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Qualitative Analysis of Atorvastatin Raw Material and Atorvastatin Finished Tablet

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Abstract: *Atorvastatin calcium is a widely prescribed lipid-lowering agent belonging to the statin class of drugs. The present study focuses on the qualitative and quantitative evaluation of atorvastatin calcium raw material and finished tablet dosage form according to Indian Pharmacopoeia (IP) specifications. Various analytical techniques including IR spectroscopy, UV-Visible spectroscopy, Thin Layer Chromatography (TLC), High Performance Liquid Chromatography (HPLC), dissolution testing, disintegration, friability, hardness, assay, and impurity profiling were performed. The results confirmed that both the raw material and tablet formulation complied with IP standards. The study establishes the identity, purity, strength, and performance characteristics of atorvastatin calcium.*

Keywords: Atorvastatin calcium, HPLC, Dissolution test, Assay, IP standards, Pharmaceutical analysis

I. INTRODUCTION

Atorvastatin is a synthetic lipid-lowering drug belonging to the statin class (HMG-CoA reductase inhibitors). It is marketed under the brand name Lipitor and is used for the treatment of hypercholesterolemia and prevention of cardiovascular diseases.

1.1 Mechanism of Action

Atorvastatin competitively inhibits HMG-CoA reductase, the rate-limiting enzyme in cholesterol biosynthesis. This results in:

- Decreased LDL cholesterol
- Reduced triglycerides
- Increased HDL cholesterol
- Prevention of atherosclerotic plaque formation

1.2 Importance in Therapy

Atorvastatin plays a crucial role in:

- Primary prevention of cardiovascular disease
- Secondary prevention in high-risk patients
- Management of familial hypercholesterolemia

II. EXPERIMENTAL SECTION

2.1 Qualitative analysis of atorvastatin calcium Raw Material

Description

White to off-white crystalline powder exhibiting polymorphism.

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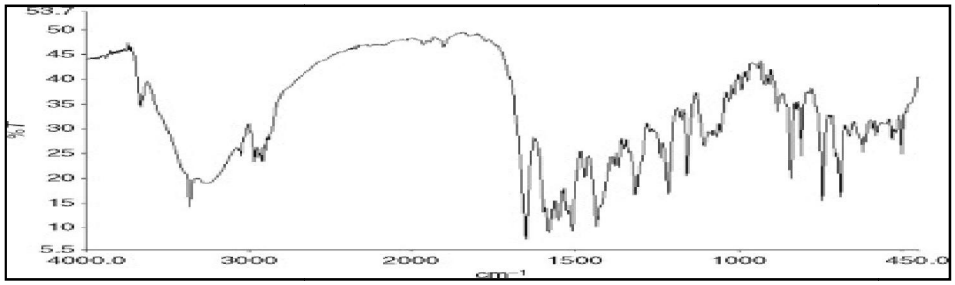
Solubility

- Freely soluble in methanol
- Slightly soluble in ethanol
- Very slightly soluble in water

Identification

IR Spectroscopy

Characteristic peaks observed for: O–H stretching , C=O stretching , Aromatic C=C ,C–F functional group. Spectrum matched with reference standard.

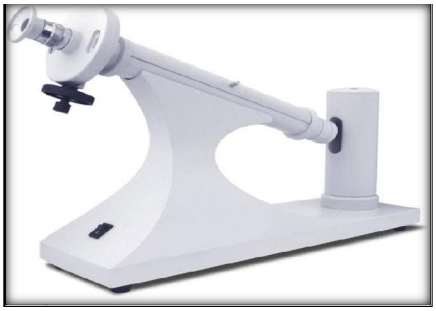


IR peaks of atorvastatin calcium raw materials

Specific Optical Rotation

The specific optical rotation of Atorvastatin Calcium raw material (active pharmaceutical ingredient) is generally defined within the range of **-6.0° to -12.0°. Confirm correct streochemical structure.**

Observed value: –9.10° **Specification:** –12.0° to –6.0° **Result:** Within limit



polarimeter

HPLC Analysis

Chromatographic Conditions

Column: C8 (250 mm × 4.6 mm, 5 µm)
Mobile phase: Buffer : Methanol (50:50)
Flow rate: 1.0 mL/min
Detection: 240 nm
Injection volume: 20 µL

Assay of Raw Material

Observed assay:

- On dried basis: 97.02%
- On anhydrous basis: 99.71%

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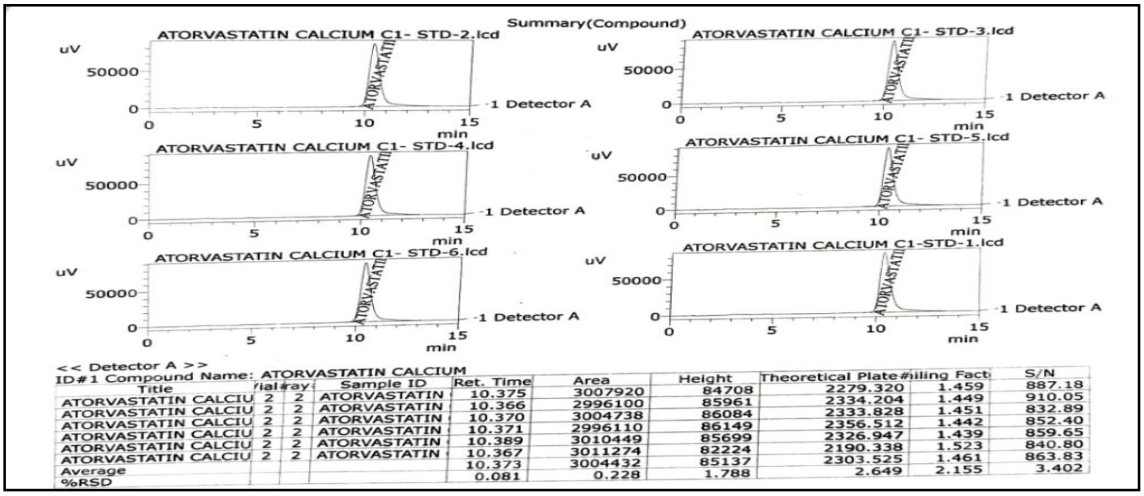
Specification: 98.0% – 102.0% Result: Complies

Figure 1: HPLC Chromatogram of Atorvastatin Standard

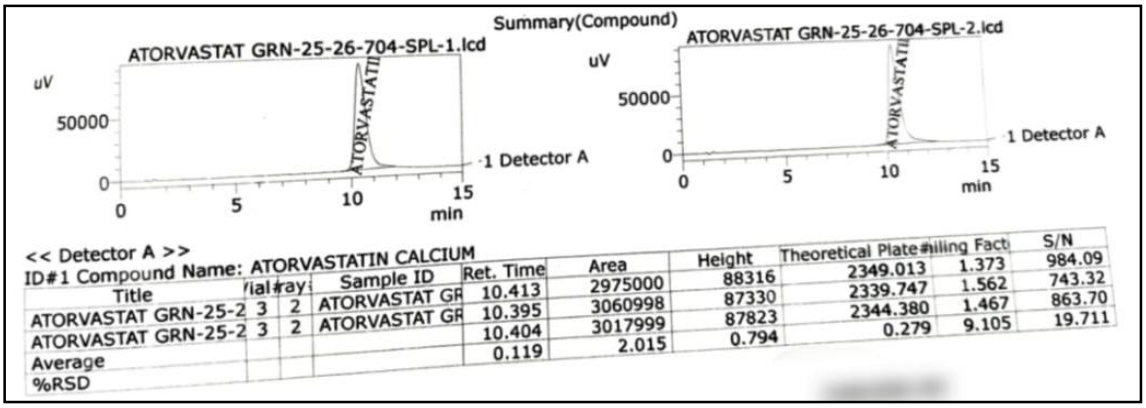
Peak Characteristics: Single sharp peak , Symmetrical shape , Consistent retention time



Title	Vial	Inj	Sample ID	Ret. Time	Area	Height	Theoretical Plate	Tailing Fact	S/N
ATORVASTATIN CALCIU	2	2	ATORVASTATIN	10.375	3007920	84708	2279.320	1.459	887.18
ATORVASTATIN CALCIU	2	2	ATORVASTATIN	10.366	2996100	85961	2334.204	1.449	910.05
ATORVASTATIN CALCIU	2	2	ATORVASTATIN	10.370	3004738	86084	2333.828	1.451	832.89
ATORVASTATIN CALCIU	2	2	ATORVASTATIN	10.371	2996110	86149	2356.512	1.442	852.40
ATORVASTATIN CALCIU	2	2	ATORVASTATIN	10.389	3010449	85699	2326.947	1.439	859.65
ATORVASTATIN CALCIU	2	2	ATORVASTATIN	10.367	3011274	82224	2190.338	1.523	840.80
ATORVASTATIN CALCIU	2	2	ATORVASTATIN	10.373	3004432	85137	2303.525	1.461	863.83
Average				0.081	0.228	1.788	2.649	2.155	3.402
%RSD									

Figure 2: HPLC Chromatogram of Atorvastatin Sample

Retention time matches standard , No significant interference peaks.



Title	Vial	Inj	Sample ID	Ret. Time	Area	Height	Theoretical Plate	Tailing Fact	S/N
ATORVASTAT GRN-25-2	3	2	ATORVASTAT GR	10.413	2975000	88316	2349.013	1.373	984.09
ATORVASTAT GRN-25-2	3	2	ATORVASTAT GR	10.395	3060998	87330	2339.747	1.562	743.32
				10.404	3017999	87823	2344.380	1.467	863.70
Average				0.119	2.015	0.794	0.279	9.105	19.711
%RSD									

Related Substances (Impurity Profiling)

The QC process ensures that the levels of all impurities are below established maximum limits to ensure the drug's safety and efficacy.

Individual impurity: 0.09% Total impurities: 0.36%

Limits: Individual NMT 0.5% Total NMT 2.0%

Result: Within acceptable limits.

2.2. Qualitative Analysis Of Finished Atorvastatin Tablets (10 Mg)

Description :

White, circular, slightly biconvex uncoated tablet.

Weight Variation

This test ensures dose uniformity across tablets. A specified number of tablets are weighed, and the deviation from the average weight must fall within a narrow percentage range specified by the I.P. Limits.

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Weight of 20 tablets = 3.295/ 20 tablets
Average weight: 0.1683 g Deviation range: –2.55% to +2.19%
Limit: ±7.5% Result: Pass

Thickness

The thickness of an atorvastatin tablet is a quality control parameter that varies depending on the dosage (e.g., 10 mg, 20 mg, 40 mg, 80 mg), formulation, and manufacturer, and it is measured during the manufacturing process to ensure uniformity.

Average: 3.40 mm
Limit: 3.20 – 3.60 mm
Result: Within limits

Hardness

Measures the tablet's crushing strength to ensure it can withstand handling and shipping without breaking. Acceptable mechanical strength observed. Average is 3 kg/cm²

Friability

Evaluates the tablet's resistance to abrasion and shock, usually by tumbling in a friabilator apparatus. The weight loss must be within I.P. limits (typically NMT 1%).

Observed: 0.1% Limit: NMT 1% Result: Pass

Friability tester

Disintegration Time

This test measures how quickly the tablet breaks down into smaller particles when placed in a specified medium (eg.phosphate buffer pH 6.8) under controlled temperature and movement, which is a prerequisite for dissolution.

Observed: 1 minute 35 seconds Limit: NMT 30 minutes Result: Pass

Disintegration tester

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Dissolution Study

A critical test that measures the rate and extent to which the active drug is released from the tablet into a solution over a specific period (e.g. NLT 80% dissolved in 30 minutes at pH 6.8 buffer using apparatus 2 at 75 rpm). This predicts how the drug will be absorbed in the body (bioavailability).

Parameters

Apparatus: USP Type II (Paddle)
Medium: 900 mL phosphate buffer pH 6.8
Speed: 75 rpm
Temperature: 37 ± 0.5°C
Time: 30 minutes

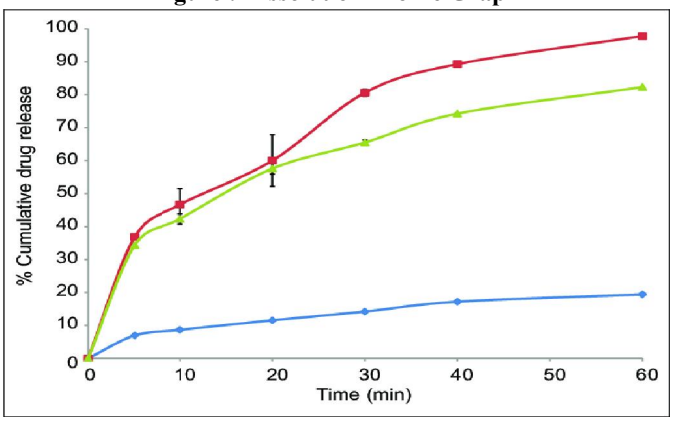
Observation :

Average drug release: 97.08%
Minimum: 95.34%
Maximum: 100.58%

Specification: NLT 70%

Result: Excellent dissolution performance.

Figure : Dissolution Profile Graph



Graph Interpretation:

- Rapid drug release
- Uniform dissolution pattern
- No lag phase observed
- Predictable bioavailability.

Assay :

An assay is an analytical procedure for assessing or measuring the presence, amount or functional activity of a specific drug substance (analyte).

Chromatographic conditions :

Column : C18,250×4.6mm, 5µm or equivalent
Flow rate : 2.0 ml/minute
Detection : 246nm
Inject volume : 20µl
Observation : 97.71%

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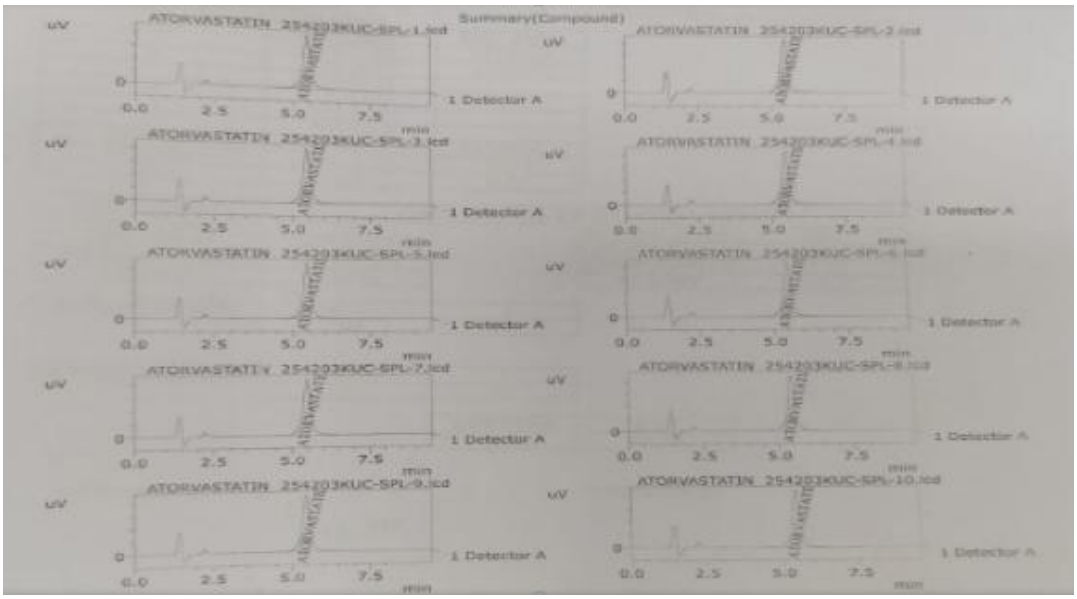

Assay of atorvastatin tablet by HPLC

Uniformity Of Content :

This test ensures that each individual tablet contains a uniform amount of the active ingredient, typically within 85 % to 115 % of the label claim, with a low relative standard deviation (RSD).

Preparation of sample solution:

Take 1 tablet in 50 ml of volumetric flask. Add 3 ml of water and 25 ml of methanol. Transfer 10 ml in 25 ml volumetric flask with solvent mixture. Additionally perform more tablets as per the above given procedure.

Standard flask with sample solution

Specification : 85 % to 115 % **observation :** 102.40%

III. RESULTS AND DISCUSSION

3.1 TEST REPORT FOR ATORVASTATIN CALCIUM IP RAW MATERIAL

S.NO.	TEST	SPECIFICATION	RESULT
1.	Description	A white to off-white, crystalline powder. It shows polymorphism	White crystalline powder.
2.	solubility	Freely soluble in methanol slightly,	complies

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		soluble in ethanol (95%) and very slightly soluble in water.	
3.	Identification		
	By IR	Compare the spectrum with that obtained with atorvastatin calcium IPRS or with the reference spectrum of atorvastatin calcium.	complies
	By atomic absorption spectro - photometry	Shows absorption at the calcium emission line at 422.7 nm	complies
4.	Specific optical rotation	-12.0º to -6.0º	-9.10º
5.	Related substances : (by HPLC)		
	Any individual impurity	Not more than 0.5%	0.09%
	Total impurities	Not more than 2.0%	0.36%
6.	Heavy metals	Not more than 20 ppm	complies
7.	water	Not more than 6.0 %	2.70 %
8.	Assay : (by HPLC) (On dried basis)	Not less than 98.0% and not more than 102 %	Such basis : 97.02%
			Anhydrous basis : 99. 71%

It complies as per IP/BP/USP/HIS with respect to the above tests carried out.

3.2 TEST REPORT OF ATORVASTATIN TABLETS IP 10 mg

S.NO.	TEST	SPECIFICATION	RESULT
1.	Description	Orange colour circular shaped slightly biconvexed film coated tablet having plain on both side.	complies
2.	Identification	The retention time of principal peak of atorvastatin of sample preparation corresponds to that of standard preparation, as obtained in the assay.	Complies
3.	Average weight	0.168 g ± 7.5 % (0.155g to 0.181g)	0.1683g
4.	Uniformity of weight	Individual weight of tablets does not deviate by more than ±7.5% from the average weight	-2.55 % to + 2.19 %
5.	Thickness	3.40 mm ± 0.3mm (3.20 mm to 3.60 mm)	3.40 mm
6.	Disintegrate time	Not more than 30 minutes	1 minutes 35 sec
7.	Dissolution	Not less than 8.000mg (Q. not less than 70.0%)	Average 97.08% Min 95.34% to max 100.58%
8.	Uniformity content (HPLC)	8.500Mg to 11.50 mg (85.0 % to 115.0 %)	Average 102.40 % Minimum 99.57 % to maximum 105 .04 %

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9.	Assay (HPLC)	9.000 mg to 11.00 mg (90.0 % to 110.0 %)	9.77 mg (97.71 %)

IV. CONCLUSION

The present study confirms that Atorvastatin Calcium IP raw material and 10 mg tablets meet required quality control standards. Analytical results demonstrate compliance with identity, purity, potency, and performance specifications.
The product is safe, effective, and pharmaceutically acceptable for therapeutic use in hypercholesterolemia and cardiovascular risk management.

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