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Analytical Method Development of Telmisartan in Bulk and Tablet Dosage Form by UV Visible Spectrophotometry

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ABSTRACT
Three simple, precise and economical UV spectrophotometric methods have been developed for estimation of Telmisartan in bulk and pharmaceutical formulations. Telmisartan has absorbance maxima at 291 nm in zero order spectrum method (Method A), in the first order derivative spectra, showed sharp peak 291.0 nm when n = 1 (Method B). Method C is based on calculation of area under curve (AUC) for analysis of Telmisartan in the wavelength range 280 nm to 305 nm. The drug followed the Beer-Lambert's law in the concentration range of 5-50 µg/ml in all three methods. Results of the analysis, validated statistically and by recovery studies were found to be satisfactory.

Key Words: Telmisartan, Ultraviolet spectrophotometry; Zero order spectrum; first order derivative spectroscopy and Area under curve (AUC).

I. INTRODUCTION

[1,2] Telmisartan, is described chemically 4'-[(1,4'-dimethyl-2'-propyl[2,6'-bi-1H benzimidazol]-1'-yl)methyl]-[1,1'-biphenyl]-2-carboxylic acid. Telmisartan is used alone or together with other medicines to treat high blood pressure (hypertension). High blood pressure adds to the workload of the heart and arteries. If it continues for a long time, the heart and arteries may not function properly. This can damage the blood vessels of the brain, heart, and kidneys, resulting in a stroke, heart failure, or kidney failure. Telmisartan is also used to lower the risk of heart attacks or stroke who have diabetes or heart problems. It works by blocking a substance in the body that causes blood vessels to tighten. As a result, Telmisartan relaxes the blood vessels. This lowers blood pressure and increases the supply of blood and oxygen to the heart.

II. MATERIALS AND METHODS

Instrument

A Shimadzu UV/VIS double beam spectrophotometer model 1700, with matched quartz cells corresponding to 1 cm path length and spectral bandwidth of 2 nm.

Materials

Standard gift sample of Telmisartan was procured from Emcure Pharmaceuticals Ltd. Tablets of 50mg strength were procured from local pharmacy.

Solvent used

0.1N HCl was used as a solvent in the study.

Stock solution

[3] Accurately about 5mg of Telmisartan was weighed and transferred to 50 ml volumetric flask. To it 15 ml of 0.1N HCl was added to dissolve the drug completely with vigorous shaking. Then the volume was made up to the mark with the 0.1N HCl to give the drug stock solution of concentration 50µg/ml.

Preparation of standard drug dilutions: [4] From the stock solution of Telmisartan appropriate volumes were pipette out and transferred to 10 ml volumetric flasks. Keep it 15-20min ultrasonicator. The volume was made up to the mark with 0.1N HCl to give the samples of desired concentrations like 5, 10, 15, 20, 25 up to 40 µg/ ml.

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Table I: Optical characteristics and other parameters.

Parameters	Method A	Method B	Method C
λ_{Max} (nm) / wavelength range (nm)	291nm	258nm	280-305
Beer's-lambert's range (µg/ml)	5-50	5-50µg /ml	5-50µg /ml
Coefficient of correlation (r^2)	0.9973	0.998	0.998
Regression equation Y = mx +c **a. Slope (m)** **b. Intercept (c)**	0.0598 –	0.003 –	0.033 –
LOD	0.0598	0.4	0.045
LOQ	0.1036	1.33	0.1363

Where, x is concentration in µg/ml and Y is absorbance unit.
A is Zero order derivative spectrum method with n = 0.
B is First order Derivative spectrum method with n = 1.
C is the AUC method

Method A:

[5] Aliquots of standard stock solution were pipetted out and suitably diluted with 0.1N HCl to get the final concentration of 5, 10, 15, 20 up to 40 µg/ml of standard solutions. The solutions were scanned in the spectrum mode from 400 nm to 200 nm wavelength range and the zero order derivative spectra were obtained (Fig.1). [6,7] The maximum absorbance of Telmisartan was observed at 291.0 nm. The drug followed the Beer-Lambert's law in the concentration range of 5-40 µg/ml. The calibration curve was plotted as absorbance against concentration of TELMISARTAN. The coefficient of correlation (r), slope and intercept values of this method are given in Table I. The concentrations of sample solutions were determined from calibration curve.

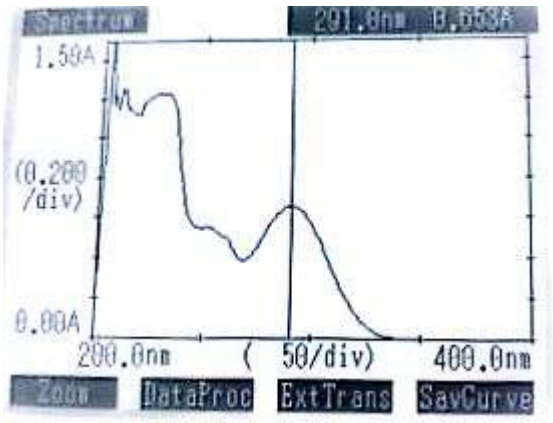

Fig. 1: Zero- order Derivative Method

Method B:

[8] The first order derivative spectra at n=1 showed a sharp peak at 258.0 nm (Fig. 2).The absorbance difference at n=1 (dA/dl) was calculated by the inbuilt software of the instrument which was directly proportional to the concentration of the standard solution. The standard drug solutions were scanned in the first order derivative spectra. A calibration curve was plotted taking the absorbance difference (dA/dl) against the concentration of TELMISARTAN . The coefficient of correlation (r), slope and intercept values of this method are given in Table I. The method was applied for determination of concentration of sample solution.

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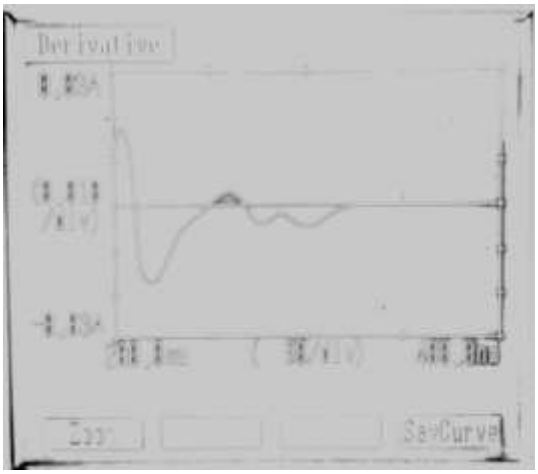

Fig. 2: First order derivative spectrum of Telmisartan perisone.

Method C:

[9,10] The AUC (Area under curve) method involves the calculation of integrated value of absorbance with respect to the wavelength between two selected wavelengths 280-305. Area calculation processing item calculates the area bound by the curve and the horizontal axis. The horizontal axis is selected by entering the wavelength range over which the area has to be calculated. This wavelength range is selected on the basis of repeated observations so as to get the linearity between area under curve and concentration. Suitable dilutions of standard stock solution (100 µg/ml) of TELMISARTAN were prepared and scanned in the spectrum mode from the wavelength range 400 nm to 200 nm (Fig. 3) and the calibration curve was plotted as AUC against concentration of TELMISARTAN. The method was checked by analyzing the samples with known concentration. As the results obtained were satisfactory the method was applied for pharmaceutical formulation.

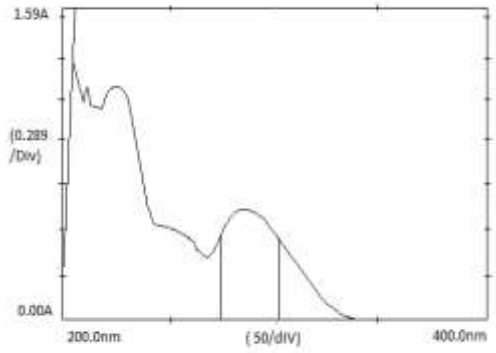

Fig. 3: Area under curve of Telmisartan.

Analysis of tablet formulation

[11,12] For estimation of Telmisartan in Telgard tablet 40 mg by formulation, twenty tablets were weighed. The tablet content was weighted and triturated to fine powder. Tablet powder equivalent to 20 mg of Telmisartan was weighed and transferred to 50 ml volumetric flask and dissolved in15 ml 0.1N HCl. It was kept for ultrasonification for 10-15 min. Finally the volume was made up to the mark with 0.1N HCl. this was then filtered through Whatman filter paper no. 41 to get tablet stock solution of concentration of 50 µg/ml. Appropriate dilutions were done using 0.1N HCl and the absorbance were measured at 291 nm against reagent blank in quantitation mode. The procedure was repeated six times.

Table II: Estimation of Telmisartan in tablet formulation

Sr.No.	Tablet Sample	Recovery (%)	% Mean	S.D.	%RSD.	S.E.
1	**T1**	80	99.82	0.1054	0.1055	0.0608
2		100	99.92	0.1250	0.1251	0.07219
3		120	99.84	0.07767	0.07779	0.04485

Where, T1 (Rilutek) is brand of tablet formulation.
* Mean of six estimations (n=6).

III. RESULTS AND DISCUSSION

All methods A, B and C for the estimation of Telmisartan in tablet dosage form were found to be simple, accurate, specific and reproducible. Beer-Lambert's law was obeyed in the concentration range of 5-40 µg/ml in all the methods. The values of standard deviation were satisfactory low and the recovery studies were close to 100%. TELMISARTAN showed a broad spectrum, the derivative spectroscopy method applied has the advantage that it locates the hidden peaks in the normal spectrum when the spectrum is

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not sharp and it also eliminates the interference caused by the excipients present in the formulation. The AUC method has advantage that it is applicable to be drug which shows the broad spectra without a sharp peak. Hence these methods can be useful in the routine analysis of TELMISARTAN in bulk drug and formulation.

Table III: **Recovery study data**

Tablet Sample	Level of Recovery (%)	Amount present (mg/tab)	Amount of Std. added (mg)	Total amount recovered (mg)	% Recovery
T1	80	20	16	35.95	99.87
		20	16	35.89	99.72
		20	16	35.97	99.94
	100	20	20	39.936	99.84
		20	20	39.96	99.90
		20	20	39.87	99.68
	120	20	24	43.964	99.92
		20	24	43.894	99.76
		20	24	43.947	99.88

* Mean of six estimations (n=6)

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