Original Article

Validated spectrophotometric methods for the simultaneous determination of telmisartan and atorvastatin in bulk and tablets

Abstract

Aim: Three simple, accurate, and reproducible spectrophotometric methods have been developed and validated for simultaneous estimation of telmisartan (TELM) atorvastatin (ATV) in combined tablet dosage form. **Materials and Methods:** The first method is based on first-order derivative spectroscopy. The sampling wavelengths were 223 nm (zero crossing of TELM) where ATV showed considerable absorbance and 272 nm (zero crossing of ATV) where TELM showed considerable absorbance. The second method Q-analysis (absorbance ratio), involves formation of Q-absorbance equation using respective absorptivity values at 280.9 nm (isobestic point) and 296.0 nm (λmax of TELM). The third method involves determination using multicomponent mode method; sampling wavelengths selected were 296.0 and 246.9 nm. **Results**: TELM and ATV followed linearity in the concentration range of 5–40 and 4–32 μg/ml for method I, 5–30 μg/ml and 2–24 μg/ml for method II and III, respectively. Mean recoveries for all three methods were found satisfactory. All methods were validated according to International Conference on Harmonization Q2B guidelines. **Conclusion:** The developed methods are simple, precise, rugged, and economical. The utility of methods has been demonstrated by analysis of commercially available tablet dosage form.

Key words: Absorbance ratio, atorvastatin, derivative spectroscopy, multicomponent analysis, telmisartan

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INTRODUCTION

Telmisartan (TELM) chemically 4′-[(1, 4′-Dimethyl–2′-propyl-[2, 6′-bi-1H-benzimidazol]-1′-yl) methyl]-[1, 1′-biphenyl]-2-carboxylic acid, is a nonpeptide angiotensin-II receptor antagonist, which selectively and insurmountably inhibits angiotensin-II AT1 receptor subtype without affecting other systems involved in cardiovascular regulation [Figure 1]. Atorvastatin (ATV) calcium chemically [R-(R*, R*)]-2-(4-fluorophenyl)-β, δ, dihydroxy-5-(1-methyl ethyl)-3-phenyl-4 [(phenyl-amino)-carboxyl]-1 H-pyrrole-1-heptanoic acid calcium salt is a second generation synthetic 3-hydroxy-3-methyl glutaryl-coenzyme A (HMG-CoA) reductase inhibitor, which decreases *de novo* cholesterol synthesis [Figure 2]. ATR decreases the amount of low-density lipoprotein (LDL)-cholesterol in blood, reduces blood levels of triglycerides and slightly increases levels of high-density lipoprotein (HDL)-cholesterol.[1-3] Literature survey reveals several methods for determination of TELM and ATV individually in biological fluids and formulation like HPLC, TLC-densitometric, and derivative spectrophotometry.[4-14] HPLC and HPTLC methods were reported for determination of TELM and ATV in combination.[15,16]

However, due to lack of such equipments in many resources-limited countries and high costs of HPLC grade solvents and columns, alternative methods are needed to facilitate and increase the speed of analysis, with relatively few costs. Spectrophotometry continues to be very popular, because of its simplicity, versatility and low cost. In this paper, a successful attempt has been

made to estimate two drugs simultaneously by UV spectrophotometric analysis. This paper describes three simple, rapid, accurate, reproducible, and economical methods for simultaneous determination of TELM and ATV in tablet formulation using first order derivative, Q-analysis, and multicomponent mode method.

MATERIALS AND MEHODS

Chemicals and reagents

Pharmaceutical grade TELM and ATV were supplied by Atoz laboratories, Chennai, India. Tablets labeled to contain 40 mg TELM and 10 mg ATV were manufactured and supplied by Dr. Reddy's Laboratories Ltd., Hyderabad, India. Methanol (analytical grade) was obtained from Merck Chemicals, Mumbai, India.

Equipment

A double beam UV/Visible spectrophotometer (Schimadzu, Japan) model UV-1700 with quartz cell 1 cm path length, connected to HP computer version 2.21 was used. Shimadzu balance (AUW-120D) was used for all weighing.

Standard stock solution

Standard stock solution (1.0 mg/ml) each of TELM and ATV was separately prepared by dissolving in methanol. These stock solutions were further diluted to get working standard stock solutions (each 100 μg/ml).

Sample preparation

Twenty tablets were accurately weighed and tablet powder equivalent to 100 mg of TELM was transferred into a 100 ml volumetric flask; 50 ml methanol was added, dissolved and completed to 100 ml with same solvent. The resulting solution is filtered through Whatmann filter paper, discarding first few millilitres. From the above solution suitable aliquots were completed to volume with methanol to get concentration in the ratio of 4:1, taking into consideration its amount present in combined tablet formulation.

Method I

First order derivative spectroscopy

The first derivative (D1) spectra of TELM and ATV was found to show zero crossing point and assisted in their simultaneous estimation [Figure 3]. First

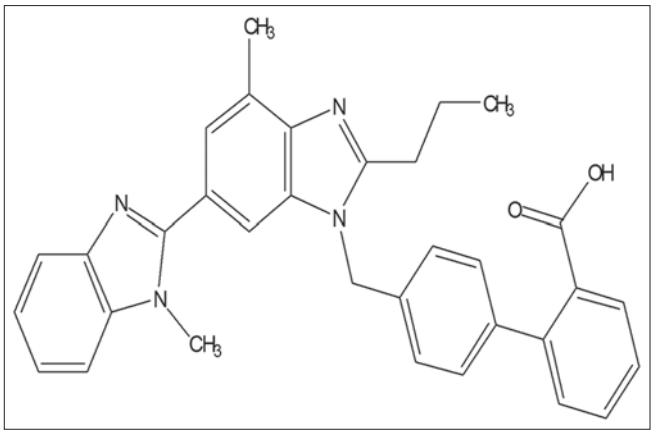

Figure 1: Chemical structure of telmisartan

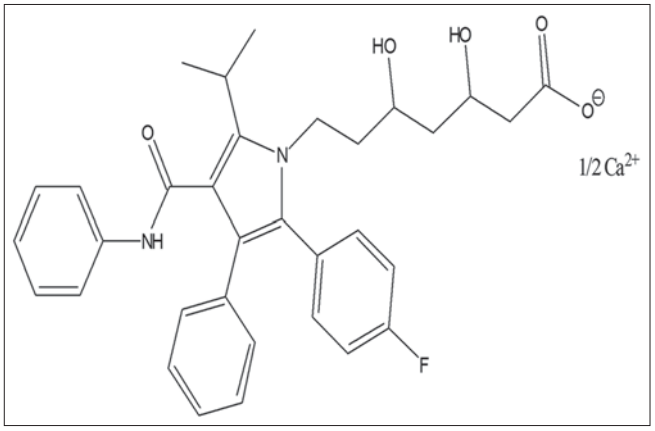

Figure 2: Chemical structure of atorvastatin calcium

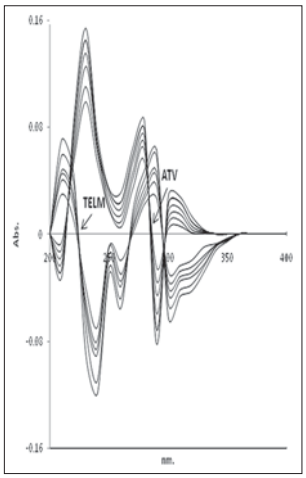

Figure 3: First order derivative spectra of TELM and ATV for different linear concentrations

derivative values of TELM and ATV were measured at 272 and 223 nm. Calibration curves were constructed by analysis of working standard solutions of TELM and ATV with six different concentrations in the range between 5–40 and 4–32 μg/ml for TELM and ATV, respectively. Each concentration was analyzed