DEVELOPMENT AND VALIDATION OF SPECTROPHOTOMETRIC AND STABILITY INDICATING HPLC METHODS FOR SIMULTANEOUS ESTIMATION OF NIFEDIPINE AND CANDESARTAN CILEXETIL IN SYNTHETIC MIXTURE

By

DHOBI PRIYANKABEN ARVINDKUMAR
[Enrollment No.132140804004]

Supervised by:
Ms. JIGNASA MODI
Assistant Professor
Department of Quality Assurance

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PARUL INSTITUTE OF PHARMACY AND RESEARCH
LIMDA, TA. WAGHODIA, DIST. VADODARA-391 760

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ABSTRACT

A simple accurate and precise UV Spectroscopic (Simultaneous Equation Method) and Stability Indicating HPLC methods were developed and validated for simultaneous estimation of Nifedipine and Candesartan cilexetil in Synthetic Mixture. In Simultaneous Equation Method, drugs were determined by Absorptivity values of NIF and CAN at selected wavelength of 235nm and 255nm respectively. The Linearity range was found to be 6-21µg/ml and 3.2-11.2µg/ml for NIF and CAN respectively. The correlation coefficient of NIF and CAN was found to be 0.999 and 0.998 respectively. The Stability Indicating HPLC method has shown adequate separation of NIF and CAN in Synthetic mixture. The separation was achieved on Column Phenomenex Luna C18 (250mm X 4.6mm, i.d.5µm particle size) with mobile phase of Methanol: Phosphate Buffer (pH-4) in the ratio of (65:35v/v). The flow rate was 1.0ml/min and detection wavelength was 240nm. The retention time for NIF and CAN was obtained 4.313min and 8.116min respectively. The linearity of the proposed method was in the range of 6-18µg/ml and 3.2-9.6µg/ml for NIF and CAN respectively. Correlation coefficient was 0.999 and 0.998 for NIF and CAN respectively. The method was

validated as per ICH Q2(R1) guidelines and acceptance criteria for linearity, recovery, precision, and robustness. The Forced degradation study was carried out as per ICH guideline under acidic, basic, oxidative, thermal and Photolytic conditions. All peaks of degraded product were resolved from the drug with different retention time effectively, as it employed as a stability indicating one.

Keywords: Nifedipine (NIF), Candesartan cilexetil (CAN), Simultaneous Equation method, Force degradation Study, Validation