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UV-Spectrophotometric Method for estimation of Telmisartan in Bulk and Tablet Dosage Form

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Abstract: A simple, precise and accurate UV spectrophotometric method has been developed and validated for the estimation of Telmisartan in bulk and tablet dosage form. The zero order spectra of Telmisartan in 0.1N NaOH shows λmax at 234.0 nm and estimation was carried out by A(1% 1cm) and by comparison with standard. Calibration graph was found to be linear (r^2 =0.999) over the concentration range of 4-24 µg/mL. The proposed method was validated for its accuracy, precision, specificity, ruggedness and robustness. The method can be adopted in its routine analysis.
Keywords: Telmisartan, 0.1N NaOH, UV-spectrophotometric.

Introduction

Telmisartan chemically 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[1]. It is an angiotensin II receptor antagonist, effective in the treatment of hypertension[2]. It is also effective when used alone or in combination with other drugs for the treatment of high blood pressure[3]. The pharmacokinetic properties of Telmisartan have been investigated in healthy volunteers after oral administration of the sample[4]. Ramipril, Hydrochlorothiazide, Telmisartan were determined in tablets by multicomponent mode analysis[5]. Telmisartan and Hydrochlorothiazide were determined in tablets simultaneously by HPTLC and HPLC method[6-11]. No validated UV spectrophotometric studies on Telmisartan, individually in pharmaceutical preparations have been found in the literature.

Experimental

Materials and Methods

The spectrophotometric measurements were carried out using a Shimadzu UV/Vis spectrophotometer with 1cm matched quartz cell.

Reagents

Telmisartan was obtained as a gift sample from Sun PharmaPvt. Ltd., Surat, Gujarat. Distilled water and 0.1N NaOH were used as solvents throughout the experimentation. A pharmaceutical preparation was purchased from local pharmacy.

Standard solutions

Stock solution of Telmisartan (1000µg/mL) was prepared in 0.1N NaOH. The standard solution of Telmisartan having concentration of 100µg/mL was scanned on a UV spectrophotometer in the wavelength

range of 200-400 nm in 1.0 cm cell against solvent blank and the spectra was recorded.

Construction of Calibration Curve

Working solution(100µg/mL) was prepared by appropriate dilution of stock solution in distilled water. Aliquots of stock solution of Telmisartan were transferred into a series of 10 mL volumetric flask upto mark with distilled water to get the concentration in the range 04-24 µg/mL. The absorbance of all the resulting solutions were measured at 234 nm against solvent blank. The calibration curve was plotted at concentration versus absorbance over the range of 04-24 µg/mL with correlation coefficient of 0.9989 for the proposed method. The optical characteristics are recorded in Table 1.

Table 1: Optical Characteristics

Parameters	Values
Absorption maxima	234 nm
Linearity	4 – 24 µg/mL
A (1%,1cm)	912.028
Correlation coefficient	0.9989

Determination of Absorptivity value, A(1%,1cm)

The standard solutions of Telmisartan having concentration of 16 µg/mL, the absorbance of each of the solutions were measured in triplicate in 1.0 cm cell against solvent blank at 234 nm and A(1%,1cm) values were calculated using formula. The A(1%,1cm) value is found to be 912.028.

Sample solutions

Twenty tablets were weighed; average weight was determined and finely powdered. An accurately weighed quantity of tablet powder equivalent to 20 mg of Telmisartan was transferred to 100 mL volumetric flask and dissolved by sonication with sufficient quantity of 0.1 N NaOH solution, volume was made upto mark with distilled water. The solution was then filtered through whatmann filter paper no. 41. A 5 mL portion of the filtrate was further diluted with distilled water in a 100 mL volumetric flask upto mark (10 µg/mL) on label claim basis. The absorbance of the resulting solution was measured at 234 nm against solvent blank. The results of estimation by proposed method are shown in Table 2.

Figure: Zero order spectra of Telmisartan (10µg/mL)

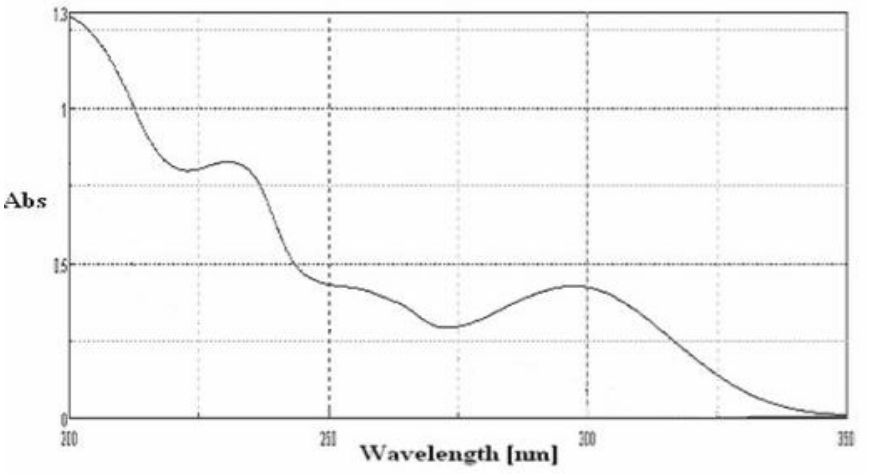

Table 2: Summary of results of estimation and recovery studies

Sample	Percent Label claim estimated*		Percent Recovery**	
	Comparison with standard	A (1%, 1cm)	Comparison with Standard	A (1%, 1cm)
Brand-1	98.44 ± 0.14	99.51 ± 0.28	100.70 ± 0.92	99.89 ± 0.52
Brand-2	100.16 ± 0.29	99.89 ± 0.11	100.21 ± 0.38	100.08 ± 1.10

*Mean of five determinations ±standard deviation, **Mean of four determinations ± standard deviation

Table 3: Results of stability studies

Sample (treated)	Percent Label claim	
	Comparison with standard	A (1%, 1cm)
0.1 N NaOH, reflux 3hr	98.47	98.11
0.1 N HCl, reflux 3hr	94.19	93.92
60ºC for 2hr	98.19	99.01
Humidity (75% RH)	93.97	93.52

Table 4: Summary of Validation parameters

Parameters	Percent Label claim	
	Comparison with standard	A (1%, 1cm)
Intra Day Precision(n=3)		
Amount found	98.05	98.54
RSD (%)	0.92	1.02
Inter Day Precision		
Amount found	96.21	96.91
RSD (%)	2.05	1.98
Ruggedness (%RSD)		
Analyst to Analyst (n=3)	0.29	0.38

Validation

Accuracy

Accuracy of the proposed method was ascertained on the basis of recovery studies performed by standard addition method. Recovery studies were performed by adding standard drug at different levels to the preanalysed tablet powder and the proposed method was followed. From the amount of drug estimated, percentage recovery was calculated. The results of the analysis are shown in Table 2.

Precision

It was ascertained by replicate analysis of the homogeneous sample of tablet powder and CV of the estimations is shown in Table 1 for the given brand of the sample by proposed method.

Interday and Intraday precision

An accurately weighed quantity of Tablet powder equivalent to about 20 mg of Telmisartan was transferred to 100 mL volumetric flask, shaken for 15 min with 0.1 N NaOH solution and diluted upto the mark with distilled water. The contents were filtered through whatman filter paper no. 41. Aliquot portions were further diluted with distilled water to get concentration of 10 µg/mL of Telmisartan (on label claim basis). The absorbance of the final solutions were read after 0 hr, 3hr and 6 hr in 1.0 cm cell at selected wavelength. Similarly the absorbance of the same solution was read on 1st, 3rd and 5th day. The amount of Telmisartan was estimated by comparison with the standard and by taking A(1%,1cm) at 234 nm. The results are recorder in Table 4.

Linearity and Range

An accurately weighed quantity of tablet powder equivalent to 80-120% of label claim of Telmisartan was transferred and procedure as described under sample solution was followed, graph was plotted as percentage label claim vs absorbance and was found to be linear with correlation coefficient value of 0.9989.

Stability

An accurately weighed quantity of tablet powder equivalent to 20 mg of Telmisartan was transferred to series of 100 mL volumetric flask and kept under following conditions viz: Alkaline (0.1 N NaOH), Acidic (0.1 N HCl) reflux for 3 hr, 3% H_2O_2 at 50ºC, heat (60ºC), humidity (75% RH) for 24 hr and after the specified time volume was made upto the mark with distilled water, filtered and procedure as described under sample solution was followed. Results of stability studies are recorded in Table 3.

Ruggedness

It was carried out by analysing the same by three different analyst and estimation of drug by proposed method. Results of studies are shown in Table 4.

Results and Discussion

The UV spectrum of standard solutions of Telmisartan was studied in 0.1 N NaOH and distilled water. Sharp peaks were observed in zero order spectra, the peak was well defined. Zero order spectra of Telmisartanis shown in Figure 1. The A (1%,1cm) value at 234 nm was found to be 912.028. All the validation parameters showed values within official limits. The percent recovery was found to be nearly 100% indicating reproducibility and accuracy of the method. The proposed method was found to be simple, precise and economical and can be adopted for routine quality control of drug.

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