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Research Article

Development and Validation of UV Spectroscopic Method for the Quantification of Telmisartan in Bulk and Marketed Formulations

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A B S T R A C T

Two new simple and accurate solvent blends have been presented for the quantification ofTelmisartan (TEL) in bulk and its tablet dosage form. The developed analytical method wasvalidated and established in ICH Q2 (R1). Telmisartan exhibit 298 nm and 291 nm forSolvent A, Solvent B respectively and found was linear for a range of 1 µg/ml to 50 µg/ml.The goodness of fit study suggests good correlation coefficient R2 - 0.9989 and 0.999 forproposed solvents. The validity of Beer's law with intercept response < 2% calculated by theleast square method indicating functional linearity between the concentration of analyte andthe absorbance. The (LOD) of Telmisartan was found to be 0.07642±0.1224µg/ml and thelimit of quantification (LOQ) of Telmisartan was found to be 0.07642±0.1224µg/ml with %RSD < 2.The analytical method validation of proposed solvent blends wasperformed bycarrying out precision and accuracy studies. The Accuracy percentage recovery on threedifferent levels i.e. 50%, 100% and 150% was found to be within the acceptable limits with RSD < 2. The proposed solvent blends were validated for specificity, precision, ruggedness, accuracy and robustness. Overall study suggest that the proposed solvent blends can be used for quantification of Telmisartan in bulk and its tablet dosage form and can be applied for the everyday quality control analysis.

Keywords: Telmisartan, UV spectroscopy, Validation, Accuracy, Precision

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INTRODUCTION

Telmisartan (TEL) is an anti-hypertensive drug under the class of angiotensin II receptor blocker, which stimulates the synthesis and release of aldosterone, blockage of its effects results in decreases in systemic vascular resistance.Chemically TEL is2-[4-[[4-methyl-6-(1-methylbenzimidazol-2-yl)-2-propylbenzimidazol-1-yl] methyl] phenyl] benzoic acid(figure1). Literature reported few analytical methods for the quantification of TEL alone and combination in pharmaceutical preparations viz., First order[1], UV[2,3], HPTLC[4,5], RP-HPLC[6-11],UPLC[12], Voltammetry[13], Human plasma[14-16] and HPLC[17].The reported methods were found to be expensive and require organic solvents, so there is a need for cost effective and reproducible method for quantification using simple solvent systems. Therefore, it was thought of interest to develop simple, accurate, fast and method for the quantification of TEL in bulk and its marketed tablets.

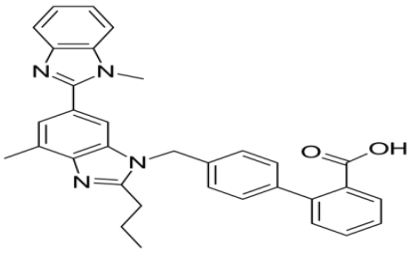

Figure1: Chemical structure of TEL

Materials

Telmisartan (TEL)obtained as gift samplefrom Caplin Point Laboratories Chennai.Telmikind 40 mg and Aquris Telartan 40mgtablets were procured from local community pharmacy. All reagents, solvents used were of analytical grade.Spectrophotometric measurement was performed by using a double beam UV-Visible Spectrophotometer (Shimadzu UV-1900/PC, Japan, Hitachi UV Spectrophotometer)connected to a compatible computer and supported with UV Probe software.

Methods

Screening of the solvents

Selection ofsolvent blends were done by screening the various solvents comprising organic solvents, aqueous solvents at varied pH and distilled wateralone and in combination at different ratios. Two ideal solvent blends viz.,Solvent A (Acetonitrile: pH 6.8 at 1:1) and Solvent B (Methanol: 0.1N HCl at 1:3) were selected based on solubilityand stability for quantification of model drug TEL.

Preparation of TEL standard stock solution

50 mg ofTEL was weighed accurately and transferred into 50 ml volumetric flask which is previously contains 40 ml of Solvent A. The mixture was shaken for 1 hr and sonicated for 10 min, further makeup the volume to 50 ml with Solvent A to get 1000 µg/ml. Similarly,TEL standard stock solution was prepared in Solvent B to get 1000 µg/ml.

Preparation of TELworking standard solution

TEL working standard solution was prepared in both the solvent blends under the study, during preparation 5ml of respective standard stock solutions were diluted with 50 mlwith Solvent A and Solvent B respectively in a separate 50ml volumetric flask to get 100µg/ml.

Assay procedure for tablets

Two marketed brands viz., Telmikind 40 mg and Aquris Telartan 40 mg were chosen for the study. The sample solution for assay of TEL in marketed tabletswere prepared in each case by crushing 10 tablets to a fine powder, further powder equivalent to 50 mg of TEL was extracted separately with 50 ml of solvent blends under the study in a two 50 ml volumetric flask for 60 min and sonicate for 30 min. The extracted mixture was filtered through Whatman filter paper no. 41, and then filtrate was appropriately diluted with solvent blends under the study in a series of 10 ml volumetric flask for further study.

Method development

Determination of absorption maxima (λ max)

The working standard solution wasappropriately dilute with Solvent A and Solvent B solution separately in 10 ml volumetric flask to get 10 µg/ml solution, Both solutions were scanned in the range of 200 to 400 nm using double beam UV spectrophotometer, and observe the characteristic peak at standard wavelength(nm).

Range

Appropriately dilute the TELworking standard solution with Solvent Ain a series of 10ml volumetric flask to obtain 1-50µg/ml concentrations and measure the absorbance at 298 nm,similarly prepare series of TEL working standard solution i.e. 1-50 µg/ml concentrations in Solvent B solution, measure the absorbance at 291 nm keeping respective medium as blank.

Linearity

The linearity is the ability of analytical procedure to produce test results, which are proportional to the concentration (amount) of analyte in samples within a given concentration range. Appropriately dilute TEL working standard with Solvent Ain a series of 10ml volumetric flask to obtain2,4,6,8,10,12,14,16,18 and 20µg/ml concentrations and measure the absorbance at 298 nm. Similarly prepare series of TELworking standard solution viz., 1, 3, 5, 7, 10, 14,16,18 and 22 µg/mlconcentrations in Solvent B,measure the absorbance at291 nm, keeping respective solvent mediumsas blank, plot the concentration vs absorbance curve and regression equation was computed.

LoD and LoQ

Limit of detection (LoD) is the lowest amount of an analyte detected in a sample and Limit of quantitation (LoQ) is the lowest amount of an analyte quantified in a sample with a suitable precision and accuracy. Both are determined based on standard deviation (SD) of response and slope (S) by using the following equations,

(LoD=3.3xSD/S); (LoQ=10xSD/S)

Validation

Precision

Precision of proposed analytical method was carried out at different concentrations prepared by diluting appropriately the TELworking standard solution in Solvent Aand Solvent B under the study and express the results in terms of % RSD, similarly interday and intraday precision were performed.

Robustness

A robustness study performs to check the influence of method parameters varied intentionally on the proposed method results. Change in the experimental parameter viz., varied wavelength ±2nm and ±5 nm and measure the recovery and interpret the results in terms of % RSD.

Ruggedness

A ruggedness study performs to check the influence of process parameters varied intentionally on the proposed

method viz., different analyst and different UV instrument. Interpret the results in terms of % RSD.

Accuracy

The most common technique for determining accuracy in analytical method development studies is the recovery method, recovery defined as the ratio of the observed result to the expected result expressed as a percentage. Standard addition method was applied for recovery studied, in which a sample assayed with spiked amount of TEL(50%, 100% and 150%)to the test working standard Solvent blends under the study, and the sample assayed as percent recovered in terms of % RSD.

Solution stability

The stability of stock solutions of TEL in proposed mediums studied at different temperature(45°C) and refrigerated temperature (2-8°C). The samples were stored in tightly sealed glass containers protected from light. Appropriately dilute the standard stock solutions of proposed methods in a series of 10ml volumetric flask and the absorbance measured at 24hr and 48hr time interval.

RESULTS AND DISCUSSION

The absorption maxima were found to be 298 nm for Solvent A and 291 nm for Solvent Bsolution with characteristic peak as shown in figure 2. Figure 3 demonstrate the linearity curve for Solvent A and Solvent B and data was given in table 1.A linear relationship found in the concentration range of 1-20 µg/ml and 1-22 µg/mlfor solvent A and Solvent B.The correlation coefficient R^2 was 0.9999 and 0.9989 for Solvent A and Solvent B shows the validity of Beer's law with intercept response < 2% calculated by the least square method indicating functional linearity between the concentration of analyte and the absorbance. Based on standard deviation of the response and slope, the LOD values for Telmisartan for the proposed mediumswas 0.07642 µg/ml, 0.1224 µg/ml and LOQ values 0.231602 µg/ml, 0.3710 µg/ml with % RSD values less than 2

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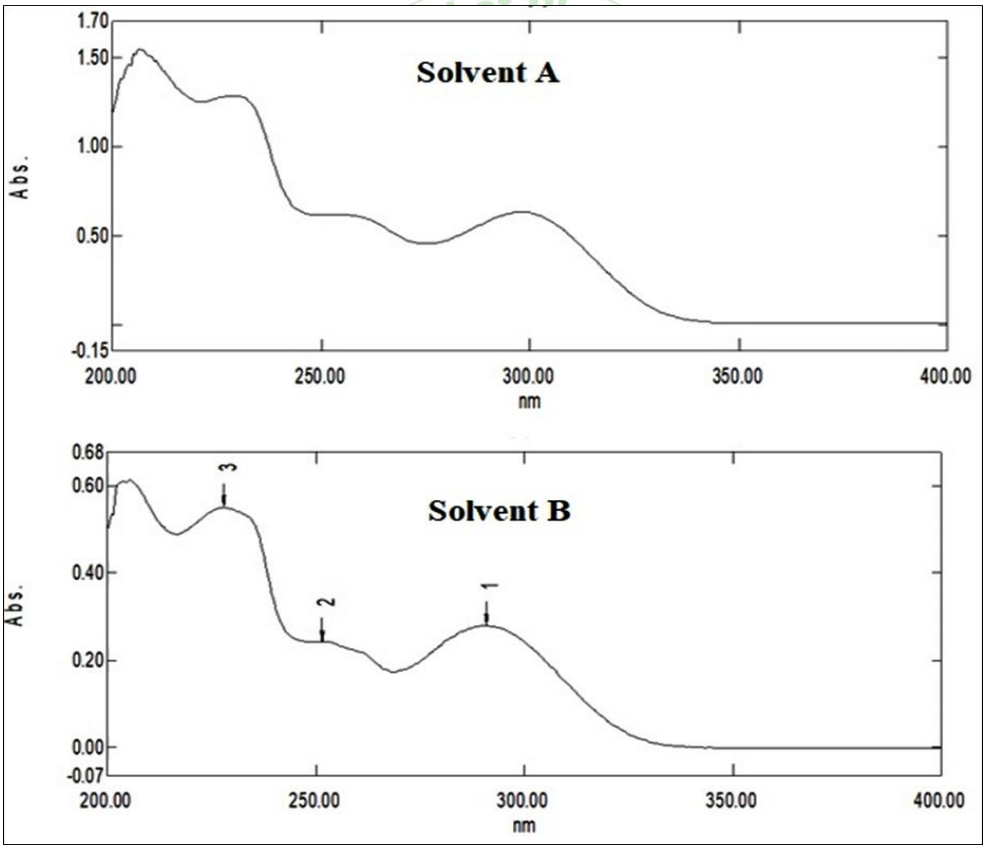

Figure 2: Absorption maxima of TEL in Solvent A and Solvent B

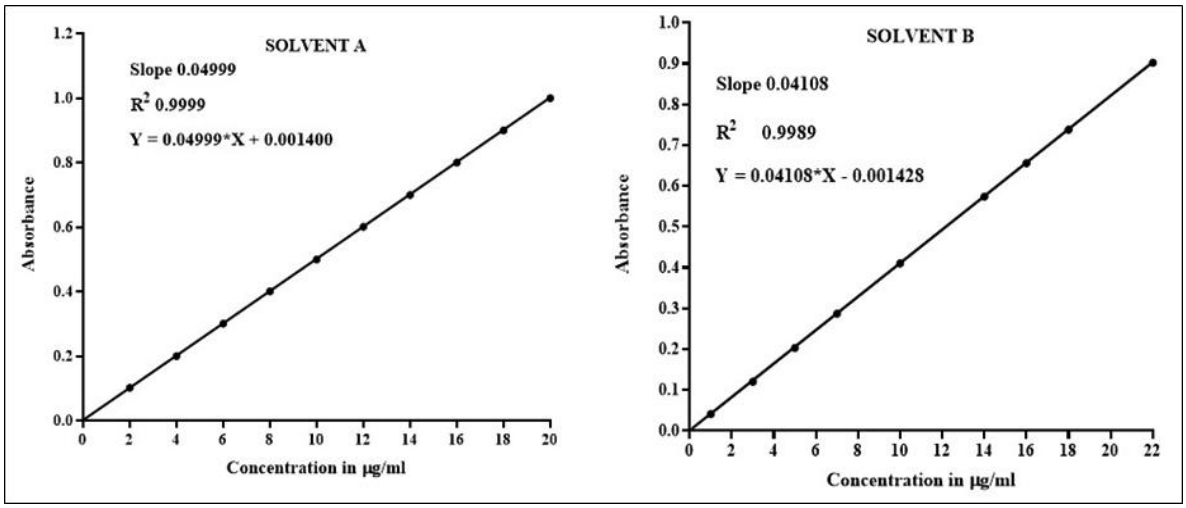

Figure 3: Linearity curve of TEL in Solvent A and Solvent B

Table 1: Linearity curve data of TEL in Solvent A and Solvent B

Solvent A			**Solvent B**		
Concentration µg/ml	**Absorbance Mean ± SD (n=6)**	**% RSD**	**Concentration µg/ml**	**Absorbance Mean ± SD(n=6)**	**% RSD**
2	0.102±0.00081	0.80	1	0.04100±0.00081	1.99
4	0.200±0.00081	0.40	3	0.1200±0.00141	1.17
6	0.301±0.00125	0.41	5	0.2030±0.00081	0.40
8	0.401±0.00025	0.12	7	0.2870±0.00081	0.28
10	0.500±0.00163	0.32	10	0.4103±0.00125	0.30
12	0.601±0.00141	0.23	14	0.5743±0.00125	0.16
14	0.700±0.00208	0.29	16	0.6560±0.00081	0.12
16	0.800±0.00191	0.23	18	0.7383±0.00050	0.06
18	0.900±0.00100	0.11	22	0.9023±0.00050	0.05
20	1.001±0.00291	0.12			

The precision of an analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions.The precisiondata in terms of repeatability, intra and inter dayof the proposed solvent blendswere given table 2, and were studied for two fixed amountswith six replicates, the % RSD was less than 2 indicate the solvent blends under the study were precise and reproducible over the period of 72 hrs.

In accuracy studies the Solvent A and Solvent B were analyzed for assay in two marketed TEL tablet formulations viz., TELMIKIND 40 mg; AQURIS TELARTAN 40mg at fixed labelled claim anddata was given in table 3, 4. The percentage recovery was found to be between 98.77±0.1963 to101.2±0.1350. Further the recovery study was performed by standard addition method and the % recovery found within the permissible limits with % RSD was less than 2% indicate non-interference of the excipients in the formulations. The accuracy results indicate TEL content of two marketed products determined by the proposed solvent blends were in good agreement with the label claim with % RSD less than 2.

In robustness the experimental variations viz., change in λ max of ± 5nm and ± 2 nm to the actual λ max was studied on Solvent A and Solvent B, data was given in table 5. The result suggests the both proposed solvent blendswere highly robust. In ruggedness, analysis by different analyst indicates the proposed solvent blends were significantly rugged as shown in table 6. The stability of proposed solvent blends were studied and % recovery was found to be within the acceptable limits indicate stable at stored temperature viz., 40^{o}C and 4-8^{o}Cover the period of 24 hr.

Table 2: Precision Intraday and Interday data of TEL in Solvent A and Solvent B

Precision	Solvent A				Solvent B			
	Labelled claim µg/ml	**Amount recovery µg/ml**	**Mean % Recovery ±SDn=6**	**% RSD**	**Labelled claim µg/ml**	**Amount recovery µg/ml**	**Mean % Recovery ±SDn=6**	**% RSD**
	6	6.02	100.3±0.4427	0.441	18	18.45	102.5±0.5164	0.504
	18	18.02	100.10±0.117	0.117	7	7.175	102.6±0.1549	0.151
Intraday Precision								
24 hr	6	6.02	100.3±0.6702	0.668	7	7.18	102.6±0.4099	0.399
24 hr	18	18.02	100.1±0.2163	0.216	18	18.44	102.5±0.2367	0.231
Interday Precision								
0 hr	6	6.02	100.4±0.5132	0.511	7	7.19	102.7±0.2021	0.197
	18	18.01	100.1±0.2134	0.203	18	18.44	102.5±0.1350	0.132
24 hr	6	6.07	101.2±0.3464	0.342	7	7.14	102.0±0.7438	0.729
	18	18.04	100.2±0.1732	0.173	18	18.46	102.7±0.2095	0.204
48 hr	6	6.01	100.1±0.1732	0.173	7	7.13	101.9±0.4157	0.408
	18	18.02	100.1±0.1732	0.173	18	18.45	102.5±0.2750	0.268
72 hr	6	6.02	100.4 ±0.513	0.511	7	7.19	102.7±0.2021	0.197
	18	18.01	100.1±0.1725	0.172	18	18.44	102.5±0.1350	0.132

Table 3: Drug content data of TEL in two marketed tablets

Assay	**Solvent A**			
Brand name	**Labelled claim µg/ml**	**Amount recovery µg/ml**	**Mean % Recovery ± SD N=6**	**% RSD**
TELMIKIND 40 mg	6	5.92	98.66 ±0.1963	0.1987
	12	11.95	99.58±0.09238	0.09274
	18	18.08	100.4±0.1100	0.1095
AQURIS TELARTAN 40 mg	6	6.03	100.5±0.5085	0.5057
	12	12.06	100.5±0.2887	0.2873
	18	18	100.0±0.1328	0.1327
Assay	**Solvent B**			
TELMIKIND 40 mg	7	7.07	101±0.3550	0.3513
	12	12.06	100.5±0.2425	0.2412
	18	18.28	101.6±0.2139	0.2106
AQURIS TELARTAN 40 mg	7	7.06	100.9±0.4041	0.4004
	12	12.08	100.6±0.2425	0.2407
	18	18.22	101.2±0.1350	0.1334

Table 4: % recovery data of TEL in two marketed tablets

% Recovery studies	Solvent A					
	Labelled claim µg/ml	% Addition	Amount add	Amount recovery µg/ml	Mean % Recovery ± SD N=6	% RSD
TELMIKIND 40 mg	10	50	5	4.92	98.4 ±0.9238	0.9375
	10	100	10	9.88	98.80±0.200	0.2024
	10	150	15	14.84	98.93±0.1300	0.1314
AQURIS TELARTAN 40 mg	10	50	5	4.96	99.20±0.4000	0.4032
	10	100	10	9.9	99.00±0.4000	0.4040
	10	150	15	14.84	98.93±0.2762	0.2793
% Recovery studies	Solvent B					
TELMIKIND 40 mg	10	50	5	4.92	98.40±0.5000	0.5076
	10	100	10	9.93	99.30±0.3819	0.3844
	10	150	15	14.82	98.80±0.2007	0.2032
AQURIS TELARTAN 40 mg	10	50	5	4.92	98.40±0.5000	0.5176
	10	100	10	9.93	99.30±0.1443	0.1453
	10	150	15	14.86	99.06±0.2007	0.2025

Table 5: Robustness data for TEL in Solvent A and Solvent B

λmax	Labelled claim µg/ml	Amount recovery µg/ml	Mean % Recovery ± SD N=6	%RSD
± 2	Solvent A			
298	6	6.00	100.1± 0.5085	0.5079
	18	18.00	100.0±0.1432	0.1324
300	6	6.03	100.6±0.4225	0.4202
	18	18.30	101.8±0.1270	0.1248
296	6	6.03	100.7±0.5321	0.5321
	18	17.78	98.77±0.1100	0.1114
298	6	6.10	101.8± 0.3868	0.3801
	18	18.04	100.2±0.1732	0.1729
303	6	6.01	100.3±0.6772	0.6753
	18	18.02	100.1±0.1732	0.1730
293	6	6.00	100.1±0.4225	0.4221
	18	18.00	100.0±0.1423	0.1391
± 5	Solvent B			
291	**7**	7.02	100.3±0.6568	0.655
	18	18.00	99.99±0.1102	0.1102
293	**7**	7.07	101±0.6461	0.6394
	18	18.00	99.99±0.1963	0.1963
289	**7**	7.10	101.3±0.5145	0.508
	18	18.06	100.4±0.0808	0.8050
291	**7**	7.04	100.7±0.363	0.360
	18	18.01	100.1±0.2163	0.2162
296	**7**	7.04	100.7±0.3623	0.3599
	18	7.99	99.93±0.2082	0.2083
286	**7**	6.99	99.95±0.297	0.297
	18	17.68	98.24±0.0808	0.0822

Table 5: Ruggedness data for TEL in Solvent A and Solvent B

Analyst	Labelled Claim µg/ml	Amount recovery µg/ml	Mean % Recovery ± SD N=6	% RSD
Solvent A				
Analyst -1	6	6	100.1±0.5085	0.5079
	18	18.01	100.1±0.06351	0.06346
Analyst -2	6	6.10	101.8±0.3868	0.3801
	18	18.13	100.7±0.06351	0.06305
Solvent B				
Analyst -1	7	7.07	101.1±0.3550	0.3513
	18	18	99.99±0.1102	0.1102
Analyst -2	7	7.1	101.9±0.4157	0.4079
	18	18.07	100.4±0.2800	0.2789

CONCLUSION

The results demonstrate that the proposed solvent blends viz., Solvent A and Solvent Bwere found to be simple, specific, accurate and precise. Therefore, this method can use for the quantification of TELin tabletdosage formulations without interference with commonly used excipients and related substances by UV spectroscopic method.

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Author's contribution

The collaborative efforts of all authors have successfully led to study of Development and validation of uv spectroscopic method for the quantification of Telmisartan in bulk and marketed formulationsunder the mentorship of DrNSrinivasulu,Professor and Head, Department of Pharmaceutical Chemistry conducted the research study. Dr Y Anand Kumar Professor and Head, Department of Pharmaceutics V L College of Pharmacy, Raichur provided guidance in crafting the manuscript and structuring the research paper in accordance with the journal's guidelines.

Conflict of interests

No conflict of interest

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