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NEW FACILE AND SENSITIVE METHODS FOR THE ESTIMATION OF TELMISATRAN

Y. KRANTI KUMAR, K. VANITHA PRAKASH* and GUTHI LAVANYA

Department of Pharmaceutical Analysis, SSJ College of Pharmacy, V. N. Pally, Gandipet,
HYDERABAD – 500075 (A.P.) INDIA

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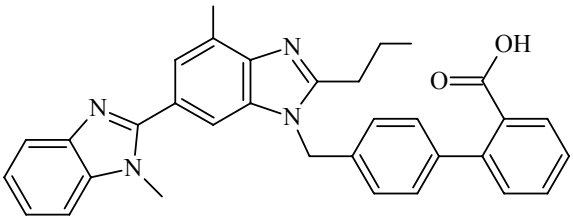
ABSTRACT

Two simple, accurate, rapid and sensitive Methods (A and B) have been developed for the estimation of Telmisatran in its pharmaceutical dosage form. The method A is based on the formation of yellow colored chromogen, due to reaction of Telmisatran with Alizarin red dye. The formation of ion association complexes of the drug with dyes in acidic phthalate buffer of pH 2.8 was followed by their extraction in chloroform, which exhibits λ_{max} at 423 nm. The method B is based on the formation of golden yellow colored chromogen due to reaction of Telmisatran with Bromophenol blue dye. The formation of ion association complexes of the drug with dyes in acidic phthalate buffer of pH 2.8 was followed by their extraction in chloroform, which exhibits λ_{max} at 416 nm. The absorbance-concentration plot is linear over the range of 100-150 mcg/mL for method A and 20-50 mcg/mL for method B. Results of analysis for all the methods were validated statistically and by recovery studies. The proposed methods are precise, accurate, economical and sensitive for the estimation of Telmisatran in bulk drug and in its tablet dosage form.

Key words: Telmisatran, Alizarin red, Bromophenol blue.

INTRODUCTION

Telmisartan is an angiotensin II receptor antagonist used in the management of hypertension. Chemically telmisartan is 2-(4-{[4-methyl-6-(1-methyl-1H-1,3-benzodiazol-2-yl)-2-propyl-1H-1,3-benzodiazol-1-yl]methyl}phenyl)benzoic acid. Only few analytical and spectrophotometric methods are in the literature for the estimation of Telmisartan in bulk and in pharmaceutical formulations[1-7]. 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.



Structure of telmisatran

Available online at www.sadgurupublications.com
*Author for correspondence; E-mail: prakash.karnam@gmail.com; Mo.: 9885355562

EXPERIMENTAL

Instrument

Elico double beam Ultra Violet-Visible double beam Spectrophotometer SL-244 with 1 cm matched quartz cells was used for all spectral measurements.

Preparation of reagents

All chemicals used were of analytical reagent grade.

(i) **Preparation of Alizarin red (0.1% w/v):** 100 mg of Alizarin red was weighed accurately and transferred into a 100 mL volumetric flask, dissolved by adding distilled water and made up to the mark.

(ii) **Preparation of Bromophenol blue solution:** 100 mg of Bromophenol blue was weighed accurately and transferred into a 100 mL volumetric flask, 0.5 mL of 0.1 M NaOH was added with gentle heating. Then 20 mL of ethanol was added to produce 100 mL.

(iii) **Preparation of acid pthalate buffer (2.8):** 50 mL of 0.2 M potassium hydrogen phthalate was taken in 200 mL volumetric flak and 28.9 mL of 0.2M HCl was added. Then volume was made up to the mark with distilled water.

(iv) **Preparation of standard solution of 100 mg in 100 mL stock solution:** 100 mg of bulk drug (Telmisatran) was weighed, dissolved in 0.01 N sodium hydroxide and made up to 100 mL to give a stock solution of 1 mg/mL.

Assay procedure

Method A: Aliquots of standard drug solution of Telmisatran (1.0-1.5 mL) of (100 mcg/mL) were taken and transferred into series of 100 mL separating funnels. To each funnel, 2 mL of buffer solution (pH 2.8) and 2 mL of Alizarin red was added. Then 5 mL of chloroform was added to each separating funnel and the contents were shaken for 2 minutes and allowed to separate. The absorbances of the chloroform solutions were measured at 423 nm against reagent blank, and the calibration curve was plotted. Similarly, the absorbance of the sample solution was measured, and the amount of Telmisatran was determined by referring to the calibration curve.

Method B: Aliquots of standard drug solution of Telmisatran (0.2-0.5 mL) of (100 mcg/mL) were taken and transferred into series of 100 mL separating funnels. To each funnel, 1.5 mL of buffer solution (pH 2.8) and 2.5 mL of Bromophenol blue was added. Then 5 mL of chloroform was added to each separating funnel and the contents were shaken for 2 minutes and allowed to separate. The absorbances of the chloroform solutions were measured at 416 nm against reagent blank, and the calibration curve was plotted. Similarly, the absorbance of the sample solution was measured, and the amount of Telmisatran was determined by referring to the calibration curve.

Preparation of sample solution

20 Tablets of Telmisatran were accurately weighed and powered. Tablet powder equivalent to 100 mg of Telmisatran was dissolved in 5.0 mL of 0.01 N sodium hydroxide and made up to 100 mL with distilled water, sonicated for 15 min and filtered. The solution was suitably diluted and analyzed as given under the assay procedure for bulk sample. The analysis procedure was repeated three times with Tablet formulations and the results of analysis for the method are shown in Table 2.

Recovery studies: To ensure the accuracy and reproducibility of the results obtained, known concentration of the pure drug solution was added to the previously analyzed formulated solution samples. These samples were reanalyzed by the proposed method and recovery studies was also preformed. The percentage recoveries, thus obtained for method is given in Table 2.

Table 1: Optical characteristics and precision data

Parameter	Values Method A	Values Method B
λ_{max} (nm)	423	416
Beers law limit (µg/mL)	100-150	20-50
Molar absorbtivity (L/mol.cm)	$0.58x10^4$	$1.62x10^4$
Sandell's sensitivity (µgm/cm^2/0.001 Absorbance unit)	1.7241	0.6172
Regression equation		
Slope (m)	0.011	0.016
Intercept (c)	0.736	0.011
Correlation coefficient	0.991	0.996
Precision (% Relative standard deviation)	0.033	0.047
Standard error of estimate	0.0221	0.0144

Table 2: Assay of Telmisatran in tablet formulations

Tablet formulation	Labelled amount (mg)		*Amount obtained (mg) by proposed		% **Recovery by the proposed method	
	Method A	Method B	Method A	Method B	Method A	Method B
1	100	100	97.8 ± 2	98.3 ± 2	98.73 ± 2	98.92 ± 2
2	100	100	98.5 ± 1	99.2 ± 1	99.01 ± 1	99.7 ± 1
3	100	100	99.7 ± 1	99.8 ± 1	101.1 ± 1	101.37 ± 1

*Average of three determinations

**After spiking the sample

RESULTS AND DISCUSSION

The optimum conditions were established by varying one parameter at a time, keeping the others fixed and observing the effect on absorbance of chromogen.

In the present study, the methods A and B involve the formation of ion association complexes of the drug with dyes Alizarin red and Bromophenol blue, respectively with acid phthalate buffer of pH 2.8 followed by their extraction in chloroform, which gives yellow colored chromogens, having absorbance maximum at 423 nm and 416 nm, respectively. Stability studies of the developed chromogens were carried out by measuring the absorbance values at time intervals 15 min for 2 hrs, and the yellow colored

chromogens were found to be stable for more than 2 hrs at room temperature. The linearity was found to be in the concentration range of 100-150 mcg/mL and 20-50 mcg/mL for methods A and B, respectively.

Statistical analysis was carried out and the results were found to be satisfactory. Relative standard deviation values were low, indicating the reproducibility of the proposed methods. Recovery studies were close to 100% that indicates the accuracy and precision of the proposed methods. The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity, Sandell's sensitivity and other parameters are presented in Table 1.

This new procedure for the spectrophotometric determination of Telmisatran described here is simple, rapid, cost-effective with high accuracy and precision, when compared with previously reported procedures. It could find application as a convenient technique for the in-process control analysis of Telmisatran in bulk and its pharmaceutical formulations.

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