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DEVELOPMENT OF UV-VISIBLE SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF ATAZANAVIR IN TABLET DOSAGE FORM

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ABSTRACT

The method is simple, accurate and precise for estimation of Atazanavir in bulk drug by UV-VIS spectrophotometry. The Atazanavir is an anti-HIV drug. Atazanavir is soluble in water, methanol, chloroform, ethanol, acetonitrile, 0.1 N NaOH and 0.1 N HCl. New method has been developed for estimation of Atazanavir in tablet dosage form using 0.1 N HCl. The λ_{max} was found to be 300 nm in 0.1 N HCl. The Beers-Lamberts law was obeyed in the range of 5-30 µ/mL with a regression coefficient 0.992. Accuracy of proposed method was obtained by recovery studies and the results are obtained on the basis of statistical parameters as per ICH guidelines. The proposed method is found to be accurate, precise, reproducible and economical and it can be employed for routine quality control of Atazanavir in its tablet dosage form.

Key words: Atazanavir (ATZ), 0.1 N HCl, UV-VIS spectrophotometry.

INTRODUCTION

Chemically Atazanavir[1] is methyl N-[(1S)-1-{[(2S, 3S)-2-hydroxy-4-[(2S)-2-[(methoxy carbon)amino]-3,3-dimethyl-N'{[4-(pyridine-2-yl)phenyl}butanehydrazido]-1-phenylbutan-2-yl]carboxy}-2,2-dimethylprpryl]carbamate. It is white amorphous powder, an antiviral drug and soluble in water, 0.1 N hydrochloric acid, 0.1 N sodium hydroxide, ethanol, methanol, chloroform and acetonitrile. Literature survey revealed that no method has been developed for estimation of Atazanavir in bulk drugs and tablet dosage form by using UV-Spectrophotometer.

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An attempt was made to develop analytical UV-Visible spectroscopic method for estimation of Atazanavir in tablet dosage form. Here, the present work reports simple, accurate and precise spectrophotometric method for the estimation of Atazanavir in tablet dosage form.

EXPERIMENTAL

Materials and methods

Instrument

A double-beam Shimadzu 1800 UV-Visible spectrophotometer, with spectral bandwidth of 2 nm, wavelength accuracy ± 0.5 nm and a pair of 1-cm matched quartz cells was used to measure absorbance of the resulting solution. Weighing was done on electronic balance Shimadzu AUX 220. Atazanavir gift sample was obtained from Lupin Pharmaceuticals Ltd.

Procedure

Preparation of standard drug solutions

The standard stock solution of ATZ was prepared by taking 50 mg of drug in 50 mL volumetric flask and the volume was made up with 0.1 N HCl to give the concentration of 1000 µg/mL. out 10 mL of this solution was pipetted in 100 mL volumetric flask and made upto the volume with 0.1 N HCl.

Further 0.5 mL, 1.0 mL, 1.5 mL, 2.0 mL, 2.5 mL and 3.0 mL from this stock solution was pipetted out in 10 mL volumetric flask and the volume was made up with 0.1 N HCl to give the concentration of 5 µg/mL, 10 µg/mL, 15 µg/mL, 20 µg/mL, 25 µg/mL and 30 µg/mL, respectively. All the solutions were scanned in the range of 200 nm to 400 nm. The absorbance was observed at 278 nm for all dilutions. The calibration curve was determined at this wavelength. The precision and recovery studies were observed by calculating the observations.

Preparation of tablet solution

The tablet stock solution of ATZ was prepared by taking ATZ equivalent to 50 mg in 50 mL volumetric flask and the volume was made up with 0.1 N HCl to give the concentration of 1000 µg/mL. 10 mL of this solution was pipetted out in 100 mL volumetric flask and the volume was made up with 0.1 N HCl to give the concentration 100 µg/mL.

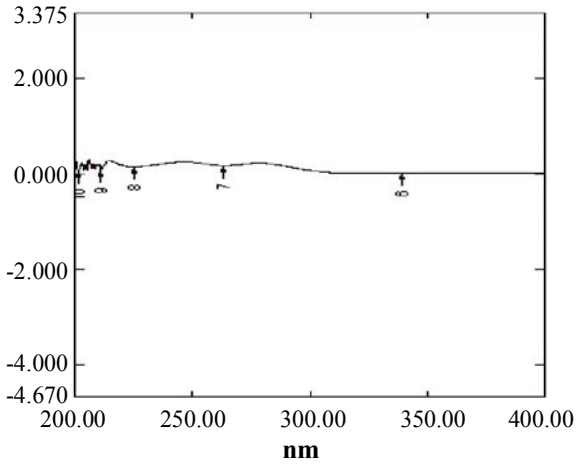

Fig. 1: Spectra of Atazanavir

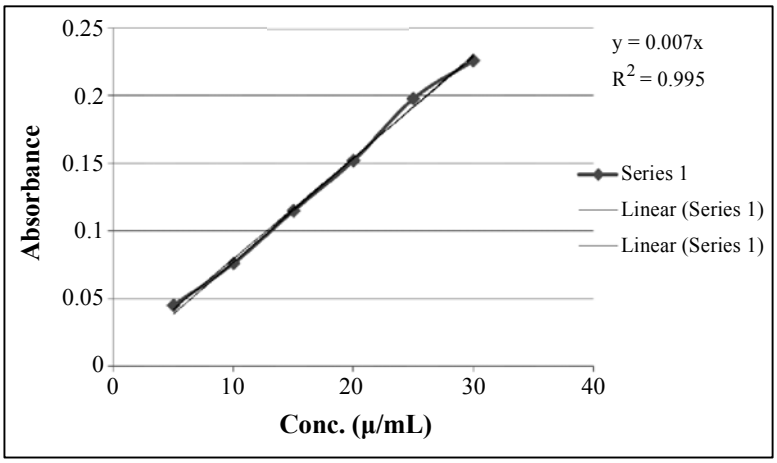

Fig. 2: Calibration curve for Atazanavir

1.0 mL from this stock solution was further pipetted out in different 10 mL volumetric flask and 0.5 mL, 1.0 mL and 1.5 mL from standard stock solution was added for 50, 100 and 150% recovery and the volume made up with 0.1 N HCl. All the solutions were scanned in the range of 200 nm to 400 nm. The absorbance was observed at 278 nm for all dilutions. The precision and recovery studies were observed by calculating the observations as shown in the Table 1.

Validation[2-4]

The method was validated with respect to linearity, accuracy, precision and selectivity.

To ascertain the accuracy of proposed methods, recovery studies were carried out by standard addition method at three different levels (50%, 100% and 150%). Percent recovery for ATZ, by all three methods, was found in the range of 98.00% to 102.00%. The linearity of measurement was evaluated by analyzing different concentrations of the standard solution of ATZ. Beer-Lambert's concentration range was found to be 5-30 µg/mL for all the three methods. The reproducibility of the proposed method was determined by performing drug at different time intervals (morning, afternoon and evening) on same day (Intra-day assay precision) and on three different days (Inter-day precision). Result of intra-day and inter-day precision is expressed in % RSD.

RESULTS AND DISCUSSION

The method is convenient and accurate for analysis of Atazanavir in its pharmaceutical dosage form. Absorbance maxima of Atazanavir at 278.0 nm. Linearity was observed in the concentration range of 5-30 µg/mL for this method. Percent recovery for ATZ in drug was found in the range of 98.00% to 102.00%. Standard deviation and coefficient of variance for five determinations of drug was found to be less than ± 2.0 indicating the precision of the method. Accuracy of proposed method was obtained by recovery studies and the results are expressed as % recovery. Based on the results obtained, it was found that the proposed method is accurate, precise, reproducible, economical and can be employed for routine quality control of Atazanavir in its bulk drug. The results are shown in the Table 1.

Table 1: Statistical validation of Atazanavir

Name of the drug	% Recovery level	Mean	Standard deviation	% Relative standard deviation	Standard error
Atazanavir	50	98.26	0.87	87.00	0.5023
	100	98.56	0.688	68.8	0.3972
	150	98.81	0.773	77.3	0.4463

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