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UV Spectrophotometric Method For Estimation Of Telmisartan.

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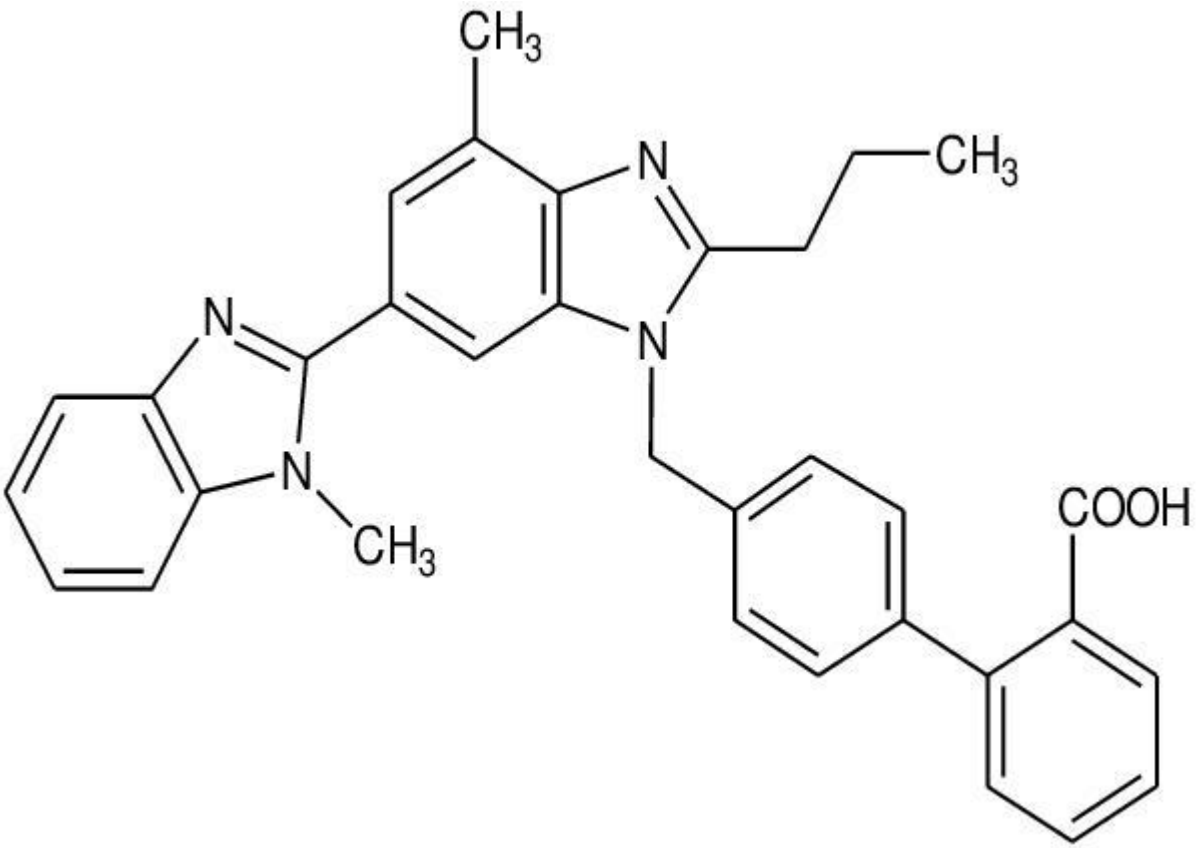
Abstract: This article offers an analytical technique for UV Spectrophotometric Telmisartan Validation. The technique made use of UV spectroscopy (Shimadzu, model 1700). The solvent system has a Methanol to water ration of 90:10 at a maximum wave length of 298 nm. System applicability, specificity, precision, linearity, accuracy, interday and intraday assays, robustness, ruggedness, LOD, and LOQ were demonstrated by validation trials. Over the concentration range of 5-45 mg/ml, the technique was linear. The recovery investigations were carried out by adding various amounts (80%, 100%, & 120%) of bulk samples of telmisartan, and the method demonstrated good recoveries (98.04–101.04%). For the determination of telmisartan, the proposed approach was straightforward, sensitive, and reliable with good precision, accuracy, and reproducibility, when calculating the cost.

Keywords: Telmisartan, 0.1 N NaOH, Distilled water, UV- spectrophotometry

Introduction: Chemically, telmisartan is known as 4'[(1,4'-dimethyl-2'propyl[2,6-bi-1 H-benzimidazol]-1'yl]] methyl [1,1'[-biphenyl]-2- carboxylic acid. It is an antihypertensive and angiotensin ll type l blocker. Telmisartan has a lower incidence of cough than ACE inhibitors and is well tolerated in the treatment of mild to severe hypertension. There have been reports on a number of spectrophotometric, chemometric, and chromatographic procedures using a variety of organic solvents, alkalis, acids, and buffers. Following a review of the literature, it has been proposed to create a few straightforward, quick, and precise analytical procedures for estimating. In order to lessen the toxicity, expense, and uncertainty of irritating operations.



Structure of Telmisartan:

Materials and procedures:

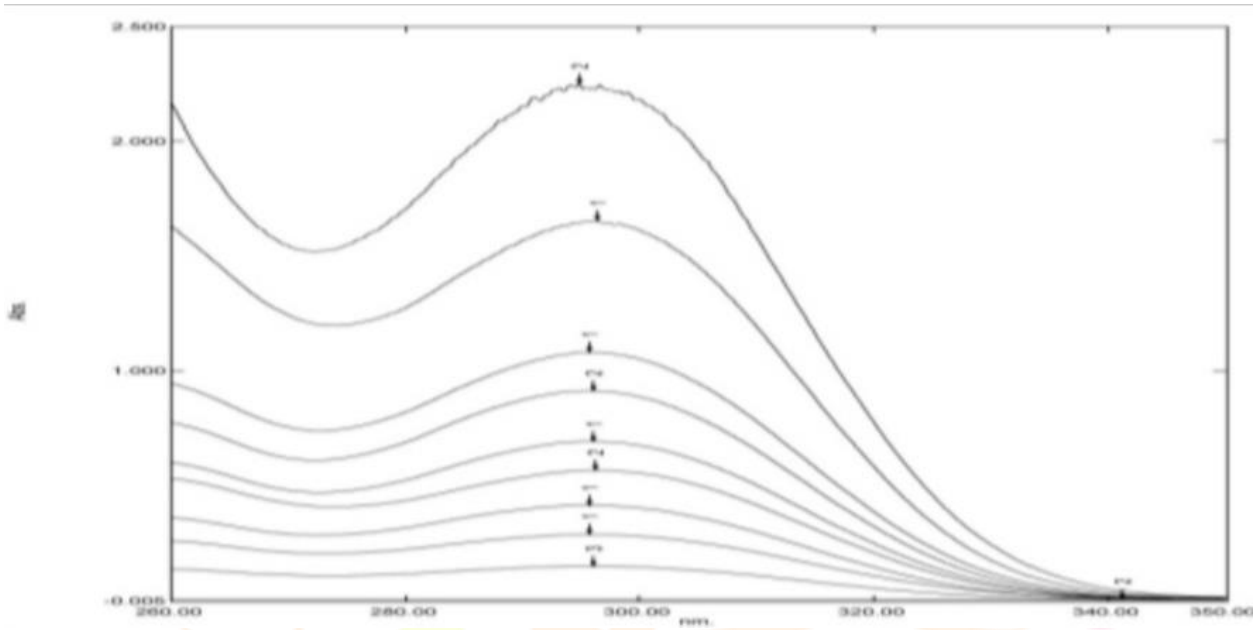
• **Chemicals and reagents**: Extra-pure methanol and distilled water, telmisartan, and 0.1 N NaOH were used as solvents throughout the experiment. A pharmaceutical preparation was purchased from a nearby pharmacy.

•**Equipment**: sonicator, double-beam UV-visible spectrophotometer, and digital balance.

Building a stock solution:

Telmisartan stock solution was created by dissolving 10 mg of each medication in 100 ml of methanol: water (9:1), properly shaking the mixture to ensure complete drug dissolution, and then adjusting the volume with methanol:water (9.1) to get 100 mg/ml

Fig. 1: A typical UV chromatogram showing Telmisartan at 298 nm.



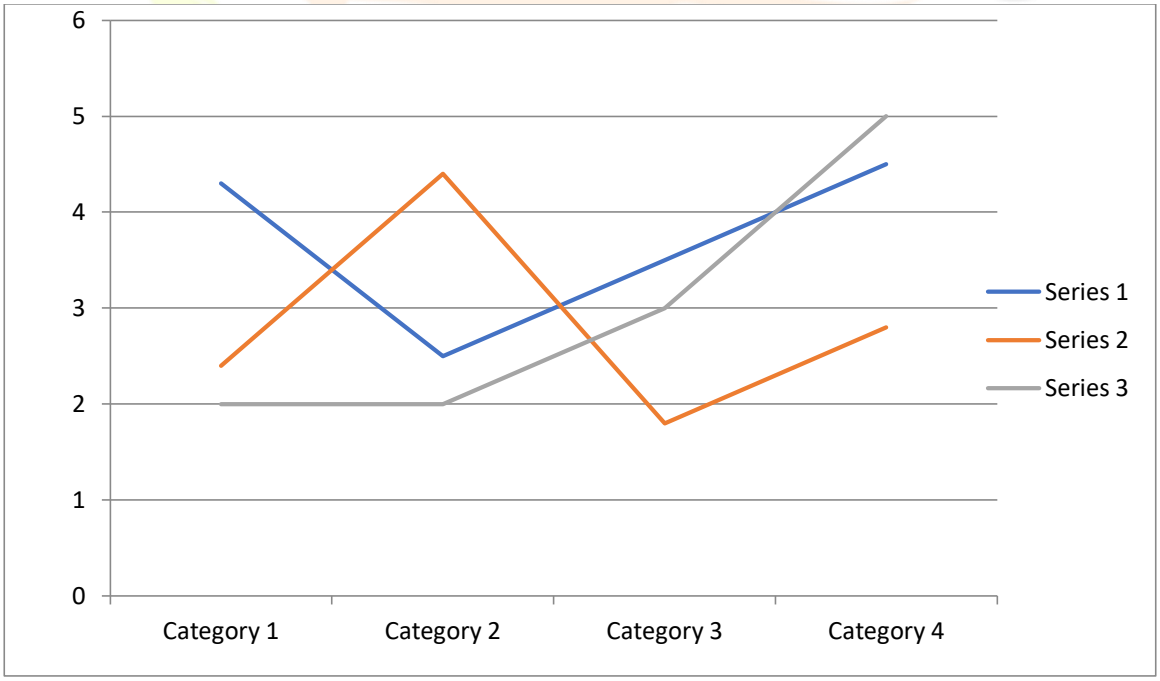


Fig2: linearity graph of Telmisartan

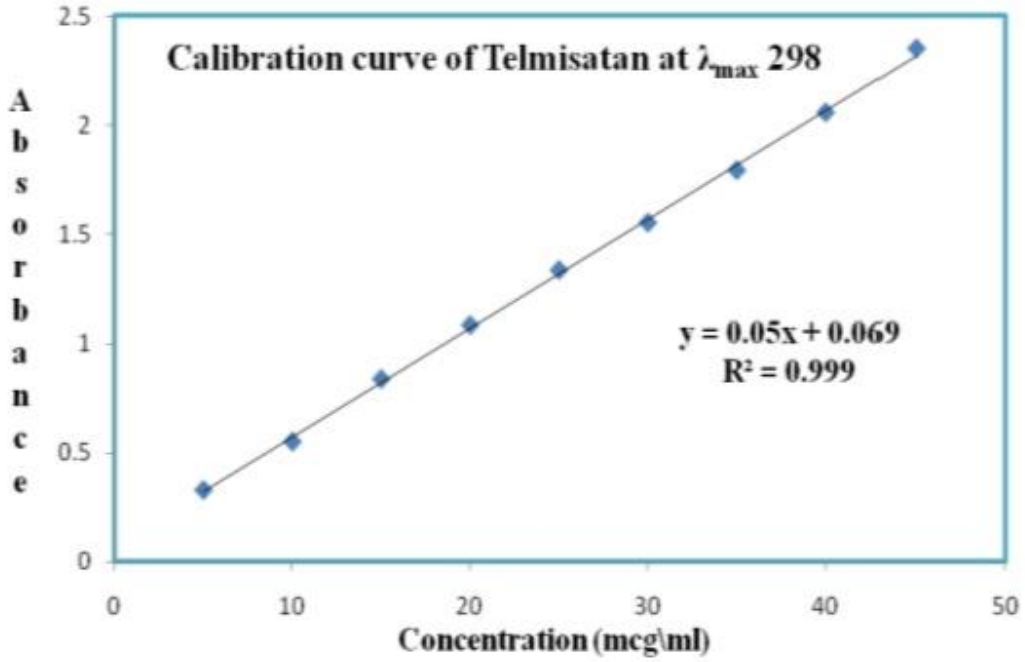


Table1: Linearity table of Telmisartan in methanol: water(90:10).

Sr. No.	Concentration (ug/ ml)	Absorbance
1.	5	0.326
2.	10	0.548
3.	15	0.835
4.	20	1.082
5.	25	1.334
6.	30	1.551
7.	35	1.791
8.	40	2.056
9.	45	2.349

*Results are the absorbance of nine different drug concentration.

Table 2: Optical characteristics of Telmisartan

Sr. No.	Optical characters*	Values
1.	Absorbance maxima	298 nm
2.	Beers limit	5.45 ug/ ml
3.	% RSD	0.228647
4.	Regression equation (y*)	0.05×+ 0.069
5.	Slope (a)	0.05
6.	Intercept (b)	0.069
7.	Correlation coefficient	0.999

- Results are the different optical characteristics of the drug.

Making working standard solutions: To make working standard solutions of 5 ppm, 10 ppm, and 45 ppm for Telmisartan's Beers law plot, the prepared stock solution was further diluted with a methanol: water (9:1) ratio. At 298 nm, the absorbance of each solution was measured against a blank of methanol: water (9:1). Telmisartan's typical graph was constructed by placing concentration on the X-axis and absorbance on the Y-axis.

Scanning and determination of maximum wavelength (λmax):

The maximum wavelength (λmax) of the pharmacodynamics agent solutions of specific drug concentrations of 100 mg/ml and 10 mg/ml in methanol: water (9:1) were scanned within the wavelength range of 200-400 nm against a corresponding reagent blank in order to determine the wavelength of maximum absorbance (max). Fig. 1 displayed the resulting spectra. The absorption curves revealed classic Telmisartan absorption peaks at 298 nm.

Table 3: Precision results showing repeatability of Telmisartan

Concentration (ug/ ml)	Absorbance	Calc. Amt.	Statistical analysis
20	1.082	20.26	*Mean-20.28
20	1.078	20.18	
20	1.089	20.4	**St.Dev-0.08
20	1.08	20.22	
20	1.086	20.34	
20	1.083	20.28	***%RSD – 0.394477

*Results is the mean calculated amount of drug after repeatability study; Results is the standard deviation of the drug after repeatability study; ***Results is the % relative standard deviation of the drug after repeatability study.

Table4: Inter day assay of Telmisartan

Concentration (ug/ ml)	Absorbance 1	Absorbance 2	Absorbance 3	Statistical analysis
20	1.084	1.083	1.082	Mean-20. 32778
20	1.089	1.083	1.085	
20	1.083	1.089	1.089	
20	1.088	1.088	1.086	Std. Dev. -0. 013878
20	1.081	1.082	1.086	
20	1.092	1.084	1.083	
Mean	1.086167	1.084833	1 085167	%RSD- 0.06827
Calc. Amt.	20.34333	20.31667	20.32333	

*****Results are the absorbance of the drug at fixed concentration in first preparation in same day, **Results are the absorbance of the drug at fixed concentration in second preparation in same day;***Results are the absorbance of the drug fixed concentration in third preparation in same day.

Table 5: Inter day assay of Telmisartan

Sr. No.	Concentration	Day1*	Day2*	Day3*	Statistical analysis
1.	20	1.084	1.079	1.082	Mean-20. 26111 Std. Dev. -0. 038634 %RSD- 0.190681
2.	20	1.087	1.078	1.085	
3.	20	1.083	1.08	1.087	
4.	20	1.085	1.08	1.08	
5.	20	1.081	1.077	1.081	
6	20	1.08	1.085	1.083	
	Mean	1.083333	1.079833	1.083	
	Calc. Amt.	20.28667	20.21667	20.28	

*Results are the absorbance of drug at fixed concentration in day 1;**Results are the absorbance of drug at fixed concentration in day 2; *** Results are the absorbance of drug at fixed concentration in day 3.

Results and Discussion:

With 0.1 N NaOH and distilled water, the Uv-spectrum of a standard solution of telmisartan was investigated. Spectra showed sharp peaks with well identifiable peaks. All validation parameters displayed values that were within set boundaries. The fact that the recovery percentage was almost 100% shows that the procedure is accurate and reproducible. The suggested method was proven to be straightforward, accurate, and cost-effective; it can be used for standard drug quality control.

Curve of Preparation and Calibration

In Fig. 2, the calibration curve is depicted. It was created by plotting the drug concentration on the x-axis and the absorbance on the y-axis. The drug obeyed Beer's law in the concentration range of 5-45 g/ml, and it was discovered to be linear with a R 2 value of 0.999.

Linearity

Graphics were used to demonstrate how the system fits linearly.

The slope, intercept, and correlation coefficient underwent least square regression analysis. It was discovered that the linearity range fell between 5 and 45 g/ml. Table 1 displays the linearity range, linearity graphs, and table 2 displays the optical features.

Precision

By actually determining eight duplicates of a fixed drug concentration within the range of beer and determining the absorbances using the suggested approach, the precision of the procedure was confirmed.

Standard deviation and percent R.S.D. were computed from this absorbance's mean and are shown in table 3.

Also, the intra- and inter-day variance in the absorption for a group of drug solutions on three distinct days was used to assess the assay's precision. The results of the calculation to determine the intra- and inter-day variation in the absorption of the standard drug solution are shown in tables 3.

Accuracy

Recovery studies were conducted to ascertain the precision of the suggested approach by adding various concentrations (80%, 100%, and 120%) of bulk samples of telmisartan together with an internal standard (I.S) within the linearity range to the preanalyzed formulation of concentration 20 g/ml. Values based on that % recovery were computed. The outcomes were displayed in table 4.

Formulation evaluation

To analyse commercial formulations, two tablets were weighed, crushed, and the powder equivalent to 10 mg of telmisartan was placed into 100 ml volumetric flasks, where it was dissolved in a 9:1 mixture of methanol and water to produce solutions containing 100 g/ml. Once the concentrations were within the linearity range of the individual medications, the solution was sonicated for 15 minutes, filtered, and further diluted with methanol: water (9:1), and the absorbance at 298 nm for the solution against methanol: water was determined (9:1). Here, 10ml was diluted from 3ml. The standard graph was used to estimate the amount of medication in each pill.

Ruggedness: In order to assess ruggedness, a different analyst carried out the same operation, and the outcomes were compared using the same methodology.

Robustness: This process involved varying the ratios of the solvent system's component parts. Results were then contrasted.

LOD and LOQ: The ICH guidelines' equation was used to compute Telmisartan's limit of detection (LOD) and limit of quantification (LOQ).

Sr. No.	**Parameters**	**S. D***	**B****	Formula***	Calculation
1.	LOD	0.002515	0.05	3.3(S.D/ b)	0.16599
2.	LOQ	0.002515	0.05	10(S.D/ b)	0.5030

*Results are the standard deviation of the drug obtain from the linearity table.

** Results are the slope drug obtains from the calibration curve.

***Formula for calculation of limit of detection and limit of quantification.

Conclusion:

To estimate the commercial formulation without the interference of excipients or other additives, the suggested approach is straightforward, sensitive, and dependable with good precision and accuracy. As a result, the method can be applied to the regular measurement of Telmisartan. The proposed Uv-spectrophotometric approach is demonstrated to be practical and efficient for the quality control of Telmisartan after comparison to the LOD and LOQ.

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