ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF PRAVASTATIN SODIUM AND FENOFIBRATE IN COMBINATION

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A

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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 Pravastatin sodium and Fenofibrate in combination. A simple and rapid UV spectrophotometric methods has been developed for simultaneous quantification of Pravastatin sodium and Fenofibrate. First order derivative method based on the measurement of absorbance at two wavelengths, 275 nm and 239 nm, ZCP of Pravastatin sodium and Fenofibrate respectively. The calibration curve was linear in a concentration range of 1-6 µg/ml for Pravastatin sodium and 4-24 µg/ml for Fenofibrate. Absorbance Correction method based on the measurement of absorbance at two wavelengths, 237 nm for Pravastatin sodium and 286 nm for Fenofibrate. The calibration graph was linear in the concentration range of 1-6 µg/ml for Pravastatin sodium and 4-24 µg/ml for Fenofibrate. The RP-HPLC method performed on a Phenomenex Luna C18 (250mm X 4.6 mm i.d., 5 µm particle size) with an Isocratic system of Methanol : Buffer (pH 3) in the ratio of 90:10 v/v at flow rate of 1.0 ml/min and wavelength of detection used was 247 nm. The retention time for Pravastatin sodium and Fenofibrate was obtained at 3.13 min and 7.32 min, respectively.

Calibration curves were linear (R^2 = 0.998 for Pravastatin Sodium and 0.998 for Fenofibrate) in the concentration range of 2–12 and 8–48 µg/ml for Pravastatin sodium and Fenofibrate, respectively.

The developed method was validated as per ICH guideline.

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