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Research Article

Development and Validation of RP-HPLC Method for Estimation of Telmisartan in Bulk and Tablet Dosage Form

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ABSTRACT: A simple RP-HPLC method in bulk and formulation dosage form for Estimation of Telmisartan has developed. Mobile phase potassium di-hydrogen phosphate and Acetonitrile (60:40) ph adjust with ortho phosphoric acid , C18 sun fire column (250mmx4.6mmx5µm) flow rate 1ml/min, wave length 243 nm, column temperature 45ºc, injection volume10 µl. system suitability parameters of Telmisartan retention time 3.4, plate count 8968, tailing 1.086, % RSD 0.1 those all are within the limit method is suitable for analysis. Validation parameters selectivity, precision, linearity, accuracy, Robustness all are within the limit so method was validated it is use full to pharmaceutical analysis.

Key words: Telmisartan, RP-HPLC, C18 sun fire column (250mmx4.6mmx5µm), bulk and Tablet dosage form.

INTRODUCTION

Pharmaceutical analysis plays a vital role in the Quality Assurance and Quality control of bulk as well as finished drugs. It involves separating, identifying and determining the relative amounts of components in a sample matrix. The RP-HPLC is a method of choice for assay that involves sophisticated equipment. The aim was to develop a simple, rapid, specific and sensitive RP-HPLC method for the Telmisartan in bulk and Tablet dosage form.

Telmisartan chemically 2-(4-{[4-methyl-6-(1-methyl-1*H*-1, 3-benzodiazol-2-yl)-2-propyl-1*H*-1,3-benzodiazol-1-yl]methyl}phenyl)benzoic acid[1] is a type of angiotensin II receptor blocker that is prescribed for the treatment of hypertension.[2].

Several spectroscope and chromatographic methods like UV-spectroscopy [3], Liquid chromatography [4], HPLC [5], HPTLC [6] and RP-HPLC [7, 8] were reported for estimation of Telmisartan and its different combinations. A successful attempt is made to estimate both bulk and tablet formulation simultaneously. Therefore it was thought worthwhile to develop an accurate and rapid RP-HPLC method for simultaneous estimation.

MATERIALS AND METHODS

Drugs and Chemicals and instrumentation:

Telmisartan gift sample is given by Dr. Reddys Lab, Hyderabad, A.P. Formulation Tablets (Targit) was purchased from Pfizer India .HPLC System-waters e2695 with empower 2 software PDA detector. Reagents: Acetonitrile HPLC grade rankem New Delhi. Milli-Q water it was purified by Millipore Corporation's system mfg Barnstead. Ortho phosphoric acid AR grade, Fisher scientific Pvt. Ltd, Potassium Di hydrogen Phosphate AR grade, Merck Specialities Pvt. Ltd.

Buffer preparation (1 molar): 174.18 mg of potassium dihydrogen phosphate dissolved in 1000ml of water and sonicate 30 minutes adjust the pH with ortho-phosphoric acid filter through the 0.45µm filter paper.

Standard preparation: 8mg of Telmisartan standard transfer into 25 ml volumetric flask make up with diluent sonic ate for 10 minutes and filter through the 4.5µ filter paper.

Sample preparation: Accurately weigh 10 tablets and calculate average weight of tablets then crush the tablets . Transfer the tablet powder equal weight of single tablet in 25 ml volumetric flask and make up with diluent sonic ate for 10 minutes after that filter through the 0.45 µm filter paper .

Chromatographic conditions: Mobile phase buffer: Acetonitrile (60:40), C18 sun fire column, Flow rate 1 ml/ min, Injection Volume 10 µl, wave length 242nm, sample temperature 25ºc, column temperature45ºC, run time 15minutes.

System suitability parameters: System suitability of the method was performed by six replicate analysis of the standard solution at 100% concentration levels. These method was evaluated by analyzing these parameters retention time, resolution, theoretical plates, tailing and % relative standard deviation.

METHOD VALIDATION

Specificity: To determine the specificity of the drug carried out by inject the blank, excipients, standard one by one and same manner blank, excipients and sample at this time blank and excipients peaks are not interference with standard and sample peaks. It proves method is highly selective.

Linearity: Method linearity is performed by prepare five replicate samples in different concentration levels (50%,75%,100%,125%,150%) inject into hplc system. Plot the graph concentration verses area and calculate corelation co efficient.

Accuracy: The method accuracy was determined by Recovery studies using method of standard additions to pre analyzed formulation of Telmisartan. known amount of three spike level (50%,100%,150%) six replicate samples are inject into HPLC .then accuracy was calculate as per test method assay results

Precision: Method precision was carried out by prepare six replicate samples from single formulation and samples run by on the same day and on three different days over a period of one week.

Robustness: Method robustness was evaluated by carrying deliberate changes in flow rate ±0.2, temparature±5 run the samples as per test method. Those results are compare to other trails they were not observed significant changes.

RESULTS AND DISCUSSION

System suitability results were given by table: 1and table: 2. six replicate standards System suitability parameters are retention time, resolution, tailing, and plate count were shown uniformity and % RSD was less than 1 so we can say system is suitable for analysis. Method Specificity was concluded by figure: 1 and figure: 2. Those figures are telmisartan standard chromatogram and other one is formulation they were not observed plcebo and excipient peaks interference with standard and analytic peak so it proves method is selective. The method accuracy was evaluated by recovery studies those values are given by table 3. Telmisartan recovery was founded 97.33 as per ICH 97% to 103%and also % RSD was very low so method is accurate. Linearity calibration curve was given below figure 3and plot the graph three different concentration v/s areas to construct the linear regression equation and to calculate the value of correlation co efficient. Linear correlation was found to be y=87030.527x(r=1.000). Precision results were shown by table 4. The intra day and inter day variations was calculated in terms of % RSD and result was found to be for intra day and inter day respectively. Method robustness results were given table by 5. They were not observed marked changes of those trailes compare to other trails so it proves method was robust.

CONCLUSION

The % RSD was very low and also standad diveation as required by ICH guidlens it indicates high degree of precision . The accuracy results was found with in the limit hence it proves method is highly validated so it use full quality controle and stability departments for simultanious estimation of telmisatran in bulk and tablet dosage form.

Table -1: Standard 1 results of Telmisartan

	Sample name	Name	RT	Area	Tailing	Plate count
1	STD1	Telmisartan	3.410	8933127	1.079	8941

Table-2: Standard 2 result of Telmisartan

	Sample name	Name	RT	Area	Tailing	Plate count
1	STD2	Telmisartan	3.412	8938563	1.086	8968
2	STD2	Telmisartan	3.410	8933127	1.090	8941
3	STD2	Telmisartan	3.410	8953757	1.079	8918
4	STD2	Telmisartan	3.409	8964585	1.079	8957
5	STD2	Telmisartan	3.406	8946917	1.067	8832
Mean				8947390		
STD				12428		
%RSD				0.1		

Table-3: Accuracy results of Telmisartan

TLMISARTAN						
Spiked level	Sample Weight	Sample Area	µg/mL added	µg/mL found	%Recovery	Mean
50%	900.00	4360423	160.000	155.95	97	98
50%	903.00	4385575	160.533	156.85	98	
50%	902.00	4369162	160.356	156.26	97	
50%	901.50	4381823	160.267	156.71	98	
50%	900.00	4376724	160.000	156.53	98	
50%	900.00	4362508	160.000	156.02	98	
100%	1803.5	8713821	320.622	311.65	97	97
100%	1810.0	8716921	321.778	311.76	97	
100%	1803.5	8712401	320.622	311.60	97	
150%	2700.00	13019887	480.000	465.65	97	97
150%	2705.00	13079102	480.889	467.77	97	
150%	2699.00	13030482	479.822	466.03	97	
150%	2705.00	13030482	480.889	466.83	97	
150%	2705.00	13052866	480.889	467.73	97	
150%	2701.00	13078136	480.178	466.33	97	

Table -4: Precision result of Telmisartan

S.NO	Sample weight	Area	% Assay
1	1804	8790776	98
2	1804	8777920	98
3	1804	8776584	98
4	1804	8711160	97
5	1804	8780551	98
6	1804	8729256	97
Avg			98
STD			0.36
%RSD			0.37

Table-5 : Robustness result of Telmisartan

	Sample name	Change	Name	RT	Area	Tailing	Plate count
1	Flow1	1.2ml/	Telmisartan	2.954	10780408	1.251	4972
2	Flow2	0.8ml/min	Telmisartan	4.092	8893781	1.134	6386
3	Temp1	50ºC	Telmisartan	3.399	8888995	1.301	5215
4	Temp2	40ºC	Telmisartan	3.406	7545056	1.262	5298
Mean					9027060		
Std					1330087		
%RSD					14.7		

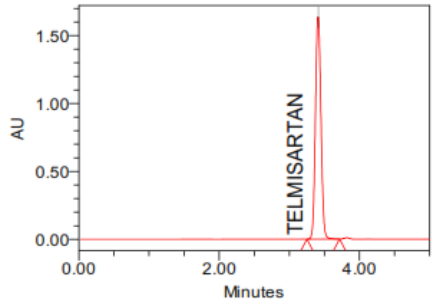

Figure -1: A typical std. chromatogram of Telmisartan

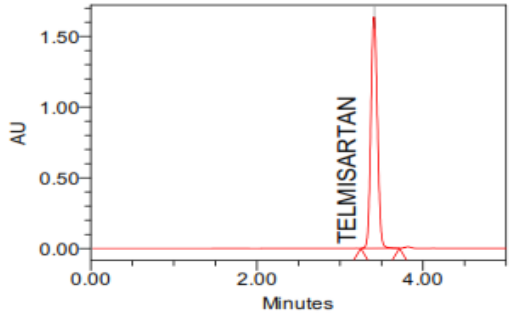

Figure-2: A typical formulation chromatogram of Telmisartan

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