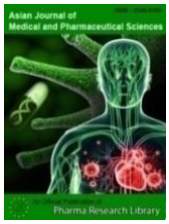

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# Analytical Method Development and Validation for the Simultaneous Estimation of Telmisartan and Carvedilol by RP-HPLC Method

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**A B S T R A C T**

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)5µmcolumn 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

**A R T I C L E I N F O**

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**C O N T E N T S**



## 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. 2487UV detector, Software-EMpower. The stationary phase used was XterraC185µm (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) pH4.6:MeOH Phosphatebuffer (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 ina 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 specificationLevel) | Area | Amount added (mg) | Amount found(mg) | % Recovey | Mean Recovery |
|---|---|---|---|---|---|
| 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 7: Specificity results**

| S.No | Peakname | Rt | Area | Height | USP Plate count | USP Tailin | 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 |

**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 | |

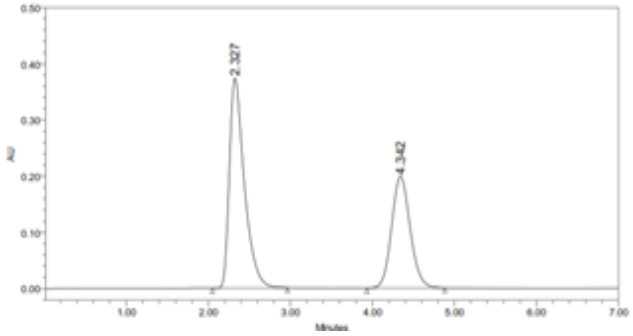


**Figure 1: Chromatogram of Standard Injection**

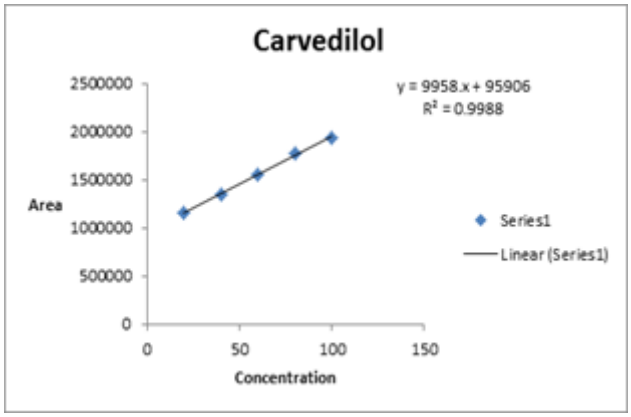


**Figure 2 Calibration curve of Carvedilol**

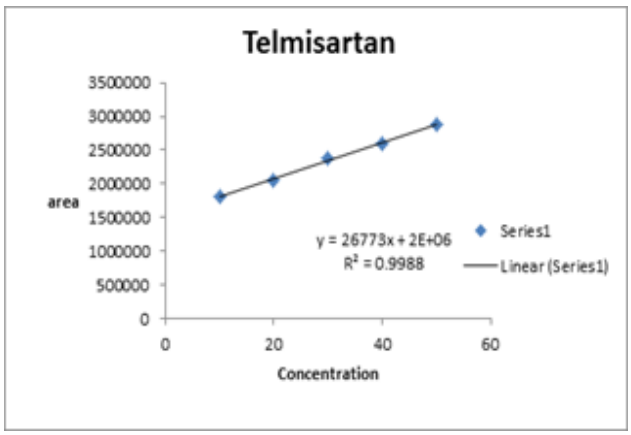


**Figure 3 Calibration curve of Telmisartan**

**Table 10: System suitability results For Carvedilol (Flow rate)**

| S.No | FlowRate(ml/min) | Systemsuitabilityresults | |
|---|---|---|---|
| | | USPPlatecount | USPTailing |
| 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 | FlowRate(ml/min) | Systemsuitabilityresults | |
|---|---|---|---|
| | | USPPlatecount | USPTailing |
| 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 | ChangeinOrganic Compositionin the MobilePhase | Systemsuitabilityresults | |
|---|---|---|---|
| | | USPPlatecount | USPTailin |
| 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 | ChangeinOrganic Compositionin the MobilePhase | Systemsuitabilityresults | |
|---|---|---|---|
| | | USPPlatecount | USPTailin |
| 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 XterraC185µm (4.6*250mm) column, flowrate was 1ml/min, mobilephase ratio was Phosphatebuffer (0.05M) pH4.6: ACN (55:45%v/v) (pHwas adjusted with orthophosphoricacid), detection wavelength was 260nm. The instrument used was WATERS HPLC Auto Sampler, Separation module 2695, PDA Detector 996, Empower-softwareversion-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 theoreticalplates 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 inconcentration range of 1µg-5µg and 100µg-500µg and correlation coefficient (r2) was found to be 0.999and 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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