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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 spectra of Telmisartan in 0.1 N NaOH and distilled water (20:80) shows λ_{max} at 234 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 2-10 µg/mL. The proposed method was validated for its accuracy, precision, specificity, ruggedness and robustness. The method can be adopted in its routine analysis.

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 analysis5. 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.

Fig. 1 shows the structure of Telmisartan.

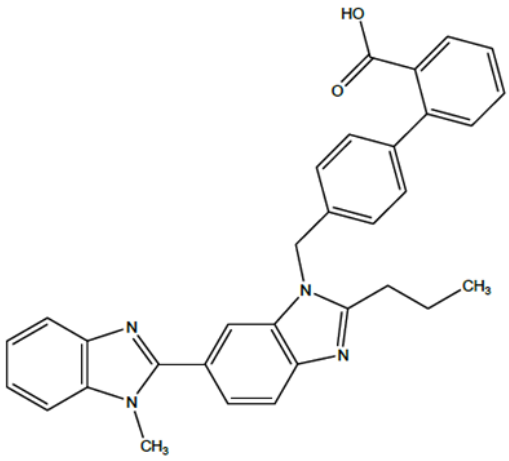

FIG. 1: STRUCTURE OF TELMISARTAN

MATERIALS AND METHODS: A double beam UV/Vis spectrophotometer, Shimadzu UV- 1700 Pharmaspec, was employed with a pair of 1 cm quartz cells for all analytical work.

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Reagents: Telmisartan was obtained as a gift sample from Zim Pharma Pvt. Ltd, Nagpur, Maharashtra. Distilled water and 0.1 N NaOH were used as solvents throughout the experimentation. A pharmaceutical preparation was purchased from local pharmacy.

Standard solutions: Stock solution of Telmisartan (100µg/mL) was prepared in methanol. The standard solution of Telmisartan having concentration of 10µg/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 (10µg/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 2-10 µg/mL. The absorbance of all the resulting solutions was measured at 234 nm against solvent blank. The calibration curve was plotted at concentration versus absorbance over the range of 2-10 µg/mL with correlation coefficient of 0.996 for the proposed method. Linearity range is shown in **fig. 2**.

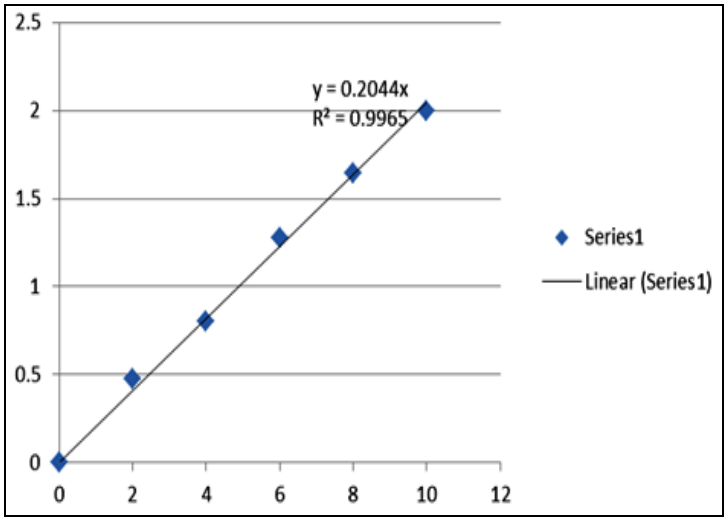

FIG. 2: LINEARITY

Determination of Absorptivity value, A (1%, 1cm): The standard solutions of Telmisartan having concentration of 10 µg/mL, the absorbance of each of the solutions were measured in triplicate in 1.0 cm cell against solvent blank at 295.0 nm and A (1%, 1cm) values were calculated using formula. The A (1%, 1cm) value is found to be 1109.167; **fig. 3** shows the spectra of telmisartan.

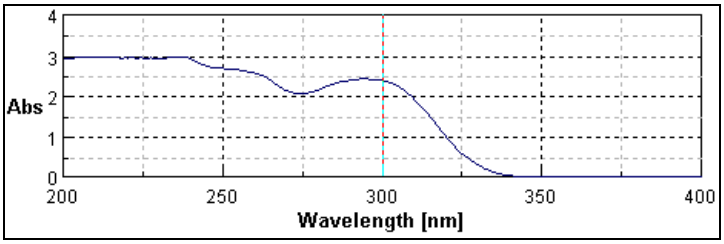

FIG. 3: SPECTRA OF TELMISARTAN

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 and distilled water solution(20:80), volume was made upto mark with distilled water. The solution was then filtered through Whatman 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 295 nm against solvent blank. Fig. 3 shows the spectra of telmisartan.

Validation:

1. **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 1.**

2. **Precision:** It was ascertained by replicate analysis of the homogeneous sample of tablet powder and CV of the estimations is shown in **Table 3** for the given brand of the sample by proposed method.

3. **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 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 amount of Telmisartan was estimated by comparison with the standard and by taking A (1%, 1cm) at 295.0nm. The results are recorder in **table 3**.

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 0.996 shown in **table 2**.

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 spectra, the peak was well defined. A spectrum of Telmisartan is shown in Figure 3. The A (1%, 1cm) value at 295.0 nm was found to be 1109.167. 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.

TABLE 1: DETERMINATION OF ACCURACY BY PERCENTAGE RECOVERY METHOD FOR TELMISARTAN

Ingredients	Tablet amount (µg/ml)	Amount added (µg/ml)	Level of addition	Amount recovered (µg/ml)	Percentage recovery	Average % recovery
telmisartan	20(µg/ml)	16(µg/ml)	80%	35.31(µg/ml)	98.08%	100.47±0.4789
	20(µg/ml)	20(µg/ml)	100%	40.14(µg/ml)	100.35 %	
	20(µg/ml)	24(µg/ml)	120%	45.56(µg/ml)	103%	

TABLE 2: SUMMARY OF VALIDATION PARAMETERS

Sr. No.	Parameters	Results
1	Absorption (nm)	234nm
2	Linearity range	2-10µg/ml
3	(µg/ml)	y=0.204x
4	Standard regression	r^2=0.996
5	equation	145.42
6	Correlation	100.47±0.4789
7	coefficient (r^2)	101.5 %, 100.9%
8	A (1%, 1cm) Accuracy (% recovery± SD) Precision (% CV) Specificity	A 4 µg/ml solution of candidate drug in solvent (0.1 N NaOH and distilled water mixture in the ratio of 50:50 respectively) at UV detection ʎ of 234 nm

TABLE 3: PRECISION DATA FOR THE DEVELOPED METHOD

Sample number	Analyst –I (Intra- day precision)	Analyst –II (Inter- day precision)
1	101.6	101.2
2	101.9	100.1
3	101.5	100.8
4	101.4	101.0
5	101.1	100.6
6	100.3	99.9
Average	101.5	100.9
S.D.	0.324	0.493

Assays of telmisartan as % of labeled amount

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