World Journal of Pharmaceutical Sciences
ISSN (Print): 2321-3310; ISSN (Online): 2321-3086
Available online at: http://www.wjpsonline.org/
Original Article

UV Spectroscopic method for estimation and validation of Telmisartan in bulk and tablet dosage forms

Ramya Nagabathula*, G. Madhuri, U. Rama Devi, A. Vamsi, K. Bhavani

Department of Pharmaceutical Analysis, Koringa College of Pharmacy, Andhra Pradesh 533461

Received: 31-05-2019 / Revised Accepted: 13-11-2019 / Published: 01-12-2019

ABSTRACT

A simple, precise and accurate UV spectrophotometric method has been developed and validated for the estimation of Telmisartan in pure and tablet dosage form. The spectra of Telmisartan in tri ethyl amine, methanol, distilled water in ratios of 5:10:85, v/v/v shows λmax at 297 nm and estimation was carried out by comparison with standard. Calibration graph was found to be linear (r^2= 0.999) over the concentration range of 10-50 µg/mL. The proposed method was validated for its accuracy, precision, specificity, ruggedness and robustness. The method can be adopted for the estimation of telmisartan in its routine analysis.

Keywords: Telmisartan, UV Spectrophotometry, Calibration curve, Validation.

Address for Correspondence: Ramya Nagabathula, Assistant Professor, Koringa College of Pharmacy, Koringa, Andhra Pradesh; E-mail: paribells@gmail.com

How to Cite this Article: Ramya Nagabathula, G. Madhuri, U. Rama Devi, A. Vamsi, K. Bhavani. UV Spectroscopic method for estimation and validation of Telmisartan in bulk and tablet dosage forms. World J Pharm Sci 2019; 7(12): 113-117.

INTRODUCTION:

Telmisartan (fig.1) 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].

From the literature survey conducted, it was found that there are few analytical methods[5-18] are reported for estimation of telmisartan by UV spectroscopy method individually or in combination with other drugs. There are limited sensitive methods reported for the determination of telmisartan in single pharmaceutical dosage form. Hence, the authors had made an attempt to develop a sensitive analytical method for the estimation of telmisartan in various pharmaceutical dosage forms available in market.

MATERIALS AND METHODS

A double beam UV/Vis spectrophotometer, Systronics UV- 1100, was employed with a pair of 1 cm quartz cells for all analytical work.

Reagents: Telmisartan was obtained as a gift sample from PharmaTrain laboratories, Hyderabad, Telangana. Triethylamine, distilled water and methanol were used as solvents throughout the experimentation. A marketing formulation (Telmikind) was purchased from local pharmacy.

Solvent: Solubility of drug was observed by dissolving it in a highly alkalised solution. Based on the solubility we have selected tri ethyl amine, methanol, distilled water in ratios of 5:10:85, v/v/v for this study.

Selection of wavelength (for detection): In setting up the condition for the development of assay method, the choice of detection wavelength was based on the scanned absorption spectrum for telmisartan. The UV spectrum of telmisartan was obtained separately by scanning the samples over the wavelength range 200-400 nm against blank as water. The absorption curve shows characteristics at 297nm for telmisartan (fig.2).

Standard solutions: The reference standard of 50mg of telmisartan was weighed and transferred to 50ml volumetric flask and the volume is made up to 50ml with distilled water to obtain a concentration of 1000µg/ml. From the standard solution, required concentrations were prepared.

Construction of Calibration Curve: Working solution (100µg/mL) was prepared by appropriate dilution of stock solution in solvent. Aliquots of stock solution of Telmisartan were transferred into a series of 10 mL volumetric flask and made upto mark with solvent to get the concentration in the range 10-50 µg/mL. The absorbance of all the resulting solutions was measured at 297 nm against solvent blank. The calibration curve was plotted at concentration versus absorbance over the range of 10-50 µg/mL with correlation coefficient of 0.999 for the proposed method. Linearity plot is shown in **fig. 2**.

Sample solutions: Accurately 10 tablets were weighed and their average weight was found to be 180 mg. The tablets were triturated, then an equivalent quantity of 50mg of telmisartan was weighed. The weighed drug was transferred to a 50ml of volumetric flask. From the resulting solution 10ml was taken and transferred to 100ml volumetric flask and the volume is madeup to 100ml with solvent. From this solution, 3ml was transferred to 10 ml volumetric flask and made the volume with solvent upto 10ml. This solution was used to determine test absorbance.

Validation[19]:

1. Linearity and Range: Several aliquots of standard solution of Telmisartan was taken in different 10 mL volumetric flasks and diluted up to the mark with solvent such that the final concentrations were in the range of 10 to 50 µg/mL. Evaluation of the drug was performed with UV detector at 297 nm and absorbances were recorded. The correlation coefficient value was 0.999(fig. 3). The results are tabulated in table 1

2. 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.**

3. Interday and Intraday precision: An accurately weighed quantity of Tablet powder equivalent to about 50 mg of Telmisartan was transferred to 50 mL volumetric flask, shaken for 15 min with solvent 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 30 µg/mL of Telmisartan (on label claim basis). The absorbances 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 results are recorder in **table 3**.

4. LOD & LOQ: The limit of detection (LOD) and limit of quantification (LOQ) of the developed method were calculated by taking in to consideration the slope and standard deviation values.

RESULTS AND DISCUSSION

The UV spectrum of standard solutions of Telmisartan was studied in tri ethyl amine, methanol, distilled water in ratios of 5:10:85, v/v/v. Sharp peaks were observed in spectra, the peak was well defined. A spectrum of Telmisartan is shown in Figure 2. 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 assay results and validation parameters values are tabulated in tables 4 & 5. The proposed method was found to be simple, precise and economical and can be adopted for routine quality control of drug.

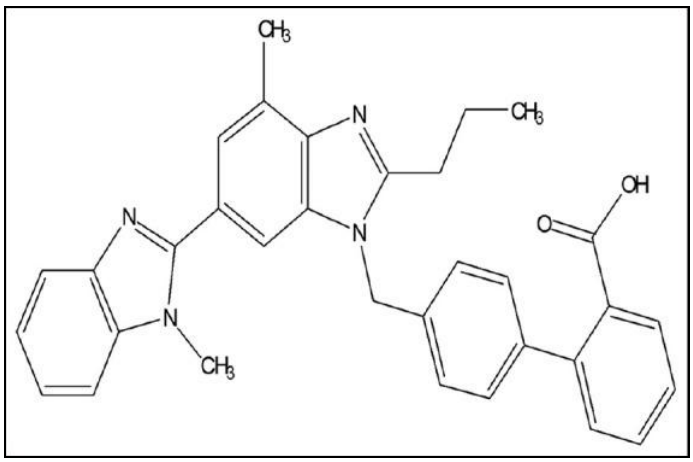

Fig. 1: Chemical structure of Telmisartan

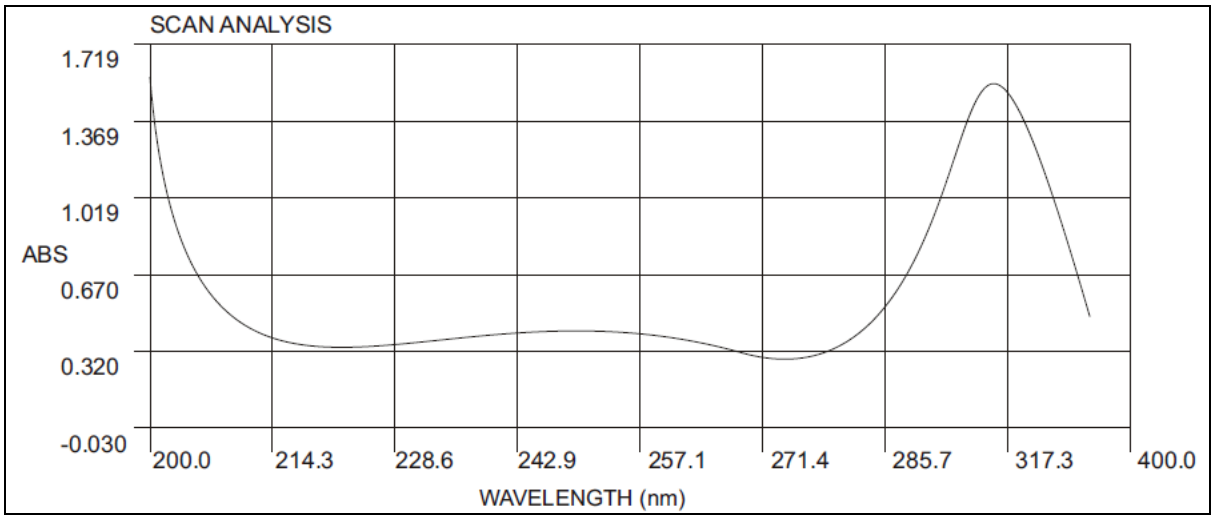

Fig. 2: UV Spectrum scan of Telmisartan

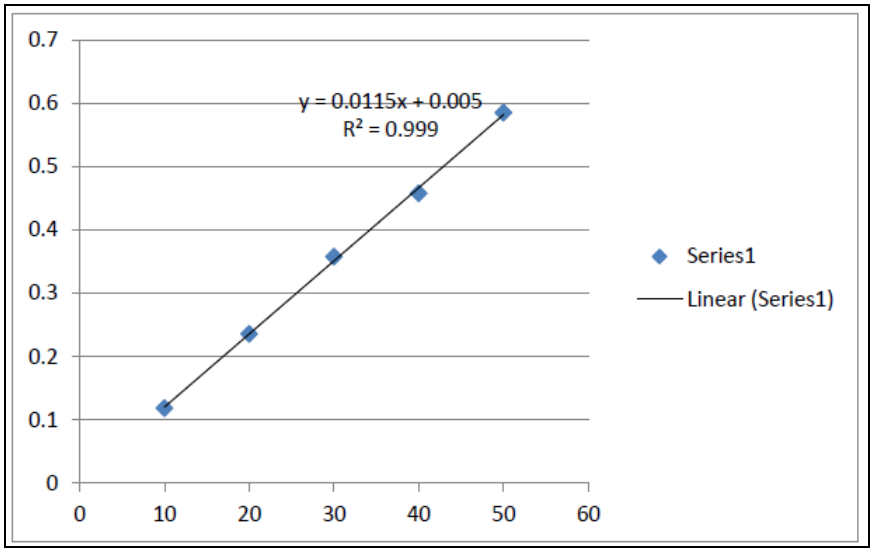

Fig. 3: Linearity Plot for Telmisartan

Table 1: Linearity data for UV Method for estimation of Telmisartan

S.No.	Concentration (µg/ml)	Absorbance at 297 nm
1	10	0.119
2	20	0.236
3	30	0.358
4	40	0.458
5	50	0.585

Table 2: Recovery results of Telmisartan

Level	Amount added(µg/mL)	Amount found(µg/mL)	% Recovery	Mean recovery
50%	15	14.96	99.80	99.84 %
100%	30	29.84	99.60	
150%	45	45.10	100.11	

Table 3: Precision studies of Telmisartan

Concentration (µg/mL)	Intra-day precision (%RSD)	Inter-day precision (%RSD)
30	0.81	0.65

Table 4: Assay results of Telmisartan

S. No.	Formulation	Label claim	Amount found	%Assay
1	Telmikind	40 mg	39.5 mg	99.89%

Table 5: Summary of validation parameters

S. No.	System suitability	Results
1	Linearity range (µg/mL)	10-50 µg/mL
2	Correlation coefficient	0.999
3	Slope	0.001
4	Standard deviation	0.0046
5	LOD (µg/mL)	0.47 µg/mL
6	LOQ (µg/mL)	1.45 µg/mL
7	Regression Equation	Y=0.0115x+0.005

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