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RP-HPLC Method Development and Validation for Analysis of Voglibose and Linagliptinin Tablet Dosage Form

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Abstract: *The development and validation of a reliable RP-HPLC method for the simultaneous analysis of Voglibose and Linagliptin in tablet dosage form are presented. The method ensures precise quantification of both compounds with optimal resolution and reproducibility. Methanol was identified as a suitable solvent for both Voglibose and Linagliptin due to its high solubility properties. A wavelength of 215 nm was selected based on peak absorption intensities for simultaneous determinations. The mobile phase comprised methanol and a 0.1% ortho-phosphoric acid (OPA) buffer solution in a 75:25 v/v ratio, adjusted to pH 4.5. Chromatographic separation was achieved using a Fortis C18 column (4.6 × 100 mm, 2.5 µm particle size) with a flow rate of 0.8 mL/min at ambient temperature. Validation followed ICH guidelines, assessing parameters such as linearity, accuracy, precision, LOD, LOQ, and robustness. Linearity was established over the range of 66-396 µg/mL for Voglibose and 10-60 µg/mL for Linagliptin, with correlation coefficients (R^2) of 0.9996 and 0.9995, respectively. Recovery studies indicated mean values within ±2% of the actual value, confirming accuracy. The LOD and LOQ were found to be 2.80 µg/mL and 8.485 µg/mL for Voglibose, and 0.55 µg/mL and 1.674 µg/mL for Linagliptin. The method proved robust against small variations in chromatographic conditions. This validated RP-HPLC method offers a reliable approach for routine analysis of Voglibose and Linagliptin in pharmaceutical formulations, ensuring consistency and compliance with regulatory standards.*

Keywords: Simultaneous analysis, RP-HPLC, Voglibose, Linagliptin, tablet dosage form, method validation, pharmaceutical analysis, chromatographic separation

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