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Extractive spectrophotometric method for the estimation of telmisartan in tablets

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ABSTRACT

A simple, rapid, sensitive, precise and economic spectrophotometric method has been developed for the estimation of telmisartan in tablet formulation. During the course of study, it was observed that the acidic solution of the drug formed colored ion-association complex with Bromocresol green (BCG) which was soluble in chloroform. This property of the drug was followed for the development of colorimetric method for analysis of the drug. The complex of telmisartan with BCG showed λ_{max} at 440 nm. This method was validated statistically. Recovery studies gave satisfactory results indicating that none of common additives and excipients interfere the assay method. The proposed method was found to be simple, accurate and reproducible that was successfully applied for the analysis of tablet formulation.

Key words: Telmisartan, Bromo Cresol Green, Extractive spectrophotometry.

INTRODUCTION

Telmisartan is a type of angiotensin II receptor blocker [1] that is prescribed for the treatment of high blood pressure. It is chemically 2-[4-{(4-methyl-6-(1-methyl benzimidazole-2-yl)-2-propyl-benzimidazole-1-yl}methyl]phenyl benzoic acid with a molecular formula , $C_{33}H_{30}N_4O_2$, and molecular structure as follows. The therapeutic importance of this drug has prompted the development of many methods for its assay. This drug is not official in any pharmacopoeia. Several methods have been reported for the analysis of telmisartan in pharmaceutical dosage forms by spectrophotometric methods[1-2], HPLC[3-7] methods, HPTLC[8] methods and Polography[9]. As there is no extractive spectrophotometric method for the analysis of telmisartan the proposed method was developed and can be used for routine analysis.

EXPERIMENTAL

Apparatus

An ELICO (SL164) double beam UV/VIS spectrophotometer equipped with 10mm matched quartz cells was used in the present investigation. A sartorius analytical balance was used for weighing.

Reagents

All chemicals used were of analytical reagent grade and double distilled water was used throughout the analysis. BCG was supplied by S.D. Fine Chem. India. Ltd. Aqueous solution of BCG (0.1%) and buffer solutions [10] from pH 2.2 to 4 were prepared. Telmisartan was generously supplied by Glenmark pharmaceuticals Ltd. The commercially available tablets were procured from local market labeled to contain 40 mg telmisartan/tablet.

Preparation of standard solutions

About 100 mg of accurately weighed telmisartan was dissolved in 20 ml of chloroform and volume made upto 100ml with chloroform to get 1 mg/ml concentration of standard solution.

Procedure

Varying quantities of working standard solution representing from 0.5 to 2.5 mg/ml of telmisartan, 1 ml of buffer and 4 ml of dye solution (pH 3.8) were added and final volume made up with chloroform and transferred into separating funnel,containing 5ml of chloroform and the contents were shaken for 2 minutes, allowed to separate and the absorbance of the chloroform layer was measured at 440 nm. Then calibration curve was plotted. The sample solutions prepared were also treated in similar manner and the exact amount of telmisartan was deduced from calibration graph.

Optimization of conditions

Condition under which reaction of telmisartan with dye fulfils the requirements was investigated. All conditions studied were optimized at room temperature (32±2°C).

Selection of suitable pH buffer solution

Buffer solutions of different pH (2.2, 2.8 and 3.8) were prepared. A 2 ml portion of standard solution was pipeted out and added to three separating funnels.1 ml of buffer and 4 ml of BCG were added to each separating funnel and shaken with three quantities each of 2ml of chloroform. Later the extracts were taken into 10 ml volumetric flasks and volume was made up, the absorbances were measured at 440nm. It was found that with BCG, the drug gave maximum absorbance at pH 3.8 (Table 1)

Stability study of drug dye complexes

A 2 ml portion of the drug with concentration 1 mg/ml was pipetted out into a separating funnel. 1ml of chloroform and 4ml of dye were added to each, shaken well for 2 minutes and extracted with three quantities each with 2ml of chloroform. Later the extracts were taken into 10 ml volumetric flasks and volume was made up and the absorbances were measured periodically at an interval of 15, 30, 60, 90 and 120 minutes at 440 nm, and it was found that BCG drug complex was stable for 2 h (Table-1).

Procedure for pharmaceutical formulation

Twenty tablets were accurately weighed and powdered. The tablet powder equivalent to 40 mg of telmisartan was extracted with chloroform. This solution was suitably diluted and then preceded as described above for pure drug. The content of the tablets was determined either from the calibration curve or using the regression equation.

RESULTS AND DISCUSSION

During the course of study, it was observed that acidic solution of the drug formed colored ion-association complexes with Bromocresol green which were soluble in chloroform. This property of the drug was followed for the development of colorimetric method for analysis of the drug. The complex of telmisartan with BCG showed λ_{max} at 440 nm. The method commonly is used in the

Table 1: Optimisation of parameters

Time Min	Absorbance BCG-Drug complex at different pH		
	2.2	**2.8**	**3.8**
0	0.5565	0.5601	1.0139
30	0.5416	0.5506	1.0217
60	0.5367	0.5489	1.0218
90	0.5304	0.5464	1.0217
120	0.5288	0.5311	1.0219

Table 2: Optical Characterstics

Parameters	
λ_{max},nm	440
Beer's law limits, mg/ml	0.5-2.5
Molar absorptivity,(L/mol/cm)*	1.238×10^5
Sandell's sensitivity,µg/cm^2/0.001 absorbance unit*	0.0005
Regression equation y= mx+c	
Slope(m)	0.0571
Intercept(c)	0.0130
Correlation coefficient(r)	0.9882

Table 3: Statistical analysis of commercial formulations.

Brand	Amount proposed mg/tab	Amount mg/tab found*	SD*	COV*	SE*	t* calcd	t* theor
A	40	39.98±0.02	0.0410	0.0673	0.0142	0.6063	1.376
B	40	40.01±0.01	0.0408	0.1009	0.0243	0.8074	

Average of six determinations

SD=Standard deviation,COV=coefficient of variation, SE=standard error' *Theoretical `t' values are calculated at 95% confidence level for (n-1) degrees of freedom `t' (0.10,5)=1.376

Table 4: Drug recovery studies

Brand	%Recovery±S.D.*.
A	99.72±0.09
B	99.89±0.11

*Average of six determinations

S.D: Standard deviation

determination of certain amines and quarternary ammonium compounds that absorb weakly in the ultraviolet region. The proposed method was based on addition of an amine in its ionized form to an ionized dye, yield a salt (ion-pair) that was extracted into an organic solvent such as chloroform or dichloromethane. The indicator dye was added in excess and the pH of the aqueous solution was adjusted to a value where both the amine and dye were in ionized state

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