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Simultaneous Estimation of Olmesartan and Rosuvastatin by RP-HPLC

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***ABSTRACT**: In the present work new method has been developed and validated for the percent drug release of Olmesartan and Rosuvastatin in Bulk and tablet dosage form. pH3.2 phosphate buffer is using the new method as well as diluent...Olmesartan and Rosuvastatin are analyzed using HPLC whose new method chromatographic conditions include Stationary phase C18 Agilent XDB, 150 x 4.6 mm, 5µ.Run time 8 mins Flow rate1mL/min.Mobile phase phosphate buffer and Acetonitrile (55:45).Diluent Methanol The method is simple, specific & easy to perform and requires short time to analyze the samples.The method was validated for specificity, linearity, accuracy, precision, robustness.The specificity study indicates that there is no interference due to excipients and buffers.Precision of the method was studied by preparing and analyzing samples and the Percentage relative standard deviation (%RSD) for Olmesartan is 1.08%and Rosuvastatin 1.62% Linearity was performed by preparing and analyzing linearity samples ranging from 20% to 150%. The correlation coefficient of both the drugs is 1.00 indicating that the method is linear over the range.The accuracy was performed by preparing solutions at , 50%, 100%, 150% and. They were analyzed and % recovery is with in the range of 95.0% - 105.0%.*

***Keywords:** OLMESARTAN; ROSUVASTATIN; WAVELENGTH; PEAK AREA;RUNTIME*

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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 buffer:

Accurately weighed 0.1% of Ortho Phosphoric acid in 1000ml of volumetric flask added about 900ml of -Q water and sonicate to dissolve make up to the final volume. PH 3.2 Mobile phase: Buffer: Acetonitrile

Preparations of Standard solutions

Olmesartan:

Weigh accurately and transfer about 20mg of Olmesartan working standard into a 10mL volumetric flask. Add about 7mL of Methanol and sonicate to dissolve. Make up the volumewith methanol and mix well.

Rosuvastatin:

Weigh accurately and transfer about 40 mg of Rosuvastatin Working standard into a 10 mL volumetric flask. Add about 7mL of methanol and sonicate to dissolve. Make up the volumewith diluent and mix well.

Preparation of Sample solution

5 tablets were weighed and calculate the average weight of each tablet then the weight equivalent to 5 tablets was transferred into a 100 mL volumetric flask, 80mL of diluent addedand sonicated for 25 min, further the volume made up with diluent and filtered. From thefiltered solution 0.2ml was pipetted out into a 10 ml volumetric flask and made up to 10ml with diluent.Wavelength 240nm.Separate and filtered portions of equal volume of (about 20ul) ofOlmesartan and Rosuvastatin standard preparation and assay preparations are injected into the chromatograph, and the chromatogram is recorded and the peak responses of the major peak is measured.

III. RESULTS AND DISCUSSION:

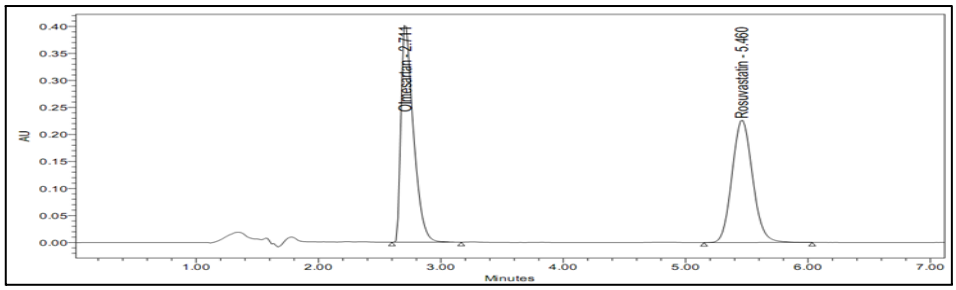


Fig.1: Optimized ChromatogramValidation Parameters:

System suitability

Preparation of Standard solutions

Prepare and analyze standard solutions of Olmesartan and Rosuvastatin. Calculate the % RS

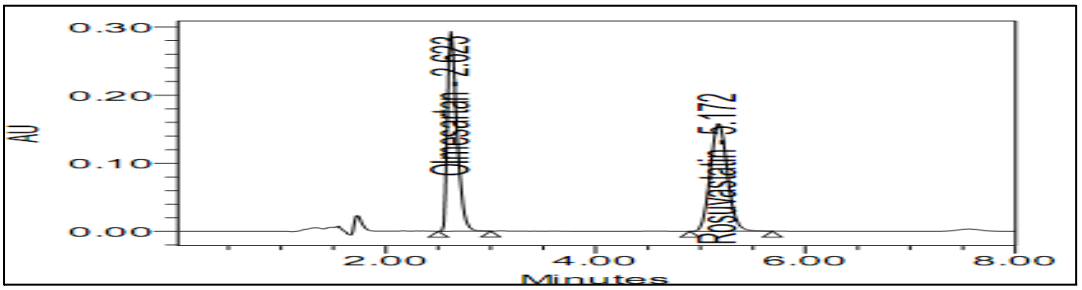


Fig: 2 Chromatogram of Standard solution

Specificity

Specificity for Olmesartan and Rosuvastatin<u>Procedure</u>

Blank,standard, sample and plain placebo (P) solutions are prepared as below and inject insinglet by using photodiode array detector and evaluate peak purity

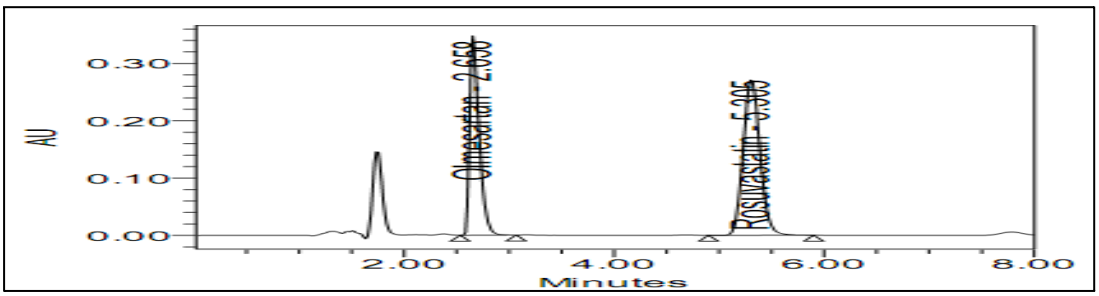


Fig: 3. Chromatogram of specificity sample solution

Precision

Method Precision Solution (Prepare in six replicates)<u>Procedure</u>

Transfer carefully one tablet content into vials containing 900 mL of pH 3.2 phosphate buffers and start the validation as per the parameters mentioned above. Withdraw 20 mL aliquot at the end of specified time. Filter through 5µm filter

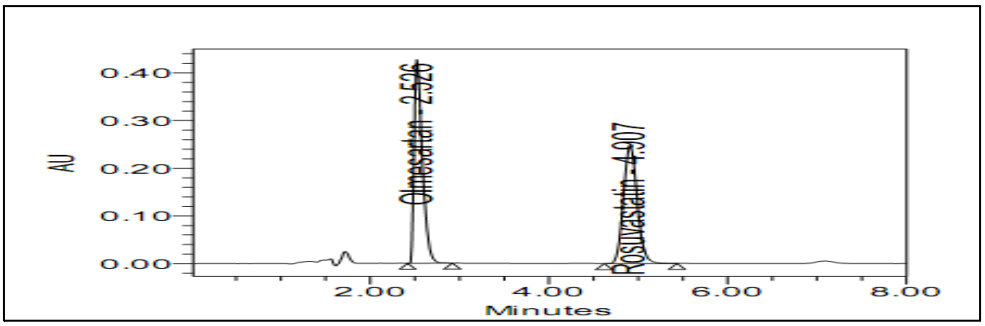


Fig:4 Chromatogram of precision sample solution

Precision data of Olmesartan

S.No	Weight of sample (mg)	Sample Area	% Drug Released
1	439.2	2685638	101.2
2	441.2	263114	99.1
3	438.9	2612626	98.4
4	441.4	2677685	100.9
5	442.3	2693582	101.5
6	446.7	2630347	99.1
Mean			100.03
SD			1.2
%RSD			1.2

Precision data of Rosuvastatin

S.No	Weight of sample (mg)	Sample peak(nm)	% Drug Released
1	439.2	2848196	98.2%
2	441.2	2843135	98.0%
3	438.9	2829552	97.5%
4	441.4	2844480	98.0%
5	442.3	2839332	97.9%
6	439.7	2849541	98.2%
Mean			98.0
SD			0.25
%RSD			0.25%

Linearity

Procedure: Ensure that the system meets the required system suitability by injecting the standard solution. Inject each solution in duplicate. Calculate y-intercept, slope, Y-bias, correlation coefficient of linear regression and residual sum of squares for each analyze

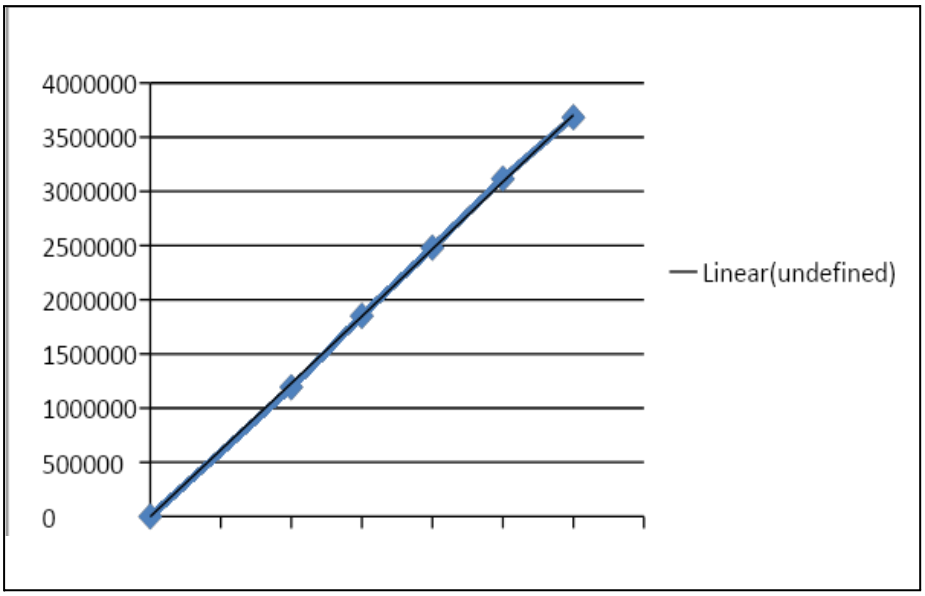
Linearity solution preparation

LevelNo:	% of Olmesartan w.r.t sampleconc.n	% of Rosuvastatin w.r.t sampleconc.n	Volume of Olmesartan n stock solutionto be taken (mL)	Volume of Rosuvastatin estock solution to be taken (mL)	Dilutedto volume(mL)
1	25	25	0.25	0.25	10
2	75	75	0.75	0.75	10
3	100	100	1	1	10

Linearity data of Olmesartan

Linearity level	Nominal Conc.(%)	Conc. (mg/mL)	Peak Area
1	25	10	1192845
2	75	15	1850914
3	100	20	2480230
4	125	25	3116334
5	150	30	3683312
Slope Y-Intercept Correlation coefficientY-Bias			123961 12077 0.999 -0.57

Figure: 5 Graph for Linearity data of Olmesartan

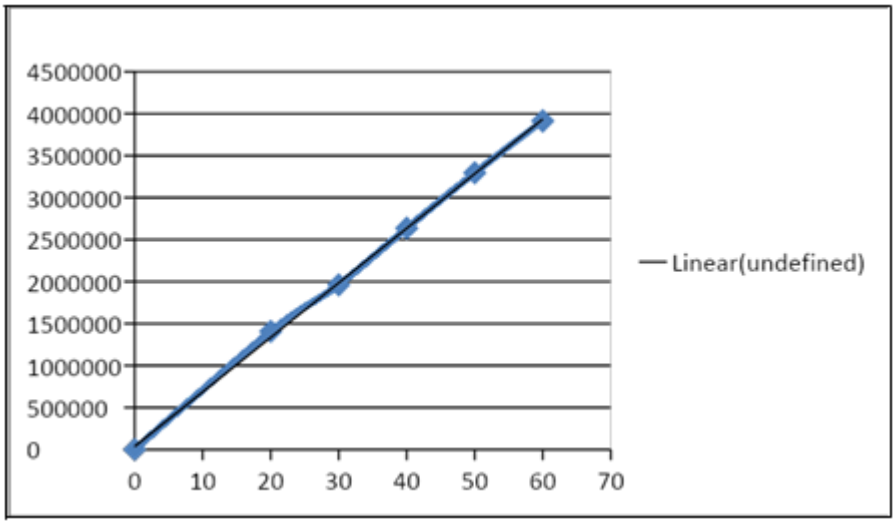


Linearity data of Rosuvastatin

Linearity level	Nominal Conc. (%)	Conc. (mg/mL)	Peak Area
1	25	10	1405952
2	75	20	1961437
3	100	30	2635705
4	125	40	3295767
5	150	50	3913594

	Slope	64963
	Y-Intercept	36659
	Correlation coefficientY-Bias	0.999
		0.18

Figure: 6 Graph for Linearity data of Rosuvastatin



Accuracy:

Procedure : Ensure that the system meets the required system suitability by injecting the system suitability solution. Prepare three sets of each level. Inject each set of a level in singlet. Calculate the % recovery of each level by using the below formula.

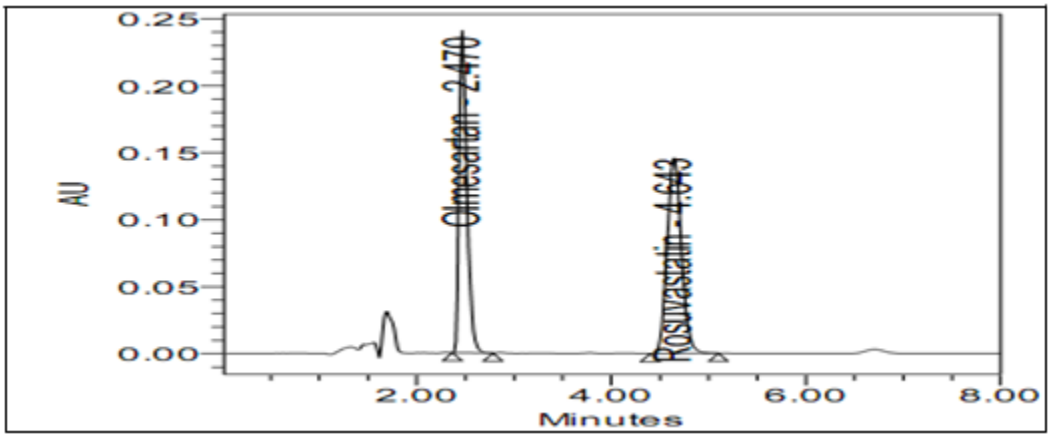


Fig :7. Chromatogram of Accuracy sample solution

Accuracy data of Olmesartan

S.No.	Wt ofOlmesartan (mg)	V4 (mL)	Amount added (mg/mL)	OlmesartanArea	Amount Found (mg/mL)	Olmesart %Recovery
50%-1	29.6	900	0.0326	384259	0.0317	97.3
50%-2	29.2	900	0.0322	389939	0.0322	100.1
50%-3	30.2	900	0.0333	407761	0.0337	101.2
100%-1	39.8	900	0.0439	531791	0.0439	100.1
100%-2	39.5	900	0.0435	530705	0.0438	100.7
100%-3	40.1	900	0.0442	543176	0.0449	101.5
150%-1	49.3	900	0.0543	655616	0.0541	99.6
150%-2	49.5	900	0.0546	660706	0.0546	100
150%-3	49.8	900	0.0549	660086	0.0545	99.3

Accuracy data of Rosuvastatin.

S.No.	Wt of Rosuvastatin(mg)	Amountadded (mg/mL)	Rosuvastatin Area	AmountFound (mg/mL)	Rosuvastatins% Recovery
50%-1	9.4	0.0104	274345	0.0104	100.7
50%-2	9.3	0.0103	273142	0.0104	101.3
50%-3	9.3	0.0103	275219	0.0105	102.1
100%-1	12.5	0.0138	369385	0.0140	101.9
100%-2	12.6	0.0139	370826	0.0141	101.5
100%-3	12.4	0.0137	364729	0.0139	101.5
150%-1	15.5	0.0171	459403	0.0175	102.2
150%-2	15.5	0.0171	453784	0.0173	101
150%-3	15.7	0.0173	454000	0.0173	99.7

Robustness

Robustness was performed by altering column temperature, Mobile phase ratio, and flow rate. The following tables represent the results of the parameters that were altered. The corresponding typical chromatograms are attached.

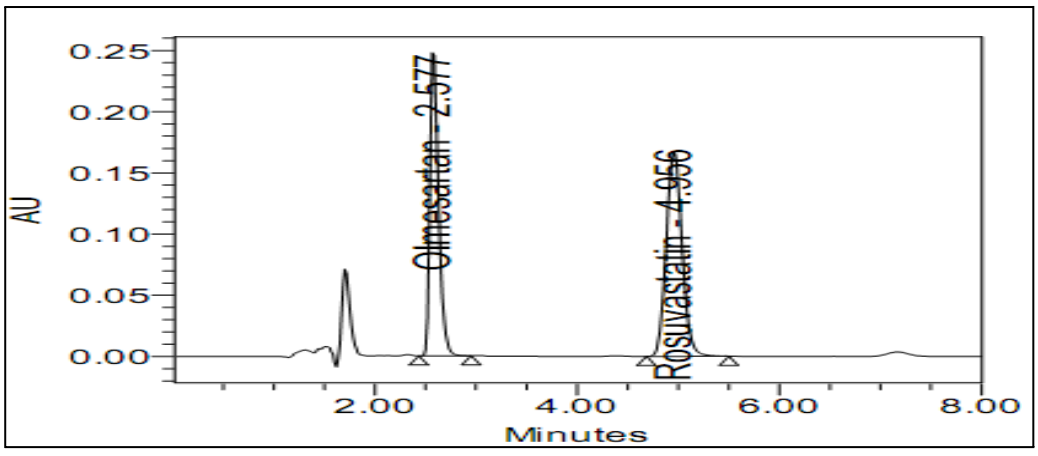


Fig :8 Chromatogram of Robustness Temperature Plussolution

Accuracy data of Olmesartan

S.No.	Wt ofOlmesartan (mg)	V4 (mL)	Amount added (mg/mL)	OlmesartanArea	Amount Found (mg/mL)	Olmesart %Recovery
50%-1	29.6	900	0.0326	384259	0.0317	97.3
50%-2	29.2	900	0.0322	389939	0.0322	100.1
50%-3	30.2	900	0.0333	407761	0.0337	101.2
100%-1	39.8	900	0.0439	531791	0.0439	100.1
100%-2	39.5	900	0.0435	530705	0.0438	100.7
100%-3	40.1	900	0.0442	543176	0.0449	101.5
150%-1	49.3	900	0.0543	655616	0.0541	99.6
150%-2	49.5	900	0.0546	660706	0.0546	100
150%-3	49.8	900	0.0549	660086	0.0545	99.3

Accuracy data of Rosuvastatin.

S.No.	Wt of Rosuvastatin(mg)	Amountadded (mg/mL)	Rosuvastatin Area	AmountFound (mg/mL)	Rosuvastatins% Recovery
50%-1	9.4	0.0104	274345	0.0104	100.7
50%-2	9.3	0.0103	273142	0.0104	101.3
50%-3	9.3	0.0103	275219	0.0105	102.1
100%-1	12.5	0.0138	369385	0.0140	101.9
100%-2	12.6	0.0139	370826	0.0141	101.5
100%-3	12.4	0.0137	364729	0.0139	101.5
150%-1	15.5	0.0171	459403	0.0175	102.2

IV. CONCLUSION:

From the above experimental data results and parameters it was concluded that, the new chromatographic method developed for the Olmesartan and Rosuvastatin in Bulk and tablet dosage form was found to be simple, precise, accurate, linear, robust and economic and it can be effectively applied for future analysis.

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