Academic Sciences International Journal of Pharmacy and Pharmaceutical Sciences

ISSN- 0975-1491 Vol 4, Suppl 1, 2012

Research Article

TWO SIMPLE EXTRACTIVE SPECTROPHOTOMETRIC METHODS FOR THE ESTIMATION OF TELMISARTAN IN PHARMACEUTICAL FORMULATION USING BROMOTHYMOL BLUE AND ORANGE -G

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Received: 17 Oct 2011, Revised and Accepted: 25 Nov 2011

ABSTRACT

Two simple extractive spectrophotometric methods have been developed for the estimation of telmisartan in pure and pharmaceutical dosage formulations by using bromothymol blue and orange G dyes. These methods are based on the formation of ion association complexes of the drug with dyes in acidic phthalate buffer of pH 2.8 followed by their extraction in chloroform. The absorbance of the chloroform layer for each method was measured at its appropriate λ max against the reagent blank. These methods have been statistically evaluated and are found to be precise and accurate.

Keywords: Telmisartan, Bromothymol blue and Orange G dyes.

INTRODUCTION

Telmisartan is an angiotensin II receptor antagonist used in the management of hypertension. Chemically telmisartan is 2-(4-{[4-methyl-6-(1-methyl-1*H*-1,3-benzodiazol-2-yl)-2-propyl-1*H*-1,3-benzodiazol-1-yl]methyl}phenyl)benzoic acid.

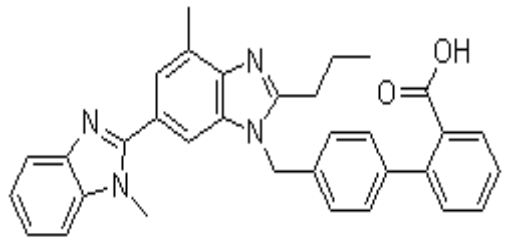

Fig. 1: Chemical structure of telmisartan

Only few analytical methods [1-5] have been reported in the literature for the estimation of telmisartan in bulk and in pharmaceutical formulations. The objective of the present work was to develop simple spectrophotometric methods with greater precision and accuracy that can be used for the routine quality control analysis of the formulations containing telmisartan.

MATERIALS AND METHODS

Materials and method

Instrument

A Shimadzu uv-1800 spectrophotometer with 1cm matched quartz cells was used for spectral and absorbance measurements. Systronics µ processor digital pH meter 361 was used for pH measurements and Metler balance to weigh the samples.

Chemicals and Reagents

Telmisartan was obtained as gift samples from M/S Aurobindo Pharmaceuticals Ltd., Hyderabad. All the chemicals used were of analytical grade and procured from Qualigens India Ltd. All the solutions were freshly prepared with double distilled water and for the present study commercial tablets of telmisartan [Telma H, Glenmark] containing 40 mg were procured from local drug store.

Preparation of reagents

Bromo thymol Blue (0.1% w/v) BTB: 100 mg of BTB was weighed accurately and transferred to 100 mL of volumetric flask and dissolved by adding distilled water and diluted up to the mark. The solution was treated with chloroform to remove any chloroform soluble impurities if present.

Orange G(0.2% w/v): 200 mg of orange G was weighed accurately and transferred to 100 mL of volumetric flask and dissolved by adding distilled water and diluted up to the mark. The solution extracted with chloroform to remove any chloroform soluble impurities if present.

Acid phthalate buffer [2.8]: 50 mL of 0.2 M potassium hydrogen phthalate taken in 200 mL volumetric flask and added 53 mL of 0.2M HCl and then volume was made up to the mark with distilled water.

Sodium hydroxide solution (0.01): 40 mg of sodium hydroxide was accurately and transferred to 100 mL volumetric flask. Dissolved with few mL of distilled water and made up to the mark.

Preparation of standard drug solution: 100 mg of telmisartan was accurately weighed and dissolved in 100 mL of 0.01 N sodium hydroxide solution in a standard volumetric flask to obtain a stock solution of 1 mg/mL.

Spectral characteristics

The drug solution after treating with buffer and dye solutions, chloroform was added to extract the colored species. The organic layer was scanned between 400 – 600 nm against reagent blank and the maximum absorbance was found to be 412 nm, for method A and 482 nm for method B.

Procedure for calibration curve

Aliquots of standard solution (0.2 to 0.8 mL and 0.5 – 2.0 mL of 1 mg/mL for method A method B) were placed separately into a series of 60 mL separating funnels. A volume of buffer solution (2.5 mL and 2.0 mL of pH 2.8 for method A method B) and dye solution (4.0 mL of BTB for method A, 1.5 mL of Orange -G for method B) were added respectively. The total volume of aqueous phase in each funnel was adjusted to 10 mL with distilled water. Then 10 mL of chloroform was added to each separating funnel and the contents were shaken for 2 minutes and allowed to separate. The organic layer was collected and the absorbance was measured at appropriate λmax (412 nm for method A 482 nm for method B) against the reagent

blank. All the colored species were stable for 1 hour. Calibration curves were plotted by taking concentration on the X- axis and absorbance on the Y- axis (Fig 2a and 2b). The amount of drug in sample solutions was obtained from Beer- Lamberts plot.

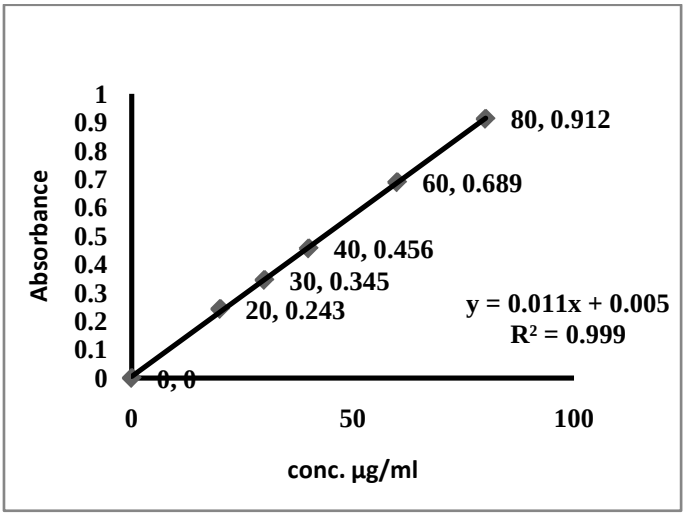

Fig. 2a: Calibration curve of telmisartan with BTB

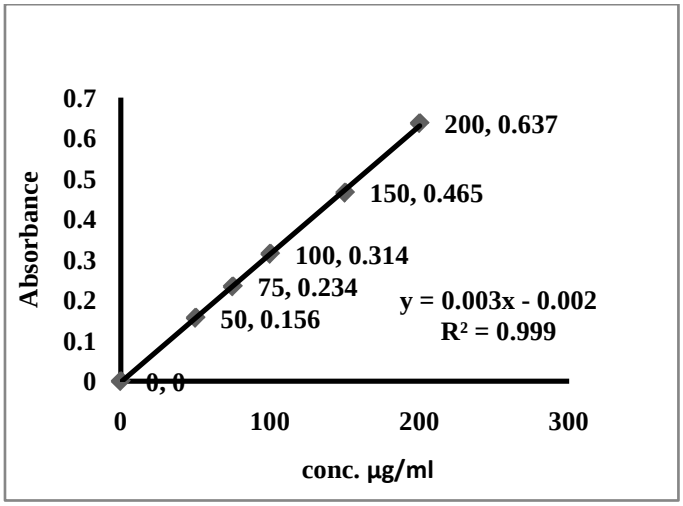

Fig. 2b: Calibration curve of telmisartan with orange - G

Assay

Twenty tablets were accurately weighed and an average weight was calculated. The tablets were powdered and the powder equivalent to 100 mg of drug was accurately weighed and 5.0 mL of 0.01 N sodium hydroxide solution was added to it to dissolve the drug. The volume was made up to 100 mL with distilled water and filtered through whatmann filter paper. Appropriate aliquots of drug solution were taken for both the methods into two 60 mL separating funnels for color development and experiment was carried out as described earlier. The amount of drug present in the tablet was calculated from the corresponding calibration curve.

Recovery experiment

To study the accuracy and precision of the methods, recovery experiments were carried out using standard addition method. The recovery of added standard was studied at 3 different levels i.e. 80%, 100%, 120% of labeled claim, analyzed in a similar manner as described earlier. Each set of addition was repeated 6 times and the % recovery for the added standard was calculated.

RESULTS AND DISCUSSION

Telmisartan was found to yield clear colored product with BTB and orange - G, followed by their extraction into chloroform having absorption maxima of 412 nm and 482 nm. The colored products were due to ion-pair formation of the drug with dye. The linearity of detector response for method I and II were 20 – 80 µg/ml and 50 – 200 µg/mL and sensitivity parameters are shown in Table 1.

The regression analysis was carried out to determine the relationship between the dependable variable (absorbance) and independent variable (concentration). Low values of % RSD indicate high precision of the proposed methods and the data is presented in Table 2.

Table 1: Optimum conditions of telmisartan of the proposed methods

Reagent	Method I	Method II
Drug solution taken (µg/mL)	20 - 80	50 - 200
Volume of pH 2.8 buffer (mL)	2.5	2.0

Volume of dye solution (mL)	4.0	1.5
λmax (nm)	412	482

Table 2: Optical and regression characteristics of the proposed methods

Parameters	Method I	Method II
λmax (nm)	412	482
Beer's law limit (µg/mL)	20- 80	50 – 200
Sandel's sensitivity (mcg/cm^2/0.001 A.U)	0.0877	0.31843
Molar absorptivity mL/mol^{-1} cm^{-1}	5.868×10^4	1.616×10^4
Regression equation Y=b+ax	0.011x + 0.005	0.003x + 0.002
Intercept (b)	0.005	0.002
Slope (a)	0.011	0.003
Correlation coefficient(r^2)	0.999	0.999
Range of errorsConfidence limit with 0.05levelConfidence limit with 0.01level*%RSD	0.59350.88210.7131	0.43890.64930.5249

*Average of six determination

Commercial formulations containing 40 mg of telmisartan were successfully analyzed by the proposed methods. The values obtained by the proposed and reference methods were compared statistically by the t- test and F- test and found not to differ statistically. The % recovery values are given in Table 3. The results of recovery indicate that there is no positive or negative interference from the common excipients present in tablets.

Table 3: Assay and Recovery studies of proposed method

Name of the dosage form	Labeled amount (mg)	Content of the drug found mg [a] ± S.D		% Recovery by the proposed method
		Proposed method	*Reference method	
Telmisartan	40	40.012.±0.6171	40.157±0.5112	100.01
Method I		F=0.7232		
		T=0.6589		
Method II	40	40.02±0.0715	40.157±0.5112	100.08
		F=0.7744		
		T=0.2253		

[a] Average ± standard deviation of eight determinations, the t and F- values referred to comparison of proposed method with reference method. Theoretical values at 95% confidence limits t = 2.365 and F=4.88

*0.01 N sodium hydroxide solution was used as solvent for reference UV method for both the methods

CONCLUSION

The proposed extractive colorimetric methods for the estimation of drug are selective, cheap, accurate and precise and can be employed for the routine quality control analysis and quantitative determination of drug from its pharmaceutical preparations.

ACKNOWLEDGEMENT

Authors wish to acknowledge the support received from Principal S.K. Gulati, Head of the department of chemistry K. Rama Subha Reddy and to the management of Sarojini Naidu Vanita Pharmacy Maha Vidyalaya, Hyderabad for providing facilities. The authors also acknowledge to M/S Aurobindo Pharmaceuticals Ltd. Hyderabad, India for providing pure drug gift sample.

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