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Simultaneous Estimation of Telmisartan and Azelnidipine by RP- HPLC

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ABSTRACT: *In the present work new has been developed and validated for the present drug release of Telmisartan and Azelnidipinein bulk and tablet dosage form. New method was established for simultaneous estimation of Azelnidipine and Telmisartan by RP-HPLC methods. The chromatographic conditions were successfully developed for the separation of Azelnidipine and Telmisartan by using Inertsil ODSC18 column (4.6×250mm)5µ, flow rate was 1ml/min, mobile phase ratio was (70:30 v/v) ACN: KH2PO4 ph 3, detection wavelength was 225nm. The instrument used for HPLC, WATERS HPLC Auto Sampler, Separation module 2695, photo diode array detector 996, Empower-software version-2. The retention times were found to be 2.798 mins and 3.587 mins. The % purity of Azelnidipine and Telmisartan was found to be 99.87% and 100.27% respectively. The system suitability parameters for Azelnidipine and Telmisartan such as theoretical plates and tailing factor were found to be 4260, 1.2 and 5085 and 1.2, the resolution was found to be 7.67. The analytical method was validated according to ICH guidelines (ICH, Q2 (R1)). The linearity study of Azelnidipine and Telmisartan was found in concentration range of 50µg-250µg and 15µg-55µg and correlation coefficient (r^2) was found to be 0.999 and 0.999, % recovery was found to be 98.56% and 99.96%, %RSD for repeatability was 1.2, % RSD for intermediate precision was 1.9. The precision study was precision, robustness and repeatability. LOD value was 3.72 and 0.0242 and LOQ value was 7.40 and 0.0202 respectively.*
Hence the suggested RP-HPLC can be used for routine analysis of Azelnidipine and Telmisartan in API and Pharmaceutical dosage form.

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I. INTRODUCTION:

HIGH PRESSURE LIQUID CHROMATOGRAPHY

High Performance Liquid Chromatography (HPLC) is a process of separating components in a liquid mixture. A liquid sample is injected into a stream of solvent (mobile phase) flowing through a column packed with a separation medium (stationary phase). Sample components separate from one another by a process of differential migration as they flow through the column.

II. MATERIALS AND METHOD:

Preparation of phosphate buffer:

3.4gm of potassium dihydrogen ortho phosphate is taken in 1000ml of hplc water pH was adjusted with 0.1M NAOH up to 3.0 final solution was filtered through 0.45 µ m Membrane filter and sonicate it for 10 min

TELMISARTAN AND AZELNIDIPINE :

Preparation of sample solution :

Accurately weigh and transfer the equivalent weight of 40 mg of Telmisartan and 8 mg of Azelnidipine Tablet powder into a 10 ml clean dry volumetric flask add about 7 mL of Diluent and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)

Further pipette 0.75 ml of the above stock solutions into a 10ml volumetric flask and dilute up to the mark with diluent.

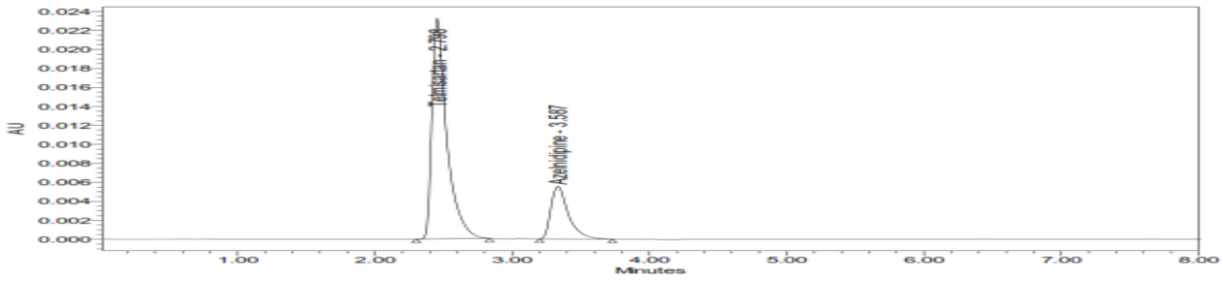
Preparation of standard solution :

Accurately weigh and transfer 40 mg of Telmisartan and 8 mg of Azelnidipine working standard into a 10 ml clean dry volumetric flask add about 7 mL of Diluent and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)

Further pipette 0.75 ml of the above stock solutions into a 10ml volumetric flask and diluteup to the mark with diluent

III. RESULTS AND DISCUSSION :

Optimized chromatogram

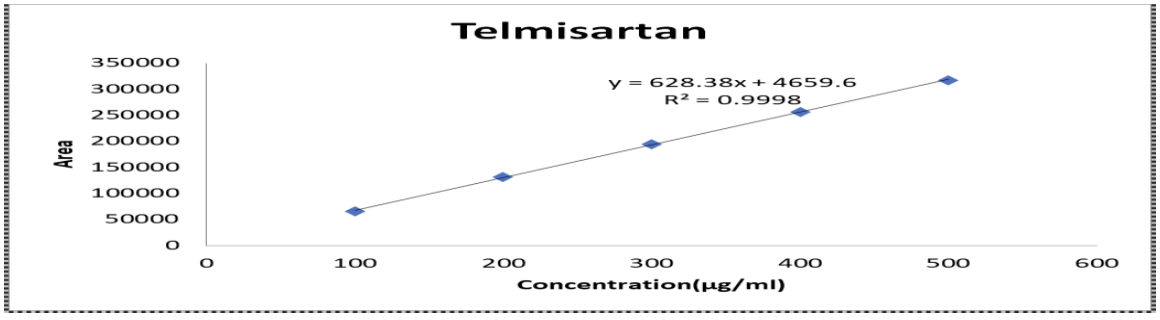


Linearity

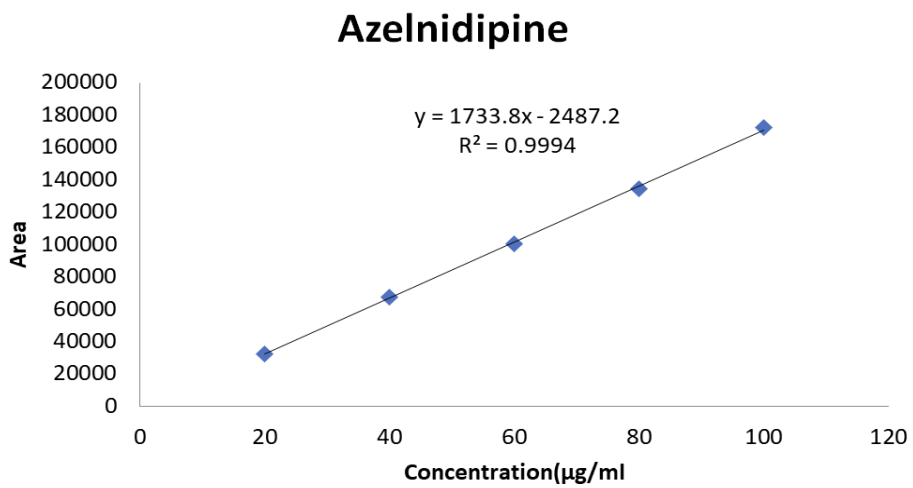
Telmisartan

S.NO	Linearity level	Cocentration((µg/ml)	Area
1	I	100	65787
2	II	200	131789
3	III	300	194311
4	IV	400	256245
5	V	500	317748
		Correlation coeffiecent	0.999

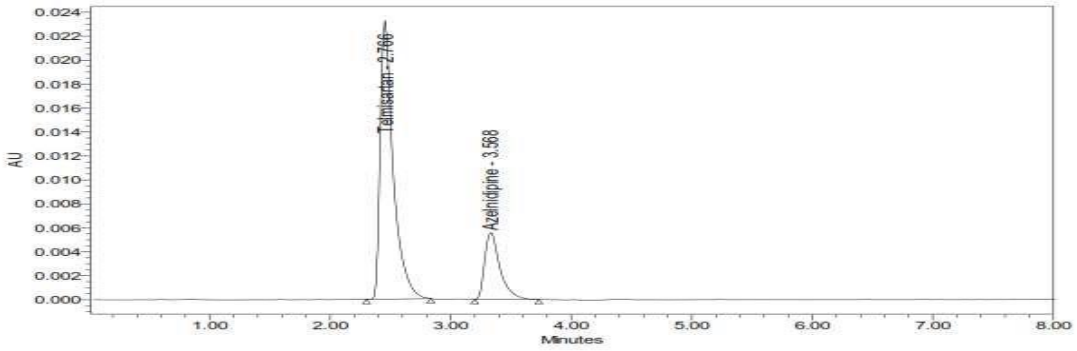
Linearity result of Telmisartan & Linearity result of Azelnidipine



S.NO	Linearity level	Cocentration((µg/ml)	Area
1	I	20	32441
2	II	40	67728
3	III	60	100630
4	IV	80	134448
5	V	100	172463
		Correlation coeffiecent	0.999



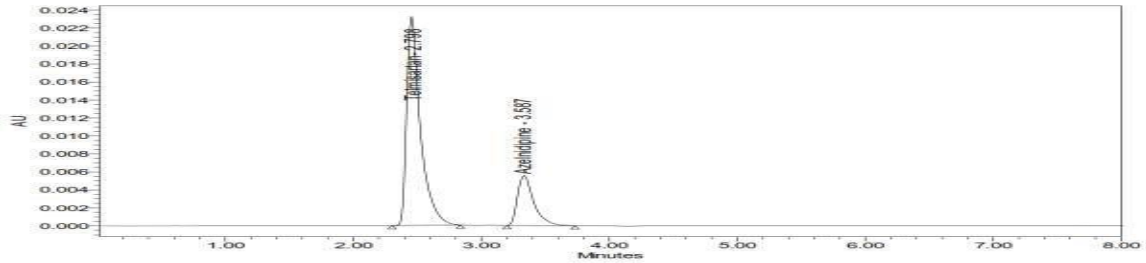
2 Accuracy: Accuracy is a measurement of exactness of the analytical method which is determined adding the known amount to test sample. Accuracy 50%, 100%, 150% are performed.



%Concentration (at specification Level)	Area	Anount added (mg)	Amount found(mg)	%Recovery	Mean Recovery
50%	95505	10	9.97	96.67	99.59
100%	191399	20	19.97	99.87	
150%	285309	30	29.77	99.25	

%Concentration (at specification Level)	Area	Anount added (mg)	Amount found(mg)	%Recovery	Mean Recovery
50%	53846	4.05	4.06	100.23	100.01
100%	1907344	8.1	8.09	99.90	
150%	159676	12.04	12.04	99.89	

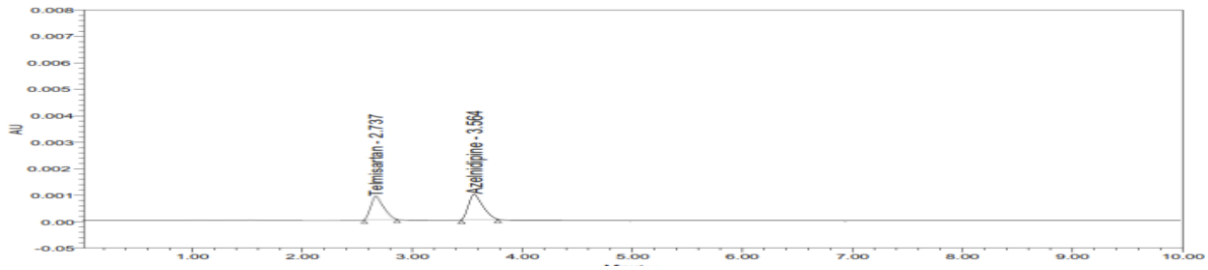
3. PRECISION



Injection	Area for Trifluridine	Area for Tiparcil

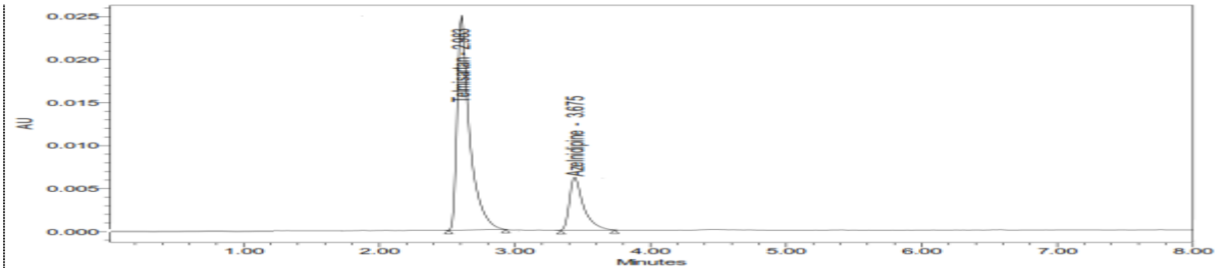
Injection-1	191345	107339
Injection-2	191232	107232
Injection-3	191671	107131
Injection-4	191999	107399
Injection-5	192898	107018
Injection-6	194679	107089
Average	192304.0	107201.3
Standard Deviation	1308.1	148.4
%RSD	0.7	0.1

4. LOD

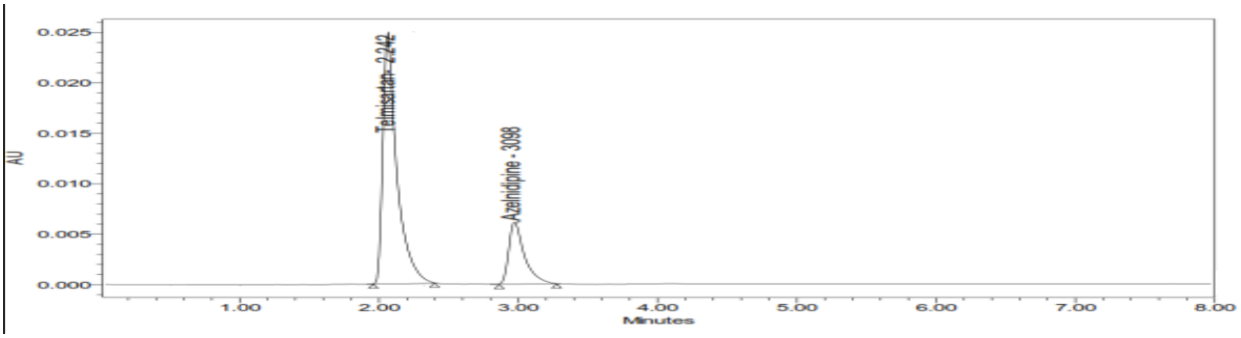


5. ROBUSTNESS

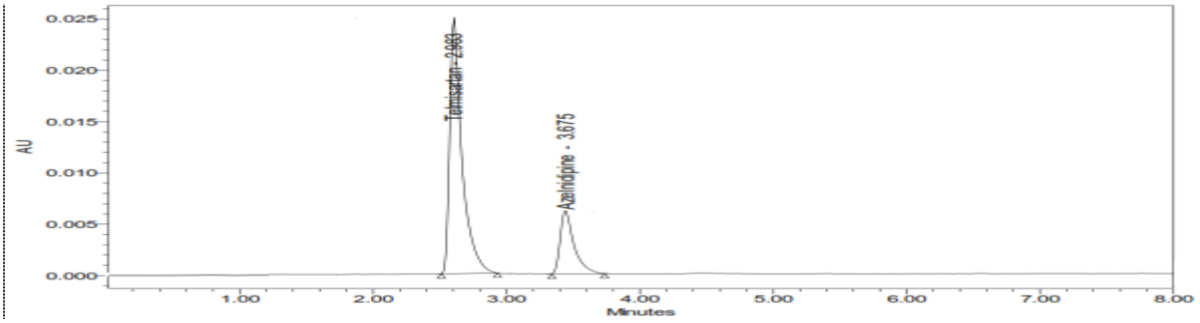
LESS FLOW



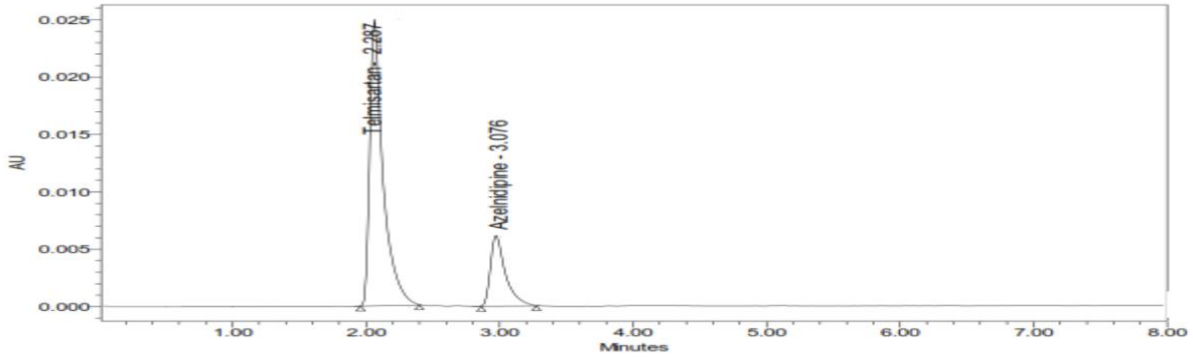
MOREFLOW



LESS ORGANIC:



MORE ORGANIC:



System suitability results:

S.No	Change in Organic Composition in Phase	System Suitability Results		
		USP Plate Count	USP Tailing	USP Resolution
1	10% less	3175.92	1.31	4.96
2	*Actual	2381.56	1.11	4.42
3	10% more	34445.92	1.23	4.96

IV. SUMMARY AND CONCLUSION

New method was established for simultaneous estimation of Azelnidipine and Telmisartan by RP-HPLC methods. The chromatographic conditions were successfully developed for the separation of Azelnidipine and Telmisartan by using Inertsil ODS C18 column (4.6×250mm)5µ, flow rate was 1ml/min, mobile phase ratio was (70:30 v/v) ACN : KH2PO4 ph 3, detection wavelength was 225nm. The retention times were found to be 2.798 mins and 3.587 mins. The % purity of Azelnidipine and Telmisartan was found to be 99.87% and 100.27% respectively. The system suitability parameters for Azelnidipine and Telmisartan such as theoretical plates and tailing factor were found to be 4260, 1.2 and 5085 and 1.2, the resolution was found to be 7.67. The analytical method was validated according to ICH guidelines (ICH, Q2 (R1)). The linearity study of Azelnidipine and Telmisartan was found in concentration range of 50µg-250µg and 15µg-55µg and correlation coefficient (r2) was found to be 0.999 and 0.999, % recovery was found to be 98.56% and 99.96%, %RSD for repeatability was 1.2, % RSD for intermediate precision was 1.9. The precision study was precision, robustness and repeatabilty.LOD value was 3.72 and 0.0242 and LOQ value was 7.40 and 0.0202 respectively.

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