NEWER RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF TELMISARTAN AND AMLODIPINE IN DOSAGE FORM

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A novel reverse-phase high-performance liquid chromatography (RP-HPLC) method for simultaneously estimating Telmisartan and Amlodipine in combined pharmaceutical dosage forms is the focus of this study. Amlodipine, a calcium channel blocker, and telmisartan, an angiotensin II receptor antagonist, are frequently combined in treatment for hypertension. The need for a reliable, accurate, and rapid analytical method to simultaneously quantify both drugs in a single formulation has become essential due to the growing use of combination therapies.

A newly optimized RP-HPLC method was developed using a C18 column with a mobile phase consisting of acetonitrile and phosphate buffer (pH adjusted to 3.5 with orthophosphoric acid) in a suitable ratio.Using a UV detector, the detection was carried out at a wavelength of 238 nm at a flow rate of 1.0 mL/min. The retention times of Telmisartan and Amlodipine were found to be well resolved with good peak symmetry and resolution.

The developed method was validated in accordance with ICH Q2(R1) guidelines for various parameters including linearity, accuracy, precision, specificity, robustness, limit of detection (LOD), and limit of quantification (LOQ). The method exhibited excellent linearity over the concentration ranges of 10–60 µg/mL for Telmisartan and 2.5–15 µg/mL for Amlodipine. The recovery studies demonstrated an acceptable percentage of recovery, demonstrating the method's accuracy. The proposed RP-HPLC method is simple, precise, and time-efficient and can be effectively employed for the

Keywords : routine quality control analysis of Telmisartan and Amlodipine in combined dosage forms, validation, pharmaceutical dosage form, ICH guidelines, analytical method, hypertension

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K.Jyothsna has her own experience in valuation and passion for ML and data. The research team built this model after many years of experience in research, evaluation, work in both hospitals and scientific laboratories. This approach meets all the requirements for precise, specific, sensitive diagnostics.

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