ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF SIMVASTATIN AND FENOFIBRATE IN COMBINED DOSAGE FORM

By

PATEL MITI ASHOKKUMAR
[Enrollment No.132140804003]

Supervised by:
Dr. T.Y.Pasha
M.pharm,Ph.D
Head and Principal

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

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Abstract

A First order derivative spectroscopic method, Absorbance Correction spectroscopic method and RP-HPLC method were developed and validated for simultaneous estimation of Simvastatin and Fenofibrate in combined Dosage form. First order derivative method based on the measurement of absorbance at two wavelengths, 239 nm and 305 nm, ZCP of Fenofibrate and Simvastatin respectively. The calibration curve was linear in a concentration range of 2-12 µg/ml for Simvastatin and 4-24 µg/ml for Fenofibrate. Absorbance Correction method based on the measurement of absorbance at two wavelengths, 237 nm for Simvastatin and 286 nm for Fenofibrate. The Linearity range for Simvastatin is 2-12 µg/ml and for Fenofibrate is 4-24 µg/ml. The RP-HPLC method has shown adequate separation of Simvastatin and Fenofibrate in Combined Dosage form. The separation was achieved on a Enable C18 H (250mmX4.6 mm i.d., 5µm particle size) with an Isocratic system of Methanol : Water (pH 3.5) in the ratio of 90:10v/v at flow rate of 1.0 ml/min, and wavelength of

detection used was 241nm. The retention time for Simvastatin and Fenofibrate was obtained as 3.349±0.042min and 6.090±0.043min, respectively. The linearity of the proposed method was investigated in the range of 4-24µg/ml and 14.5-87µg/ml for Simvastatin and Fenofibrate respectively. Correlation coefficient was 0.9994 and 0.9984 for Simvastatin and Fenofibrate respectively. The developed method was validated as per ICH guideline, for its linearity, accuracy, precision, and robustness the results were found to be satisfactory, thus the method is specific, rapid and simple for estimation of Simvastatin and Fenofibrate.

Key words: Simvastatin, Fenofibrate, First order derivative method, Absorbance Correction method, RP-HPLC Method.