# DEVELOPMENT AND VALIDATION OF STABILITY INDICATING RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF SITAGLIPTIN AND SIMVASTATIN IN BULK AND PHARMACEUTICAL DOSAGE FORM

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## ABSTRACT

**Objective:** The objective is to develop and validate stability indicating reverse-phase HPLC method for estimation of Sitagliptin and Simvastatin in bulk and pharmaceutical dosage form.

**Experimental Work:** The proposed RP-HPLC method utilizes Gradient separation mode with Phenomenex C12, (250 mm X 4.6 mm i.d., 4 μm particle size) column, at ambient temperature, optimum mobile phase consisted of acetonitrile and 50 mM Potassium dihydrogen phosphate buffer , apparent pH of buffer was adjusted to 6.0 with Potassium Hydroxide solution, effluent flow rate monitored at 2.0 ml/min and UV detection has been done at wavelength of 218 nm. The method was successfully validated in accordance to ICH guidelines Q2 (R1) in terms of specificity, linearity, precision, recovery, sensitivity and robustness. The drug product was exposed to acidic, alkaline, photolytic and oxidative stress conditions and the stressed samples were analyzed by the proposed method.

**Results & Discussions:** The retention time of sitagliptin was 5.9 min and simvastain was 14.5. The described method was linear over a range of 20-220 µg/ml for sitagliptin and 8-88 µg/ml for simvastatin. The correlation coefficient for both drugs were found to be 0.999. The accuracy of the proposed method were determined by recovery studies and found to be 99.21% to 99.54% for sitagliptin and 98.79% to 101.2 for simvastatin. The limit of detection for sitagliptin was 4.79 µg/ml and the limit of quantification is 14.53 µg/ml respectively. The limit of detection for simvastatin was 1.54 µg/ml and the limit of quantification is 4.66 µg/ml respectively There is complete separation of degradation and simvastatin and sitagliptin peak, which demonstrate the specificity of assay method for estimation of sitgliptin and simvastatin in presence of its degradation products.

**Conclusion:** All the method was found to be simple, accurate, economical, robust and reproducible. There was no interference of any degradants and excipients in the determination of drugs in tablets so it can be employed as a stability-indicating one. The method can be successfully applied for routine QC analysis.

**Key words:** Simvastatin, Sitagliptin, Stability indicating RP-HPLC method, Validation.