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DEVELOPMENT AND VALIDATION OF RP–HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF ATORVASTATIN AND METOPROLOL SUCCINATE IN COMBINED PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

A simple and accurate method was developed using Reverse Phase-High Performance Liquid Chromatography (RP-HPLC) to measure Atorvastatin calcium (ATS) and Metoprolol Succinate (MET) together for pure drug and in tablets. The separation was done using a Shimadzu Shim-pack C8 column with dimensions 4.6 mm by 250 mm and a particle size of 5 micrometers. The mobile phase consisted of HPLC-grade acetonitrile, methanol, and water in a ratio of 50:30:20 by v/v, and the pH was adjusted to 3 using 1% o-phosphoric acid. The flow rate was set at 1.0 ml per minute. Both drugs were detected at a wavelength of 220 nm, with the retention time of ATS at 4.402 minutes and MET at 3.367 minutes. The method showed good linearity across the concentration ranges of 10 to 200 µg/ml for ATS and 25 to 500 µg/ml for MET, with correlation coefficient of ATS was 0.9996 and MET was 0.9999. The limits of detection and quantification were 1.026 and 3.110 µg/ml for ATS, and 5.053 and 15.31 µg/ml for MET. The method was validated for accuracy, precision, and robustness following ICH Q2 (R2) guidelines, proving it is suitable for regular use in checking the quality of combined medicine tablets.

KEYWORDS: Accuracy, Antilipidemic agent, Antihypertensive, Atorvastatin, Hypertension, Metoprolol succinate, Precision, Repeatability.

1. INTRODUCTION

Lipid-lowering drugs known as HMG-CoA reductase inhibitors, or statins, are used for both primary and secondary prevention of coronary heart disease. These drugs help increase the level of high-density lipoprotein cholesterol (HDL-C) and lower the levels of triglycerides (TG), total cholesterol (TC), and low-density lipoprotein cholesterol (LDL-C). While the FDA-approved statins may have slight differences in their effects, they are generally recommended for treating or preventing clinical atherosclerotic cardiovascular disease in both primary and secondary prevention, such as myocardial infarction and stroke.[1]

The most common cardiovascular condition is hypertension, which is defined by a continuous increase in blood pressure above the normal range, which is from 120/80 mm Hg to 140/90 mm Hg. Stroke is often caused by hypertension, and it also increases the risk for coronary artery disease, including atherosclerosis and related complications like cardiac failure, renal insufficiency, and dissecting aortic aneurysm.[2]

Blood pressure levels are categorized into stages to assess hypertension.

- Normal: Less than 120/80 mm Hg
- Elevated: Systolic between 120–129 mm Hg and diastolic below 80 mm Hg[3]
- Stage 1 Hypertension: Systolic between 130–139 mm Hg or diastolic between 80–89 mm Hg
- Stage 2 Hypertension: Systolic at or above 140 mm Hg or diastolic at or above 90 mm Hg.[4]

Atherosclerosis occurs when fatty deposits accumulate within arterial walls, contributing significantly to the development of coronary artery disease.[5] Both high blood pressure and elevated cholesterol levels are major cardiovascular risk factors, and managing them together is essential to lower the chances of severe complications.[6]

Atorvastatin belongs to the class of medications known as statins and functions as a lipid-lowering agent.[7] It inhibits the activity of the enzyme HMG-CoA reductase (3-hydroxy-3-methylglutaryl-coenzyme A reductase), which plays a key role in the body's cholesterol synthesis. This action helps to decrease endogenous cholesterol production.[8] Physically,

atorvastatin appears as a white, odorless powder. It is highly soluble in methanol, has limited solubility in water, and slightly insoluble in methylene chloride.[9]

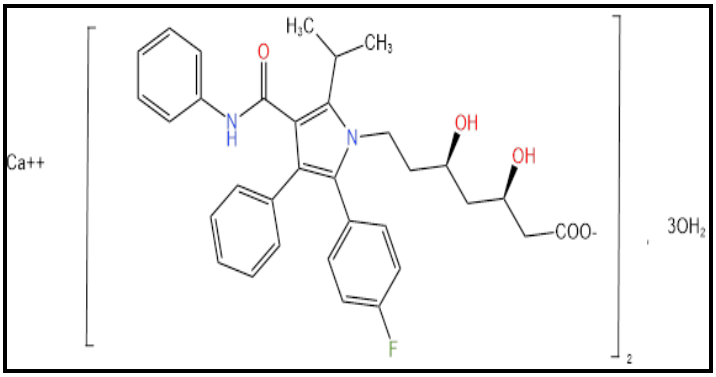

Fig No 1: Chemical Structure of Atorvastatin Calcium (ATS)[10]

Metoprolol succinate is a type of medicine used to treat high blood pressure, chest pain, irregular heartbeats, fluid buildup in the heart, and heart attacks. It works by blocking certain receptors in the heart and blood vessels. It is considered a beta-1 blocker specifically targeting the heart. This medication has a molecular weight of 652.8 and appears as a white, crystal-like powder. It does not dissolve well in solvents like ethyl acetate, acetone, diethyl ether, or heptane. However, it dissolves easily in water and methanol. It is insoluble in ethanol, dichloromethane and isopropanol.[11]

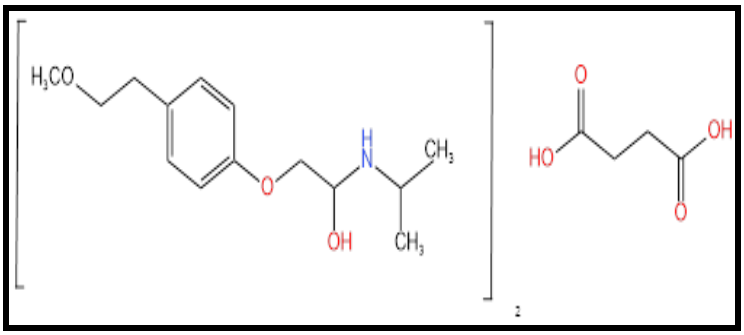

Fig No 2: Chemical Structure of Metoprolol Succinate (MET)[12]

Validation of the developed method will be carried out in accordance with International Conference for Harmonization ICH Q2 (R_1) guidelines.

According to United States Food and Drug Administration (USFDA) "Process validation is establishing documented evidence which provides a high degree assurance that a specific process (such as manufacturing of pharmaceutical dosage forms) will consistently produce a product meeting its predetermined specifications and quality characteristics".

Method validation is an integral part of method development; it is the process by which a method is tested by the developer for its specificity, accuracy, and precision.

Validation demonstrates that analytical methods are suitable for their intended use and that they support the identity, quality, purity, and potency of the drug substances and drug products.[13]

2. MATERIALS AND METHODS

2.1 Materials

The glassware and equipment utilized in the research were made of borosilicate and were properly calibrated prior to use**.** Active pharmaceutical ingredients (APIs) of Atorvastatin and Metoprolol Succinate were sourced from Zuventus Healthcare Ltd., located in Hinjewadi, Pune, and CTX Life Sciences, based in Ankleshwar, Surat-Gujarat, respectively. Commercial tablets ATS 10 mg (Lipvas®) and MET 25 mg (Prolomet® XL 25) were procured from CIPLA Ltd., Malpur, District Solan, India, and SUN Pharma Laboratories Ltd., Assam, India.

2.2 Instruments Used

- **HPLC System Liquid Chromatography :** Shimadzu LC- 20AT
- **UV – Visible Detector :** Shimadzu SPD-20A
- **Analytical Column :** Shimadzu shim-pack 5µm C8 (4.6 × 250 mm)
- **Data Processor :** LabSolutions software Version 5.90
- **Injector :** Rheodyne – 7725i (Fixed Capacity Loop of 20µl)
- **Syringe :** Hamilton, 25 µl
- **Filter :** Nylon (25 mm, 0.2 µm) filter
- **Electronic Weighing Balance (Sartorius – TE 214 S)**
- **Ultrasonicator (RC Systems – MU 1700)**
- **UV-Visible Spectrophotometer (Shimadzu – 1700, Software Version – UVProbe 2.32)**
- **Digital pH Meter (Digisun Electronics – 7007)**
- **Vacuum Pump (Value High Reliability Vaccum Pump)**
- **Supor 200 Membrane Filter, 0.2 µm (Pall India Pvt. Ltd)**

2.3 Chemicals and Reagents

HPLC grade Methanol, Acetonitrile was used as a solvent which was procured Avantor Performance Materials India Pvt. Ltd., Thane, Maharashtra India.

2.4 METHODOLOGY

2.4.1 Selection of Analytical Wavelength

To investigate the appropriate analytical wavelength for simultaneous estimation of ATS and MET, the standard solutions of ATS (10 µg/ml), and MET (25 µg/ml) were prepared with double distilled water. These solutions were scanned separately in the UV region from 200 to 400 nm and the overlain spectra for the selection of analytical wavelength were shown in **Figure No. 3.**

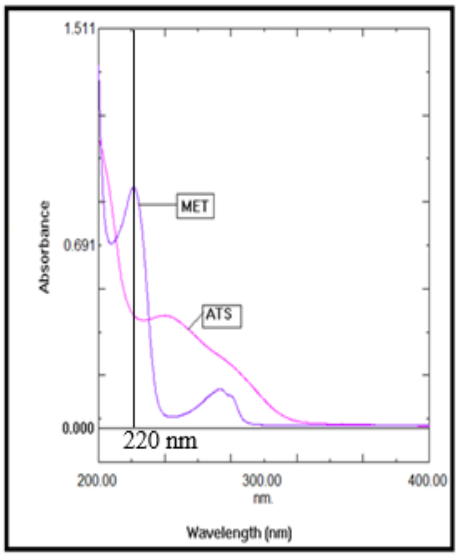

Figure No: 3. Overlain Spectra of ATS (10 µg/ml) and MET (25 µg/ml) in Methanol.

2.4.2. Finalized Chromatographic Conditions

- ✓ **Analytical Column:** Shimadzu Shim-pack 5µm C8 (4.6 × 250 mm)
- ✓ **Mobile Phase :** ACN : MEOH : Water pH3 (50:30:20 %v/v)
- ✓ **Injection volume :** 20 µl
- ✓ **Flow rate :** 1.0 ml/min
- ✓ **Detection Wavelength :** 220 nm
- ✓ **AUFS :** 0.1000
- ✓ **Pressure :** 8.2 MPa

2.4.3. Preparation of Mobile Phase

Mobile phase was prepared by mixing 50 ml of HPLC-grade Acetonitrile with 30 ml of HPLC grade Methanol and 20 ml of HPLC-grade water of pH 3. The pH of the water was

adjusted with 1% o-phosphoric acid. The Mobile Phase was filtered through a 0.2 µm Supor 200 membrane filter paper by using a vacuum pump and sonicated for 10 min.

2.4.4. Preparation of Standard Stock Solution

I. Standard Stock Solution of ATS

10 mg of Standard ATS was weighed and transferred to a 10 ml volumetric flask and dissolved it in 10 ml of HPLC grade methanol to obtain a final concentration of 1000 µg/ml of ATS. This was labelled as 'Std Stock ATS- A'. From the above solution, 1 ml of aliquot was pipetted out into a 10 ml volumetric flask and the volume was made up to the mark with HPLC grade methanol to obtain 100 µg/ml of ATS. This was labelled as 'Std Stock ATS-B'.

II. Standard Stock Solution of MET

10 mg of MET was weighed and transferred to a 10 ml volumetric flask and dissolved it into a 10 ml of HPLC grade methanol to obtain a final concentration of 1000 µg/ml of MET. This was labelled as 'Std Stock MET-A'. From the above solution, 1 ml of aliquot was pipetted out into a 10 ml volumetric flask and the volume was made up to the mark with HPLC grade methanol to obtain 100 µg/ml of MET, this was labelled as 'Std Stock MET-B'.

2.4.5. Preparation of Calibration Curve for ATS and MET

Cleaned volumetric flasks of 10 ml were taken and labelled them as C1, C2, C3, C4, and C5. From the 'Std Stock ATS- A'(1000 µg/ml) solution 0.1, 0.5, 1, 1.5 and 2 ml of aliquot were pipetted out and transferred into a C1, C2, C3, C4, and C5 volumetric flasks. The volume was made up to the mark with HPLC grade Methanol to obtain the concentration of 10, 50, 100, 150, and 200 µg/ml of ATS. Similarly From the 'Std Stock MET-A' (1000 µg/ml) solution, 0.25, 1.25, 2.5, 3.75 and 5ml of aliquot were pipetted out and transferred into a C1, C2, C3, C4, and C5 volumetric flasks and the volume was made up to the mark with HPLC grade Methanol to obtain the concentration of 25, 125, 250, 375 and 500 µg/ml of MET.

The above all solutions were filtered through a Nylon filter (25 mm, 0.25 µm) using syringe and injected into the Rheodyne injector (20 µl) of HPLC system and their chromatograms were recorded under the finalized chromatographic conditions as described above after getting a stable baseline. Peak areas were recorded for all the drugs. Overlain chromatogram for each dilution was shown in **Figure No 4.** Calibration curves of ATS and MET were constructed by plotting the peak area v/s concentration of ATS and MET respectively as shown in **Figure No 5 and 6.** The results of calibration study are given in **Table No 1 and 2.**

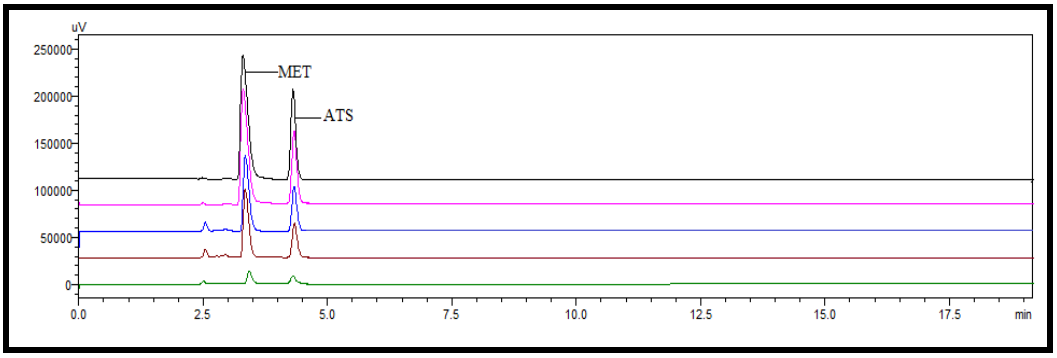

Figure No: 4. Overlain Chromatograms of Serial Dilutions of ATS (10 - 200 µg/ml), MET (25 – 500 µg/ml) in Acetonitrile: Methanol: HPLC Grade water (pH3) (50:30:20 %v/v/v) at a Flow Rate of 1.0 ml/min, at 220 nm using C8 column.

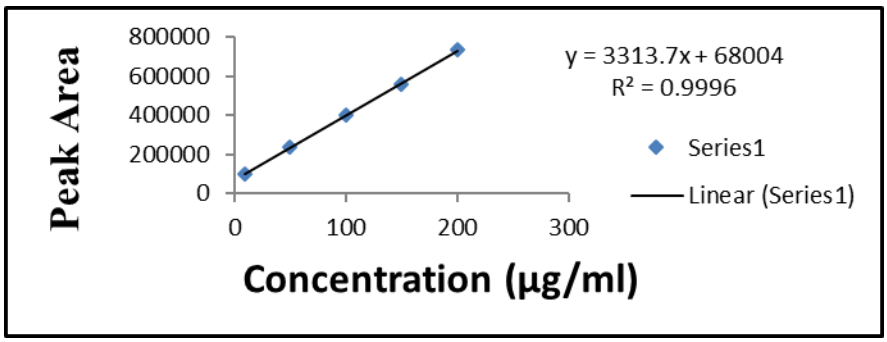

Figure No: 5. Calibration Curve of ATS by RP-HPLC Method.

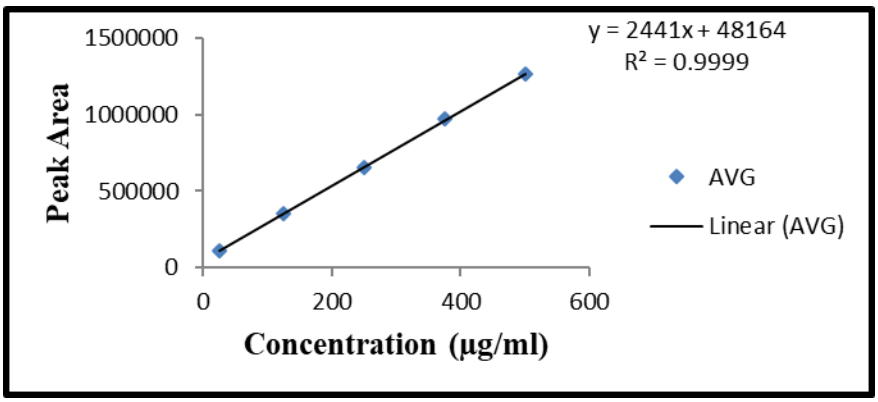

Figure No: 6. Calibration Curve of MET by RP-HPLC Method.

2.4.5. Analysis of Tablet Mixture

20 Tablets of (Lipvas®) each containing ATS 10 mg and (Prolomet® XL 25) each containing MET 25 mg were weighed and their average weight was determined and finely powdered. Weigh tablet powder equivalent to 10 mg of ATS and 25 mg of MET was transferred into a 50 ml volumetric flask, 25 ml of HPLC grade methanol was added and sonicated for 10

min. The volume was made up to the mark with the same solvent. The solution was filtered using Whatman filter paper No. 41 and labelled as 'Sample Stock A'.

From the above 'Sample Stock A' solution, 5 ml of the aliquot was pipetted out and transferred to a 10 ml volumetric flask. The volume was made up to the mark with the HPLC grade methanol. (100µg/ml of ATS and 250µg/ml of MET).

Similarly, from the 'Std Stock ATS' (1000µg/ml) solution 1 ml of aliquot was pipetted out in a 10 ml volumetric flask and from 'Std Stock MET-B' (1000µg/ml) solution 2.5 ml aliquot was pipetted out in the same 10ml volumetric flask. The volume was made up to the mark with methanol to obtain a solution with a final concentration of 100 µg/ml of ATS and 250 µg/ml of MET. Both solutions (Standard and Sample) were filtered through Nylon (25 mm, 0.2 µm) filter using syringe and followed by injection into the Rheodyne injector (20 µl) of HPLC system using Hamilton Syringe. Both the sample and standard chromatograms were recorded under the finalized chromatographic conditions as described above after getting a stable baseline. Peak areas were recorded for all the peaks. The results were shown in **Table No.4** and overlain spectra are given in **Figure No. 8.**

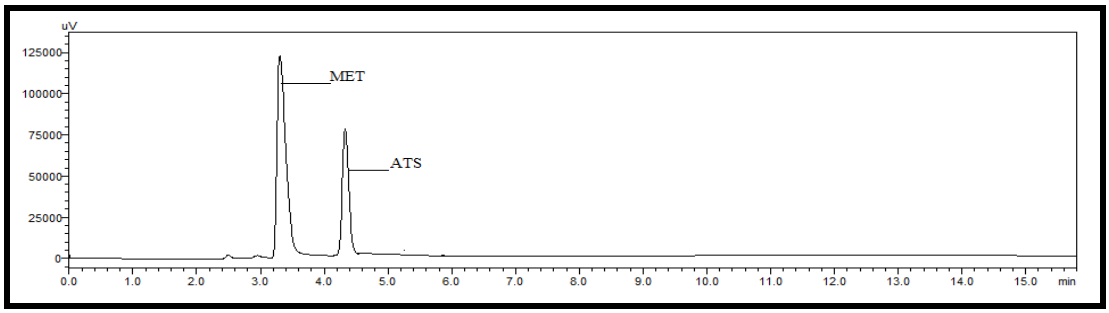

Figure No: 7. Chromatogram of mixed standard solution of ATS (10 µg/ml) and MET (25 µg/ml).

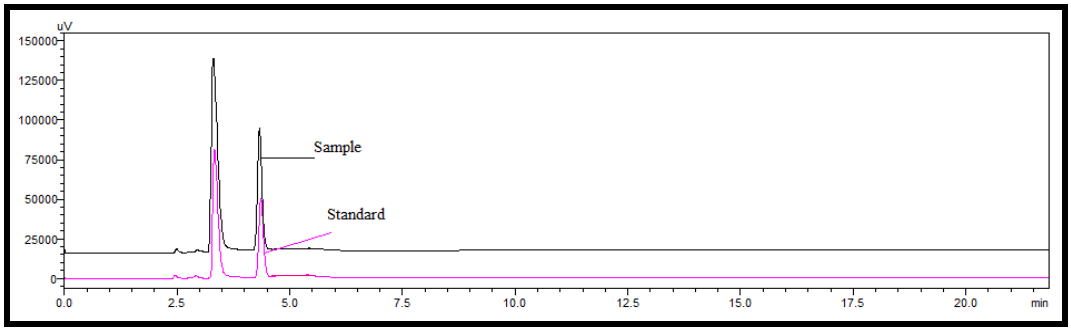

Figure No: 8. Overlain Chromatograms of Sample and Standard Solution of ATS (100 µg/ml) and MET (250 µg/ml).

2.4.6 Validation of RP-HPLC Method.

2.4.6.1 Accuracy

Twenty tablets were weighed and powdered for the study of accuracy. Recovery studies were carried out by adding the known amount of standard ATS (80, 100 and 120 µg/ml) and standard MET (200, 250 and 300µg/ml) to the pre analyzed sample at three different concentration levels i.e., 80%, 100%, and 120% and percentage recoveries were calculated. The results were shown in **Table No. 6 and 7.**

2.4.6.2 Precision

The Precision of an analytical method was studied by performing intermediate precision and repeatability.

I. Intermediate Precision

1. Intra-day precision

Intra-day precision was determined by analyzing the standard solutions of ATS (50, 100 and 150 µg/ml) and MET (125, 250, and 375 µg/ml) at three different time intervals on the same day **Table No 8 and 9.**

2. Inter-day Precision

Inter-day precision was determined by analyzing the standard solutions of ATS (50, 100, and 150 µg/ml) and MET (125, 250, and 375 µg/ml) on three consecutive days **Table No 10 and 11.**

II. Repeatability

Standard solutions of ATS (100 µg/ml) and MET (250 µg/ml) was prepared and filtered through Nylon (25 mm, 0.2 µm) filter using a Hamilton syringe and followed by injection into the Rheodyne injector. This solution was injected six times and Area under the curve was recorded **Table No 12.**

2.4.6.3.Linearity and Range

The concentration ranges 10-200 µg/ml for ATS and 25-500 µg/ml for MET were prepared and analyzed. Linearity of the method was decided by observing R^2 value.

2.4.6.4 Limit of Detection and Limit of Quantitation

Detection limit and quantitation limit were determined based on the standard deviation of Y-intercepts of six calibration curves and average slope of six calibration curves. The formula is as follows:-

$$LOD = 3.3 \times \frac{\text{Standard Deviation of y-Intercepts of Six Calibration curves}}{\text{Average Slope of Six Calibration Curves}}$$

$$LOQ = 10 \times \frac{\textit{Standard Deviation of y-Intercepts of Six Calibration curves}}{\textit{Average Slope of Six Calibration Curves}}$$

The results of LOD and LOQ are shown in the summary table.

2.4.6.5 Robustness

Standard solutions of ATS (100 µg/ml) and MET (250 µg/ml) was prepared and analyzed at different flow rate (0.98, 1.0 and 1.02 ml/min) and different mobile phase ratio (48:28:18, 50:30:20 and 52:32:22 % v/v) of Acetonitrile: Methanol: water pH3 and different wavelengths (218, 220 and 222 nm). The results were shown in **Table No 13,14 and 15.**

2.4.6.6 System Suitability

Standard solutions of ATS (100 µg/ml) and MET (250 µg/ml) were prepared and analyzed six times. Chromatograms were studied for different parameters such as tailing factor, resolution and theoretical plates to see that whether they comply with recommended limit or not. Results of validation parameters are shown in **Table No 16.**

3. RESULTS

Table No: 1 Results of Calibration Curve of ATS.

Conc. (µg/ml)	Peak Area Mean ± SD	% RSD
10	102095.2 ± 965.5035	0.94569
50	242143.7 ± 4589.988	1.89556
100	409845.7± 5632.983	1.37441
150	559873.6± 7893.121	1.40980
200	730700.8± 0.0235	0.74044

Table No. 2: Results of Calibration Curve of MET.

Conc. (µg/ml)	Peak Area Mean ± SD	% RSD
25	109257.2 ± 508.2462	0.46518
125	352398.5 ± 4792.211	1.35988
250	655057.5± 6253.089	0.95458
375	972622.2± 4609.571	0.47393
500	1263721± 3209.675	0.25398

Table No: 3 Linear Regression Analysis of Calibration Curves for ATS and MET.

Parameters	ATS	MET
Linearity Range (µg/ml)	10-200	25-500
Slope	3313	2441
Intercept	63551	48164
Correlation Coefficient (R^2)	0.9996	0.9999
LOD (µg/ml)	1.026	5.053
LOQ (µg/ml)	3.110	15.31

Table No: 4 Assay Results of Tablet Mixture.

Sl. No.	Amount Present (mg/tab)		Amount Found (mg/tab)		% Assay	
	ATS	MET	ATS	MET	ATS	MET
1	10	25	9.90	24.98	99.00	99.92
2	10	25	9.93	24.62	99.30	98.48
3	10	25	10.01	25.03	100.10	100.12
4	10	25	9.89	24.93	98.90	99.72
5	10	25	10.26	25.76	102.60	103.04
6	10	25	10.07	25.58	100.70	102.32
Mean			10.01	25.15	100.10	100.60
±SD			0.1284	0.4311	1.4071	1.7247
%RSD			1.2832	1.7144	1.3029	1.7144

Table No: 5 Results of Chromatogram of Sample Solution.

Analyte	Retention Time (min)	Area (mV. s)	Tailing Factor (T)	Theoretical Plates (N)	Resolution (R)
ATS	4.402	373562	1.216	9954	4.871
MET	3.367	690952	1.719	2450	1.928

Table No: 6 Results of Accuracy for RP-HPLC Method.

Level of % Recovery	Sl. No.	Amount of Standard Drug Added (µg/ml)		Total Amount Found (µg/ml)		Total Amount Recovered (µg/ml)		%Recovery	
		ATS	MET	ATS	MET	ATS	MET	ATS	MET
80 %	1	80	200	179.36	450.31	79.36	200.31	99.20	100.15
	2	80	200	179.96	450.01	79.96	200.01	99.95	100.00
	3	80	200	180.03	449.25	80.03	199.25	100.21	99.62
100 %	1	100	250	199.42	500.21	99.42	250.21	99.42	100.08
	2	100	250	199.53	500.03	99.53	250.03	99.53	100.03
	3	100	250	200.21	500.54	100.21	250.54	101.21	100.54
120%	1	120	300	220.32	550.74	120.32	300.74	100.20	100.24
	2	120	300	220.74	549.94	120.74	299.94	100.61	99.98
	3	120	300	220.85	550.86	120.85	300.86	100.70	100.28

Table No: 7 Statistical Validation Data for Accuracy Study.

Level of % Recovery	Mean* (% Recovery)	±SD	%RSD

	ATS	MET	ATS	MET	ATS	MET
80%	99.78	99.92	0.5244	0.2731	0.5255	0.2734
100%	100.05	100.21	1.0032	0.2811	1.0026	0.2805
120%	100.50	100.16	0.2665	0.1628	0.2651	0.1626

*Mean of 3 estimations

Table No: 8. Results of Intra-day Precision of ATS.

Concentration (µg/ml)	Peak Area at Following Time (hr)			Mean	±SD	%RSD
	0	2	4			
50	247865	249897	246894	248218.7	1532.42	0.6173
100	379865	378965	376784	3785380	1584.62	0.4185
150	546793	535678	547845	5478450	6741.48	1.2405

Table No: 9. Results of Intra-day Precision of MET.

Concentration (µg/ml)	Peak Area at Following Time (hr)			Mean	±SD	%RSD
	0	2	4			
125	346789	358964	353248	353000.3	6091.27	1.7255
250	658328	659843	645321	654497.3	7982.95	1.2197
375	968324	968932	974328	970528	3304.90	0.3405

Table No: 10: Results of Inter-day Precision of ATS.

Concentration (µg/ml)	Peak Area at Following Day			Mean	±SD	%RSD
	0	1	2			
50	234687	236785	236734	236068.7	1196.83	0.5069
100	398765	387976	398765	395168.7	6229.03	1.5762
150	556897	551267	556784	554982.7	3218.35	0.5799

Table No: 11: Results of Inter-day Precision of MET.

Concentration (µg/ml)	Peak Area at Following Day			Mean	±SD	%RSD
	0	1	2			
125	354328	346734	354328	351796.7	4384.39	1.2462
250	658934	648976	658943	655617.7	5751.85	0.8773
375	976532	968654	978963	974716.3	5389.00	0.5528

Table No: 12: Results of Repeatability Study for ATS and MET.

Sl. No.	Peak Area	
	ATS (100 µg/ml)	MET (250 µg/ml)
1	398765	658934
2	387976	648976
3	379865	658943
4	378965	658328
5	376784	659843
6	398765	645321
Mean	386853.3	655057.5

±SD	2867.438	2389.453
% RSD	0.224371	0.364770

Table No: 13: Results of Robustness Study: Variation in Flow Rate (ml/min).

Flow Rate (ml/min)	Analyte	Retention Time*(min)	Tailing Factor*(T)	Theoretical Plates*(N)	Resolution*(R)
0.98#	ATS	4.368	1.305	48965	4.356
	MET	3.387	1.865	18654	1.901
1.0#	ATS	4.402	1.216	50976	4.871
	MET	3.367	1.711	24189	1.928
1.02#	ATS	4.245	1.345	49722	4.286
	MET	3.967	1.887	19387	1.913

*% RSD was found to be less than 2 % for each drug; # Mean of 3estimations

Table No: 14: Results of Robustness Study: Variation in Organic Solvent Ratio in Mobile Phase.

Mobile Phase (ACN: Methanol: HPLC Grade water pH 3 %v/v/v)	Analyte	Retention Time*(min)	Tailing Factor*(T)	Theoretical Plates*(N)	Resolution*(R)
48:28:18	ATS	4.632	1.275	48722	4.136
	MET	3.254	1.987	17992	2.247
50:30:20	ATS	4.235	1.243	51158	4.411
	MET	3.154	1.926	21325	2.784
52:32:22	ATS	4.435	1.258	47862	4.257
	MET	3.232	1.941	19865	2.169

*% RSD was found to be less than 2 % for each drug; # Mean of 3 estimation

Table No: 15. Results of Robustness Study: Variation in Wavelength (nm).

Wavelength (nm)	Analyte	Retention Time*(min)	Tailing Factor*(T)	Theoretical Plates*(N)	Resolution*(R)
218	ATS	4.462	1.128	53935	4.770
	MET	3.666	1.440	74997	3.374
220	ATS	4.240	1.213	53935	4.226
	MET	3.425	1.336	85423	1.477
222	ATS	4.224	1.287	50205	4.489
	MET	3.453	1.654	75855	2.354

*% RSD was found to be less than 2 % for each drug; # Mean of 3 estimation

Table No: 16. System Suitability Results of the Proposed Method (n=6).

Analyte	R	N	T	%RSD	
				Rt	Peak Area
ATS	4.871	9954	1.216	4.402	373562

MET	1.928	2450	1.719	3.367	690952
Required limits	R>2	N>2000	T<2	RSD < 2%	

4. SUMMARY

Parameters	**ATS**	**MET**
Retention Time (min)	4.871	3.367
Linearity Range (µg/ml)	10-200	25-500
Regression Equation (y=mx+c)	0157494x-63551	2441x+49164
Correlation Coefficient (r^2)	0.9996	0.9999
LOD (µg/ml)	1.026	5.053
LOQ (µg/ml)	3.110	15.31
Analysis of Tables (%Assay)	100.27	100.55
% Recovery	99.78-100.50 %	99.92-100.16
Intra Day Precision (%RSD)	0.4185-1.2405	0.3405-1.7255
Inter Day Precision (%RSD)	0.5069-1.5762	0.5528-1.2462
Repeatability(±RSD)	0.2243	0.3647
Robustness (%RSD)	<2%	<2%

5. CONCLUSION

The validated RP-HPLC method provides a reliable, reproducible, and economical solution for the concurrent quantification of Atorvastatin and Metoprolol Succinate in pharmaceutical formulations. It demonstrated accuracy, precision, and adherence to ICH standards support its application in routine quality control and analytical procedures within the pharmaceutical sector.

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