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Application of UV-spectrophotometry and first order derivative methods for determination of Telmisartan in bulk and tablets

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ABSTRACT

Two simple, rapid, sensitive and accurate 'UV- spectrophotometry' and 'first order derivative' methods have been developed for estimation of telmisartan in bulk and tablets. 0.1M NaOH was used as solvent. In, 'UV-spectrophotometry method' absorbance of the samples was recorded at 295 nm. In 'first order derivative method', the amplitude of the troughs was recorded at 311 nm. In both the methods, telmisartan follows linearity in concentration range 2-18 µg/ml. In both the methods, assay results were in good agreement with label claim. These methods were validated statistically and recovery studies.

Key words: Telmisartan; UV-Spectrophotometry; First order derivative.

INTRODUCTION

Telmisartan, 4-((2-n-propyl-4-methyl-6-(1-methylbenzimidazol-2-yl)-benzimidazol-1-yl) methyl)-biphenyl-2-carboxylic acid is a new highly selective, non-peptide angiotensin II type 1 (AT1)-receptor antagonist[1]. Telmisartan lowers blood pressure through blockade of the renin–angiotensin–aldosterone system (RAAS) and widely used in the treatment of hypertension[2].

Literature survey revealed few analytical methods which include liquid chromatography with tandem mass spectrometry[3] solid-phase micro extraction coupled to HPLC[4], HPTLC[5] method for estimation of telmisartan in pharmaceutical formulations. Telmisartan is not official in IP, BP and USP.

The present work deals with estimation of telmisartan in tablets by 'UV- Spectrophotometry' and 'first order derivative' methods.

MATERIAL AND METHODS

Reagents

All reagents used were of analytical grade.

Procedure

Preparation of Standard Stock Solution and Study of Calibration Curve

Standard stock solution containing 100 µg/ml telmisartan was prepared in 0.1M NaOH. Different aliquots were taken from the stock, diluted to 10 ml mark with same solvent to obtain series of concentrations. The solutions were scanned on spectrophotometer (Shimadazu -2450) in the UV range 200 - 400 nm. Telmisartan showed maximum absorbance at 295 nm. The same spectra were derivatised into first order derivative, using UV probe software of instrument, where $\Delta\lambda = 2$ (Fig). The amplitudes of the corresponding troughs were measured at 311 nm. In both methods, drug follows linearity in concentration range 2 - 18 µg/ml. The optical characteristic and linear regression data is summarized in table 1.

Preparation of Sample Solution

For analysis of commercial formulation; twenty tablets were weighed, mean weight determined and crushed into fine powder. An accurately weighed quantity of powder equivalent to 20 mg of telmisartan was transferred into 100 ml volumetric flask containing 30 ml 0.1M NaOH, shaken manually for 10 min., volume was adjusted to mark with same solvent and filtered through Whatmann filter paper no. 41. After appropriate

Table 1: Summary of Optical Characteristic and Regression Studies

Parameter	UV-Spectrophotometry	First order derivative
Wavelength (nm)	295	311
Linearity equation (Y= m ×+ c)	0.0549×+ 0.0040	0.002 × + 0.0002
Range (µg/ml)	2.00 - 18.00	2.00 – 18.00
Molar Absorptivity (lit/mol/cm)	2.8298×10^4	-
Correlation Coefficient (r^2)	0.9999	0.9994
S.D. of Slope	0.0004	0.0002
S.D. of intercept	0.0018	0.0002

Table 2: Results of Assay

Label claim	* Amount found (%)	
	UV-Spectrophotometry ± SD	First order derivative ± SD
Telmisartan(20 mg /tablet)	100.30 ± 0.2177	99.25 ± 1.6355

*mean of six determinations

Table 3: Summary of Accuracy, Precision and Ruggedness

Parameters	UV-Spectrophotometry	First order derivative
Accuracy [% Recovery*]	100.29	100.05
[%RSD]	0.5334	1.2783
Precision [%RSD]		
Intra-day (n = 3)	0.177 – 0.553	0.591-1.525
Inter-day (n = 3)	0.169 – 0.295	0.861 - 1.629
Repeatability (n = 6)	0.368	1.477
Ruggedness [%RSD]		
Analyst I (n = 3)	0.400	0.751
Analyst II (n = 3)	0.587	0.776

*mean of nine estimations

dilutions of sample; in 'UV- spectrophotometry method', absorbance was recorded at 295 nm and in 'first order derivative method' amplitude of the troughs was recorded at 311 nm. The concentrations of the drug were calculated from linear regression equations; results are shown in table 2.

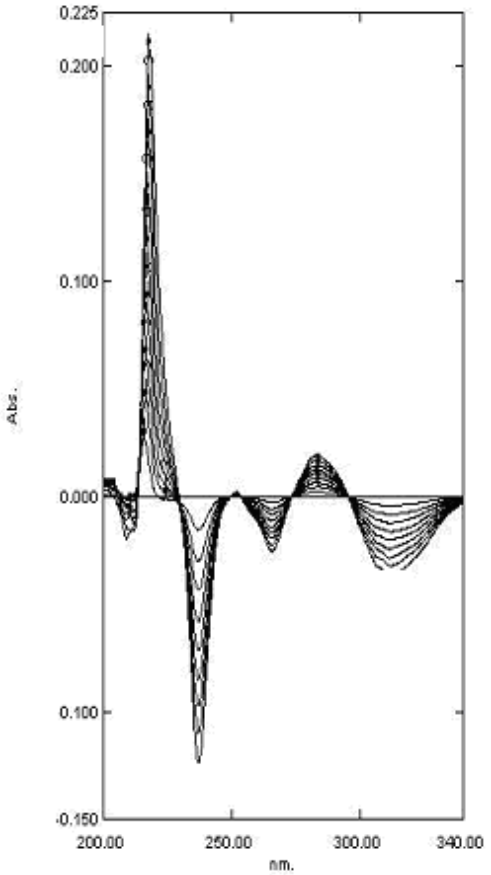

Fig. 1: Overlain first order derivative spectra of telmisartan in 0.1M NaOH

Recovery Studies

Recovery experiments were carried out by adding a known amount of drug solution to preanalysed sample at three different levels i.e.80%, 100% and 120% and re-analysed it by the proposed methods. The percentage recoveries were calculated; the results are summarized in table 3**.**

RESULTS AND DISCUSSION

Telmisartan in 0.1M NaOH showed maximum absorbance at 295 nm. In 'first order derivative' the amplitude of trough was recorded at 311 nm. In both the methods, telmisartan follows linearity in the concentration range 2 - 18 µg/ml. In both the methods amount of drug determined was in the good agreement with the label claim. The methods were validated[6] for accuracy, precision and ruggedness. Accuracy of the methods was assessed by recovery studies; as %RSD values were found to be less than 2, indicative of accuracy of the method. Precision of the methods was studied as intra-day, inter-day and repeatability. The % RSD values less than 2 indicate the methods are precise. Ruggedness of the proposed methods was studied with the help of two analysts and proven to be rugged. The results from validation studies are shown in table 3**.** Both these methods are simple, rapid, accurate and precise and can be used for routine analysis of telmisartan in tablets.

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