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Original Research Paper

QUANTITATIVE ESTIMATION OF TELMISARTAN IN BULK DRUG AND TABLETS BY UV SPECTROSCOPY

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ABSTRACT

A sensitive and rapid extractive spectrophotometer method has been developed for the assay of telmisartan in bulk drug and tablets. Telmisartan shows maximum absorbance at 216 nm. Beer's law was obeyed in the concentration range of in the range of 5-25 µg/ml. Beers law was obeyed in this concentration range with correlation coefficient of 0.999. The concentrations of this drug were evaluated in laboratory mixture and marketed formulation. Accuracy was determined by recovery studies from tablet dosages forms and ranges from 99.01 to 100.121%. Precision of method was find out as repeatability, day to day and analyst to analyst variation and shows the values within acceptable limit (R.S.D ≤ 2 percentage).

Keywords: Telmisartan, Linearity, Beer's Law, UV Spectrophotometry, Quantitative estimation.

INTRODUCTION

Telmisartan is 4'-[1, 4'-dimethyl-2-propyl [2, 6'-bi-benzimidazole]-1'-yl] methyl 1, 1'- biphenyl 2-carboxylic acid. Telmiartan is practically insoluble in water; sparingly soluble in strong acid; soluble in strong bases.[1,2] It blocks the vasoconstrictor and aldosterone secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor in many tissues, such as vascular smooth muscle and the adrenal gland Literature survey revealed that there are many methods like HPTLC[3], RP-HPLC[4] and LC–MS/MS[5] for determination of Telmisartan. The simultaneous estimation method is also available for telmisartan like HPLC.[6] As the analysis is an important component in the formulation development of any drug molecule. It becomes essential to develop a simple, sensitive, accurate, precise, reproducible method for the estimation of drug samples. Our main concern is development and validation of UV spectrophotometric method as per ICH guideline.[7]

MARERIAL AND METHODS

All spectral measurements were made on a Systronic UV-Visible recording double beam spectrophotometer (model 2101) with a 1 cm matching quartz cell. Telmisartan drug sample was supplied as gift sample by Oasis Test Laboratory Jaipur. Commercial tablets of Telmisartan were procured from the market (TETAN-20 mg from Alembic Ltd., TELDAY-40 mg from Torrent Lab. Ltd., and TELSAR-80 mg from Unichem Lab) All other chemicals used were of analytical grade.

Preliminary solubility studies of Telmisartan

solubilities of Telmisartan were determined in 10 M urea solution, distilled water sufficient excess amount of drug was added to screw-capped glass vials of 20 ml capacity, containing distilled water, and 10 M urea solution. The vials were shaken mechanically for 12 hours at in orbital shaker (Khera Instrument Pvt. Ltd., India). The solutions were allowed to equilibrate for next 24 hours and then centrifuged for 5 min at 2000 rpm. The supernatant of each vial was filtered through Whatman filter paper # 41. Filtrates were diluted suitably and analyzed against corresponding solvent blanks.

Analysis of Telmisartan in tablets using 10 M urea solution

Twenty tablets of formulation-I (TETAN) were weighed and powdered. Powder equivalent to 20 mg Telmisartan was transferred to a 50 ml volumetric flask containing 40 ml of 10 M urea solution. The flask was shaken for about 5 min to solubilize the drug.

Then volume was made upto the mark with distilled water. Solution was filtered through Whatman filter paper # 41. filtrate was divided in two parts, A and B. part A was kept at room temperature for 48 hours to check the effect on stability of drug in presence of urea and also to note precipitation, if any, during this period. Part B filtrate was appropriately diluted with distilled water and absorbance was noted at 315 nm (λ_{max}) against solvent blank and the drug content was calculated (Table-1). After 48 hours, filtrate of part B was also appropriately diluted with distilled water and analyzed for drug content. There was no precipitation in the filtrate in 48 hours. Similar procedures were adopted in cases of formulation-II (TELDAY) and formulation-III (TELSAR).

Recovery Studies

Recovery studies are performed by adding extra bulk drug nearly forty percent of formulations or more. For recovery studies, tablet powder of formulation I ((TETAN) equivalent to 20 mg drug was taken in a 25 ml volumetric flask. In this flask 10 mg of pure drug (corresponding spiked drug) was transferred and 20 ml of 10.0 M UREA solution was added and the flask was shaken for about 10 min. Then volume was made upto the mark with distilled water and filtered through Whatman filter paper # 41. The solution was diluted appropriately with distilled water and analyzed for drug content. Similar procedures were adopted for formulation II (TELDAY) & formulation III (TELSAR). The results of analysis of recovery studies are presented is (Table 2).

RESULT AND DISCUSSION

The mean percent label claims estimated by proposed method for tablet formulations I, II and III were 99.01, 100.494 and 100.121 respectively which are very close to 100, indicating the accuracy of the method. This also indicates that there was no interference of urea and the commonly used additives present in the tablet formulation in the estimation by the proposed method. Validation of the proposed method is further confirmed by the low values of standard deviation, percent coefficient of variation and standard error (Table 1). The mean percent recovery values ranged from 99.13 to 100.06 and were very close to 100. Also the values of statistical parameters viz. standard deviation, percent coefficient of variation and standard error were significantly low (Table 2). Thus, the proposed method of analysis was very well validated.

CONCLUSION

Thus, it may be concluded that the proposed method of analysis, using urea as the hydrotropic solubilizing agent is new, simple, cost-effective, environmentally friendly, safe, accurate and reproducible. Urea and the commonly used tablet excipients did not interfere in Spectrophotometric estimation at 315 nm. Decided advantage is that organic solvents are precluded but not at the expense of accuracy. The proposed method is worth adopting in pharmacopoeia. By proper choice of hydrotropic agents, the use of organic solvents in analysis may be discouraged to a large extent. The

proposed method shall prove equally effective to analyze Telmisartan in the corresponding drug sample and may prove to be of great importance in pharmaceutical analysis.

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Table 1: Results of analysis of commercial tablets of Telmisartan

Tablet Formulation	Label claim (mg)	% Label claim Estimated* (Mean ± S.D.)	% Coeff. of Variation	Standard error
I (TETAN)	20	99.01 ±1.4459	1.4603	0.6466
II (TELDAY)	40	100.494 ± 0.7029	0.6995	0.3110
III (TELSAR)	80	100.121 ±0.9806	0.9888	0.2987

*Average of six determinations

Table 2: Recovery studies of commercial tablets of Telmisartan

Tablet Formulation	Label claim (mg)	Drug added (mg)	% Label claim Estimated*(Mean ± S.D.)	% Coeff. of variation	Standard error
I (TETAN)	20	10	99.13 ± 1.103	1.113	0.450
II (TELDAY)	40	20	100.06 ± 1.139	1.138	0.465
III (TELSAR)	80	40	99.41 ±0.824	0.829	0.336

*Average of six determinations

Table 3: Statistical Data & Regression Equation for Telmisartan

Sr. No.	Parameter	Value
1.	λ_{max} (nm)	315
2.	Beer's range (µg/ml)	5-20
3.	Molar absorbtivity (l/mol/cm)	4.327×10^4
4.	Correlation coefficient (r^2)	0.999
5.	Regression equation	Y=0.029X + 0.010
6.	Intercept (a)	0.010
7.	Slope (b)	0.031
8.	Limit of detection (LOD µg/ml)	0.126
9.	Limit of quantification(LOQ µg/ml)	0.406
10.	Linearity	1 – 32

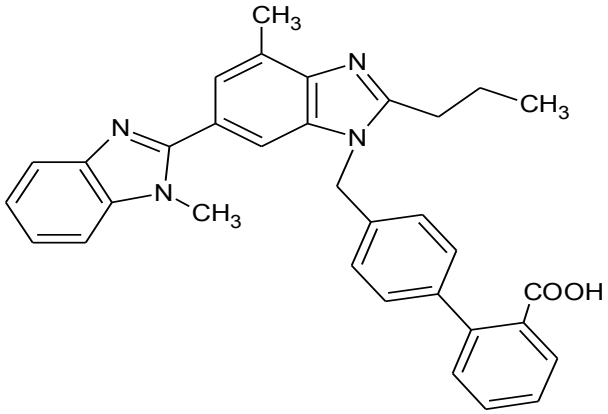

Figure 1: Chemical structure of telmisartan

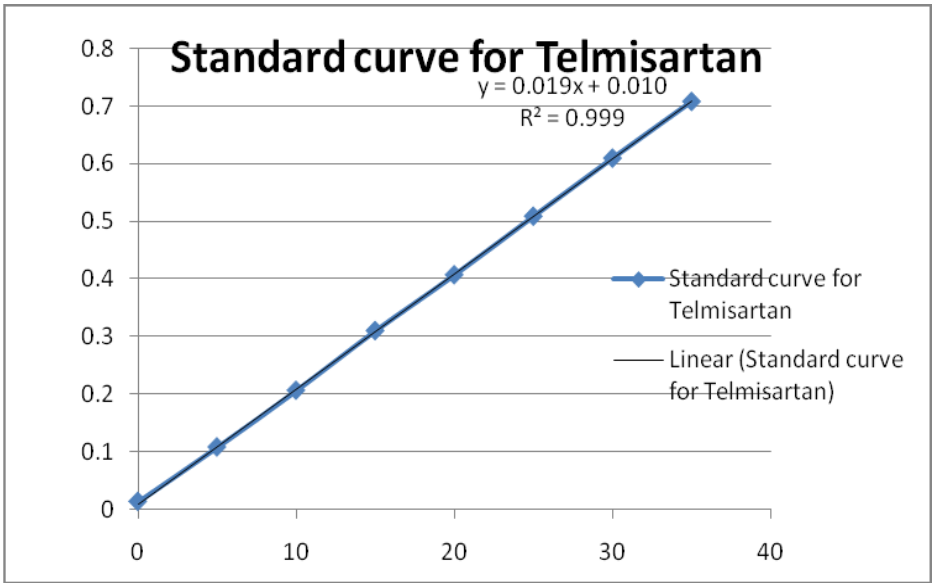

Figure 2: Standard Curve of Telmisartan

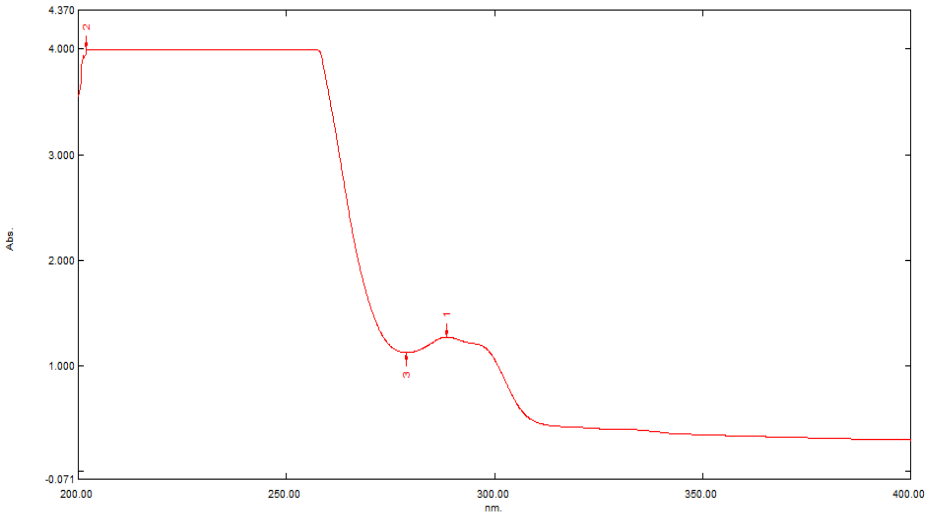

Figure 3: UV spectra of Telmisartan

REFERENCES

1. **The Merck Index**, 14th Ed., Merck Research Laboratories, Division of Merck & Co, Inc. Whitehouse Station NJ USA, 1569.
2. Martindale (2009), '**The Complete Drug Reference**', 36th Ed., The Pharmaceutical Press, London, Vol.1, 1409.
3. Chitra, P; Ganesa, SS; Arumugam, K; Suvarna, K and Mallayasamy, SR (2007), "Determination of telmisartan by HPTLC-A stability indicating assay", ***Indian Journal of Pharmaceutical science***, 20, 477-481.
4. MS, Palled; P MN, Rajesh et *al.*(2005), "RP-HPLC determination of Telmisartan in tablet dosage forms", ***Indian Journal of Pharmaceutical Science***, 67, 2005,108-110.
5. Pengfei, L *et al.* (2005), "Determination of telmisartan inhuman plasma by liquid chromatography–tandem mass spectrometry, Journal of Chromatography B", 828,126-129.
6. Rane, VP *et al.* (2008), "Simultaneous High-Performance Liquid Chromatographic Determination of Telmisartan and Hydrochlorothiazide in Pharmaceutical Preparation", ***Journal of Chromatographic Science***, 46, 887-891.
7. Validation of Analytical Procedures: Methodology (Q2B) Harmonized Tripartite Guidelines.