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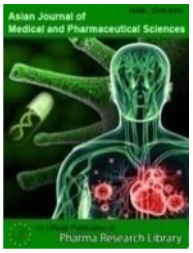

Research Article

Analytical Method Development and Validation for the Simultaneous Estimation of Telmisartan and Carvedilol by RP-HPLC Method

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Abstract

A simple precise and accurate reverse phase high performance liquid chromatographic technique was developed and validated for the simultaneous estimation of Telmisartan and Carvedilol in a combined dosage form Symmetry Agilent C18 (4.6*150mm) 5µm column in isocratic mode was used with the mobile phase comprising of Water and Methanol in the ratio of 40:60v/v, the flow rate was set at 1ml/min. The analyte was monitored with dual wavelength UV detector at 255nm. The retention time of Telmisartan and Carvedilol was found to be 2.551 and 4.879 min respectively. The linearity range was found to lie from 10µg/ml to 50µg/ml of Telmisartan, 20µg/ml to 100µg/ml of Carvedilol. Percentage recoveries were obtained in the range of for Telmisartan 98.8% and for Carvedilol 98.5%. The proposed method is precise, accurate, selective, reproducible and rapid for the simultaneous estimation of Telmisartan and Carvedilol in combined form.

Keywords: Telmisartan, Carvedilol, UV, HPLC

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1. Introduction

Telmisartan is an angiotensin II receptor antagonist (ARB) used in the management of hypertension. Generally, angiotensin II receptor blockers (ARBs) such as telmisartan bind to the angiotensin II type 1 (AT1) receptors with high affinity, causing inhibition of the action of angiotensin II on vascular smooth muscle, ultimately leading to a reduction in arterial blood pressure. Recent studies suggest that telmisartan may also have PPAR-gamma agonistic properties that could potentially confer beneficial metabolic effects. Carvedilol is a racemic mixture where the S(-) enantiomer is both a beta and alpha-1 adrenoceptor blocker, and the R(+) enantiomer is an alpha-1 adrenoceptor blocker. It is currently used to treat heart

failure, left ventricular dysfunction, and hypertension. The dual action of carvedilol is advantageous in combination therapies as moderate doses of 2 drugs have a decreased incidence of adverse effects compared to high dose monotherapy in the treatment of moderate hypertension.

2. Materials and methods

The instrument used was HPLC Alliance Waters model No. 2695 separation module. 2487 UV detector, Software- EM power. The stationary phase used was Xterra C185µm (4.6*250mm) column. Digital weighing balance-Model number BSA224SC, Sonicator (Enertech)-SE60US, pH meter Model number Adwa–AD 1020, UV-VIS spectrophotometer UV3000 Lab India Software-UVWin5.

Materials and reagents

Vinblastine and Vincristine were gift samples supplied by Dr. Reddy's Laboratories Water, Methanol, Acetonitrile, and Potassium dihydrogen orthophosphate were supplied by Merck.

Method development

Five trials were made by changing the mobile phase ratios and solvents Water: Methanol (40:60%v/v) Water: Methanol (40:60%v/v) Phosphate buffer (0.05m) pH5.0: Methanol (50:50%v/v) Phosphate buffer (0.05M) pH 4.6:MeOH Phosphate buffer (0.05M) pH4.6:ACN (30:70%v/v). Finally, the mobile phase optimized was Water and Methanol in the ratio of 40:60v/v.

Chromatographic conditions

The chromatographic conditions were successfully developed for the estimation of Telmisartan and Carvedilol in a combined dosage form Symmetry Agilent C18 (4.6*150mm) 5µm column in isocratic mode was used with the mobile phase comprising of Water and Methanol in the ratio of 40:60v/v, the flow rate was set at 1ml/min. The analyte was monitored with dual wavelength UV detector at 255nm.

3. Results and Discussion

Table 1 Accuracy results of Carvedilol

% Concentration (at specification Level)	Area	Amount added(mg)	Amount found (mg)	% Recovey	Mean Recover
50%	2332744	5	5.10	101.8%	100.5%
100%	3132697	10	9.99	99.9%	
150%	3918997	15	14.9	99.1%	

Table 2 Accuracy results of Telmisartan

% Concentration (at specification level)	Area	Amount Added(mg)	Amount Found(mg)	% Recovery	Mean Recovery
50%	353867	5	5.0	101.3%	100.0%
100%	4735088	10	9.94	99.4%	
150%	5911798	15	14.8	99.2%	

Table 3: Repeatability results of Telmisartan

Name:telmisartan

	Name	RT	Area	Height (µV)
1	telmisartan	2.321	2235319	196999
2	telmisartan	2.317	2240678	198254
3	telmisartan	2.323	2249490	195128
4	telmisartan	2.322	2245822	196164
5	telmisartan	2.324	2251694	195887
Mean			2244601	
Std. Dev.			6656.8	
% RSD			0.30	

Table 4 Repeatability results of Carvedilol

Name: Carvedilol

	Name	RT	Area	Height (µV)
1	Carvedilol	4.304	1501417	100275
2	Carvedilol	4.300	1486940	100079
3	Carvedilol	4.308	1490656	98257
4	Carvedilol	4.310	1487329	98165
5	Carvedilol	4.314	1490384	98153
Mean			1491345	
Std. Dev.			5881.4	
% RSD			0.39	

Table 6 Ruggedness results of Telmisartan

Name: Telmisartan

	Name	RT	Area	Height (µV)
1	Telmisartan	2.328	2194758	189693
2	Telmisartan	2.326	2195700	190025
3	Telmisartan	2.327	2196191	189862
4	Telmisartan	2.326	2195326	190700
5	Telmisartan	2.331	2200951	189426
Mean			2196585	
Std. Dev.			2496.0	
% RSD			0.11	

Table 6 Ruggedness results of carvedilol

Name: Carvedilol

	Name	RT	Area	Height (µV)
1	Carvedilol	4.335	1456296	95623
2	Carvedilol	4.336	1457422	95150
3	Carvedilol	4.334	1456513	95165
4	Carvedilol	4.337	1454579	95298
5	Carvedilol	4.340	1451483	95251
Mean			1455259	
Std. Dev.			2347.6	
% RSD			0.16	

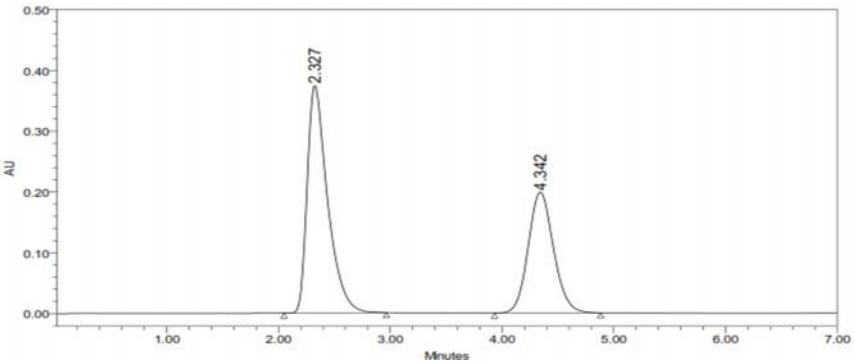

Figure 1: Chromatogram of Standard Injection

Table 7 Specificity results

S.No	Peak name	Rt	Area	Height	USP Plate count	USP Tailing	USP Resolution
1	Telmisartan	2.237	7913799	394185	2632	1.8	
2	Carvedilol	4.342	1853381	162758	2614	1.6	5.23

Table 8 Linearity results of Telmisartan

S.No	Linearity Level	Concentration	Area
1	I	20 ppm	892464
2	II	40 ppm	1904884
3	III	60 ppm	2906620
4	IV	80 ppm	3800672
5	V	100 ppm	4738193
	Correlation Coefficient		0.99932

Table 9 Linearity results of Carvedilol

S.No	Linearity Level	Concentration	Area
1	I	10 ppm	907953
2	II	20 ppm	1730043
3	III	30 ppm	2553693
4	IV	40 ppm	3283876
5	V	50 ppm	4144232
	Correlation Coefficient		0.99916

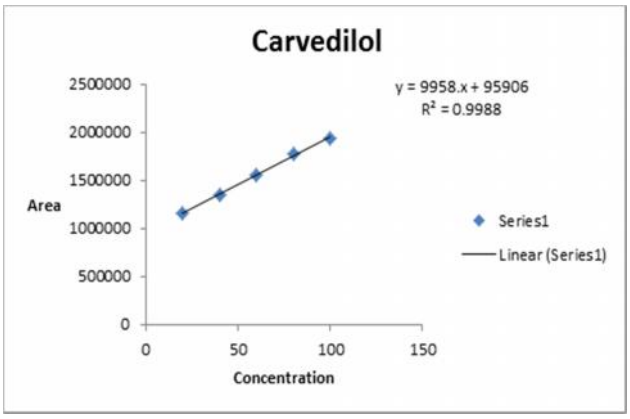

Figure 2 Calibration curve of Carvedilol

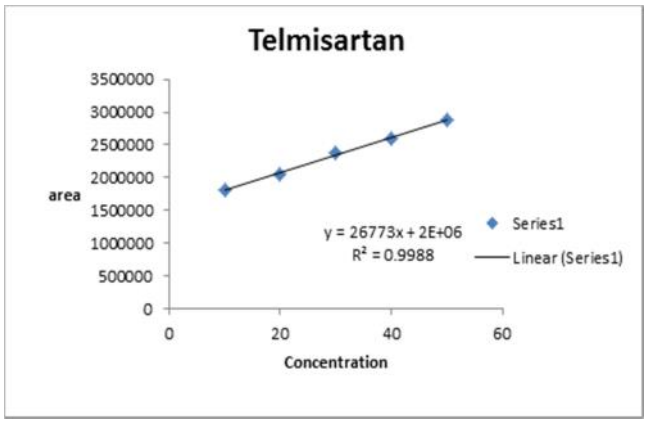

Figure 3 Calibration curve of Telmisartan

Table 10 System suitability results For Carvedilol (Flow rate)

S.No	Flow Rate(ml/min)	System suitability results	
		USP Plate count	USP Tailing
1	0.8	1748.5	1.22
2	1.0	1548.2	1.2
3	1.2	1948.0	1.2

Table 11 System suitability results for Telmisartan (Flow rate)

S.No	Flow Rate (ml/min)	System suitability results	
		USP Plate count	USP Tailing
1	0.8	883.3	1.56
2	1.0	1234.0	1.1
3	1.2	969.2	1.6

Table 12 System suitability results for Carvedilol (Mobile phase)

S.No	Change in Organic Composition in the Mobile Phase	System suitability results	
		USP Plate count	USP Tailing
1	10%Less	1748.5	1.22
2	Actual	1548.2	1.2
3	10%More	1948.0	1.2

Table 13 System suitability result for Telmisartan (Mobile phase)

S.No	Change in Organic Composition in the Mobile Phase	System suitability results	
		USP Plate count	USP Tailing
1	10%Less	883.3	1.56
2	Actual	1234.0	1.1
3	10%More	969.2	1.6

4. Conclusion

A new method was established for simultaneous estimation of Telmisartan and Carvedilol by RP-HPLC method. The chromatographic conditions were successfully developed for the separation of Telmisartan and Carvedilol by using Xterra C185µm (4.6*250mm) column, flow rate was 1ml/min, mobile phase ratio was Phosphate buffer (0.05M) pH4.6: ACN (55:45%v/v) (pH was adjusted with orthophosphoricacid), detection wavelength was 260nm. The instrument used was WATERS HPLC Auto Sampler, Separation module 2695, PDA Detector 996, Empower-software version-2. The retention times were found to be 2.399mins and 3.907 mins. The % purity of Telmisartan and Carvedilol was found to be 100.7 % and 101.4 % respectively. The system suitability parameters for Telmisartan and Carvedilol such as theoretical plates and tailing factor were found to be 1.3, 5117.5 and 1.4,3877.3 the resolution was found to be 8.0. The analytical method was validated according to ICH guidelines (ICH,Q2(R1)). The linearity study for Telmisartan and Carvedilol was found in concentration range of 1µg-5µg and 100µg-500µg and correlation coefficient (r2) was found to be 0.999 and 0.999, % mean recovery was found to be 100% and 100.5%, %RSD for repeatability was 0.2 and 0.4, %RSD for intermediate precision was 0.5 and 0.1 respectively. The precision study was precise, robust, and repeatable. LOD value was 2.95 and 3.04, and LOQ value was 9.87 and 10 respectively. Hence the suggested RP-HPLC method can be used for routine analysis of Telmisartan and Carvedilol API and Pharmaceutical dosage form.

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