLC, Validation, Stress testing.

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