RP-HPLC Assay for Estimation of Pitavastatin in Bulk and Pharmaceutical Dosage Forms

K. Tirumala*, CH.V.S. Gautam, J. Gangadhar, M. Jayajeevitha, and K. Vanitha Prakash

Department of Pharmaceutical Analysis, SSJ College of Pharmacy, V.N. Pally, Gandipet, Hyderabad-500075, Andhra pradesh, India.

Received April 22, 2013; accepted August 26, 2013

ABSTRACT

Reverse phase high performance liquid chromatographic (RP-HPLC) method was developed and validated for the estimation of pitavastatin in tablet dosage form. A Phenomenex Luna C18, 150×4.6 mm i.d, 5 µm particle size with mobile phase consisting of buffer 0.01M potassium dihydrogen ortho phosphate pH (3.75) adjusted with dilute orthophosphoric and acetonitrile in the ratio of 20:80 v/v was used. The flow rate was 1.2 mL/min and eluents were monitored at 248 nm. The retention time was 4.1 min. The detector response was linear in the concentration of 25-150 µg/mL, with the regression coefficient of 0.9998. Quantification was done by calculating area of the peak and the limit of detection and limit of quantification were 1.9 µg/mL and 5.7 µg/mL respectively. The percentage assay of pitavastatin was 101.1%. The results of study showed that the proposed RP-HPLC method is simple, rapid, precise and accurate which is useful for the routine determination of pitavastatin in bulk drug and in its pharmaceutical dosage forms.

KEYWORDS: HPLC; Pitavastatin; Method validation; RP-HPLC; LOQ.

Introduction

Pitavastatin ((3R,5S,6E)-7-[2-cyclopropyl-4-(4-fluoro-phenyl) quinolin-3-yl]-3,5-dihydroxyhept-6-enoic acid) (Fig 1) is a novel synthetic statin and an inhibitor of hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase. It is used as the calcium salt in the treatment of hyperlipidemia.

![Fig. 1. Chemical structure of pitavastatin.](image)

The plasma concentration of pitavastatin acid and lactone, atorvastatin acid and lactone, and 2-hydroxy atorvastain acid were quantified by the liquid chromatography-mass spectrometry methods (Ando et al., 2005). LC-MS/MS method with electron spray ionization (ESI) was developed for the simultaneous determination of pitavastatin and its lactone in human plasma and urine (Tian et al., 2008). HPLC and UV spectroscopy methods have been reported for pitavastatin calcium in tablet formulation by (Panchal et al., 2009). This study developed a method with different mobile phase containing acetonitrile-water-triethyl amine (80:19.8:0.2 v/v/v).

Literature survey reveals few chromatographic methods for the determination of pitavastatin (Fujino et al., 2001; Hui et al., 2005). Only one procedure has been reported for the estimation of pitavastatin from Pharmaceutical dosage forms. The availability of an HPLC method with high sensitivity and selectivity will be very useful for the determination of pitavastatin in Pharmaceutical formulations. The aim of the study was to develop a simple, precise and accurate reverse-phase HPLC method for the estimation of pitavastatin in bulk drug samples and in pharmaceutical dosage form.

Materials and Methods

Pitavastatin was obtained as gift sample from Spectrum Pharma Research Solutions. Potassium dihydrogen orthophosphate and orthophosphoric acid were of analytical grade supplied by Rankem, Mumbai. Acetonitrile and water used were of HPLC grade. Commercially available pitavastatin tablets [(Pivasta 1 Zydis (Cardiva)] were procured from local pharmacy market.

Instrument

Quantitative HPLC was performed on liquid chromatography, Waters separation module 2695 equipped with Quaternary Pump and detector 2996 PDA. A Phenomenex Luna C18 (150×6.6 mm i.d, 5 µm particle size) was used. The HPLC system was equipped with Empower V 2.1 software.