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Quality Control Analysis of Ramipril Tablet

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Abstract: *Quality control analysis of pharmaceutical tablets is essential to ensure their safety, efficacy, and consistency. In this study, Ramipril tablets, an angiotensin-converting enzyme (ACE) inhibitor widely used in the treatment of hypertension and cardiovascular disorders, were evaluated using standard quality control tests as per pharmacopeial guidelines. The analysis included physical and chemical parameters such as appearance, average weight, thickness, hardness, friability, disintegration time, dissolution, assay, and uniformity of dosage units. Instrumental techniques including UV–Visible spectrophotometry and High-Performance Liquid Chromatography (HPLC) were employed for quantitative estimation of the active pharmaceutical ingredient. The obtained results were compared with official pharmacopeial limits to assess compliance. All evaluated parameters were found to be within the acceptable range, indicating that the tested Ramipril tablets meet the required quality standards. This study confirms the consistency, reliability, and therapeutic suitability of Ramipril tablets, emphasizing the importance of routine quality control testing in pharmaceutical manufacturing.*

Keywords: Ramipril tablets, Quality control analysis, Pharmaceutical evaluation, HPLC, UV–Visible spectrophotometry, Dissolution test, Assay, Tablet parameters, Pharmacopeial standards, Dosage form evaluation

I. INTRODUCTION

Introduction to Ramipril raw material

Ramipril raw material (API) is a white to off-white crystalline powder, chemically known as **(2S,3aS,6aS)-1-[(2S)-2-[[(1S)-1-(ethoxycarbonyl)-3-phenylpropyl]amino]propanoyl]octahydrocyclopenta[b]pyrrole-2-carboxylic acid.** It is a hydrophobic dipeptide ACE inhibitor used to treat hypertension and heart failure, with key raw materials including chiral 2-azabicyclooctane-3-carboxylic acid derivatives.

Synthesis of Ramipril raw material

The Ramipril raw material involves complex chiral chemistry to form a fused proline ring structure.

- **(S,S,S)-2-azabicyclo—octane-3-carboxylic acid (or its benzyl ester):** The chiral fused-proline subunit.
- **N-[1-(S)-carbethoxy-3-phenylpropyl]-L-alanine:** A key amino acid derivative used to build the side chain.
- **Catalysts and Solvents:** Palladium on carbon (Pd/C) for hydrogenation, along with ethyl acetate, dichloromethane, or acetic acid.
- **Reagents:** Sodium hydroxide, benzoyl derivatives, or chlorinated agents may be used in the coupling processes.

Active pharmaceutical ingredients

- **ChemicalName:**(2S,3aS,6aS)-1-[(2S)-2-[[(1S)-1-(ethoxycarbonyl)-3-phenylpropyl]amino]propanoyl]-octahydrocyclopenta[b]pyrrole-2-carboxylic acid.

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- **Active Ingredient (API):** Ramipril (CAS: 87333-19-5).
- **Appearance:** White to off-white crystalline powder
- **Synthesis Intermediate:** 2-azabicyclo[0]-octane-3-carboxylic acid.

Intermediates

- **(S,S,S)-2-Azabicyclooctane-3-carboxylic acid benzyl ester hydrochloride:** A crucial chiral intermediate (bicyclic amino acid derivatives.
- **L-Alanine:** Used as a building block for the side chain.
- **Ethyl 3-benzoylacrylate:** A starting material in the synthesis of the side chain.
- Benzyl ester and Ethyl ester derivatives: Used for protection of carboxylic acid grochai.
- **Organic Solvents/Reagents:** Cyclohexane, Ethyl acetate, Dichloromethane, Acetic acid, Benzene, and Triethylamine are used in the manufacturing process.
- **Catalysts:** Palladium on carbon (Pd/C) is used for hydrogenation steps.
- **Side Chain Moiety:** Prepared using materials like butenedioic anhydride and benzene.

Excipients

- **Fillers/Diluents:** Microcrystalline cellulose,pregelatinized starch.
- **Lubricants:** Sodium stearyl fumarate, magnesium stearate.
- **Binders/Disintegrants:** Hypromellose, croscarmellose sodium.
- **Colorants:** Ferric oxide yellow (1.25 mg), Ferric oxide red/yellow (2.5 mg/5 mg), FD&C dyes.
- **Other Potential Excipients:** Colloidal anhydrous silica, anhydrous calcium hydrogen phosphate.

Storage condition

Ramipril raw material (Active Pharmaceutical Ingredient – API) is highly sensitive and requires strict environmental controls to prevent degradation into impurities like ramipril diketopiperazine (DKP) and ramipril-diacid.

- **Temperature:** Store below 25°C, preferably in a cool, dry place. Some studies suggest refrigeration (5°C) is ideal to prevent degradation.
- **Atmosphere:** Store in a well-ventilated, dry area.
- **Light/Moisture:** Protect from light and moisture by keeping containers tightly closed.
- **Container:** Use original, sealed containers (typically aluminum foil bags or HDPE drums)

Handling Procedures

- **Containment:** Open handling should be avoided; use closed processing systems or, if necessary, work under a hood.
- **Dust Control:** Minimize dust generation and accumulation, as fine dust can form explosive mixtures in the air.
- **Equipment:** Ground mechanical equipment to prevent static electricity discharge.
- **Protection:** Wear personal protective equipment (PPE), including gloves and safety glasses.
- **Hygiene:** Wash hands thoroughly after handling.

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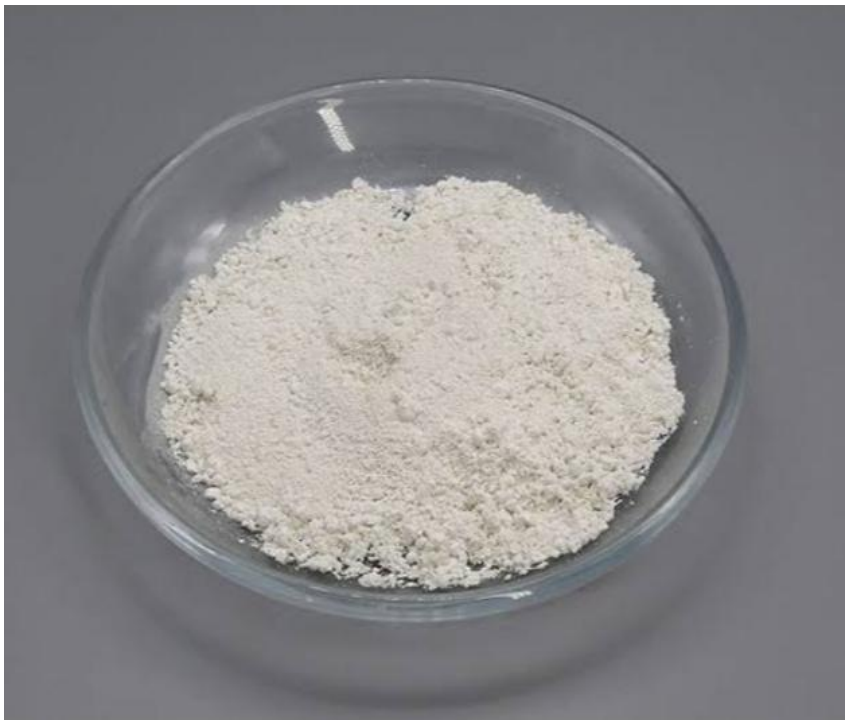
Ramipril Raw material:



About Ramipril tablet

Ramipril is a medicine that belongs to a group called ACE inhibitors (Angiotensin-Converting Enzyme inhibitors). It is mainly used to treat high blood pressure and heart-related conditions.

SCOPE AND OBJECTIVES

Scope of Ramipril Tablet

The scope of ramipril tablet covers all aspects of related to the development, manufacturing, therapeutic use, clinical, pharmaceutical, quality assurance . It's include,

- Therapeutic Scope (Indications and Effects)
- Pharmaceutical Scope (Formulation and Pharmacokinetics)
- Clinical Scope (Practice and Administration)
- Manufacturing Scope (Production and Quality) API Synthesis: Synthesis involves

Objectives of Ramipril Tablet

- Therapeutic Objectives
- Pharmaceutical Objectives
- Safety Profile
- Regulatory Objectives
- Quality Objectives
- Clinical Objectives
- Important Considerations:

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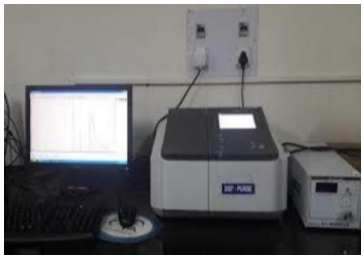
MATERIALS AND METHODS USED FOR QUALITATIVE ANALYSIS OF RAMIPRIL TABLET

D .UV visible spectroscopy

Principle

Ramipril absorbs UV radiation due to $\pi \rightarrow \pi^*$ and $n \rightarrow \pi^*$ electronic transitions.

The absorbance measured at its λmax (~210 nm) follows Beer–Lambert's law, which is used for quantitative estimation.



UV VISIBLE SPECTROSCOPY

Materials Required

- UV–Visible spectrophotometer
- Ramipril standard
- Ramipril tablets
- Methanol / 0.1 N HCl (solvent)
- Volumetric flasks, pipettes
- Whatman filter paper

Procedure

1. Determination of λmax

- Prepare a standard solution of Ramipril (10 µg/ml) in methanol.
- Scan from 200–400 nm.
- Note the wavelength of maximum absorbance (λmax ≈ 210 nm).

2. Preparation of Standard Solution

- Weigh 10 mg of pure Ramipril.
- Dissolve in 10 ml methanol → Stock solution (1000 µg/ml).
- Dilute to obtain 10–50 µg/ml working standards.

3. Preparation of Sample Solution (Tablet)

- Weigh 20 tablets and calculate average weight.
- Powder the tablets.
- Weigh powder equivalent to 10 mg Ramipril.
- Dissolve in methanol, filter.
- Make volume up to 10 ml.
- Dilute suitably to obtain 10–50 µg/ml.

4. Measurement of Absorbance

- Set blank (methanol).
- Measure absorbance of:
- Standard solutions
- Sample solution
- At λmax = 210 nm.

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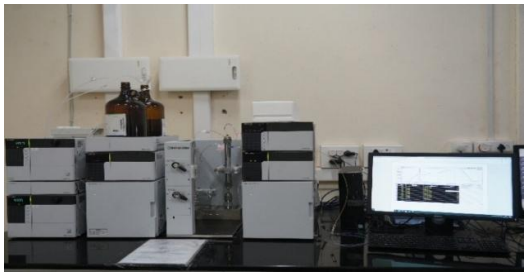
nE. High Pressure liquid chromatography (HPLC)



High Pressure liquid chromatography

1. Principle of HPLC

High Performance Liquid Chromatography (HPLC) is a separation technique based on the differential distribution of components between a stationary phase and a mobile phase under high pressure.

In Ramipril tablet analysis:

- **Stationary phase:** C18 (reverse phase column – non-polar)
- **Mobile phase:** Mixture of buffer and organic solvent (e.g., acetonitrile)
- **Detection:** UV detector (≈210 nm)

Working Principle:

- Ramipril and impurities are separated based on:
- Polarity
- Molecular interaction
- Partition coefficient
- As the mobile phase passes through the column, Ramipril elutes at a specific retention time (Rt).
- The detector measures absorbance and produces a chromatogram.
- Peak area is proportional to drug concentration.
- 2. Procedure of HPLC for Ramipril Tablet Analysis

Producer of HPLC for Ramipril tablet analysis

A. Chromatographic Conditions

Parameter	Condition
Column	C18 (250 × 4.6 mm, 5 µm)
Mobile phase	Acetonitrile : phosphate buffer (pH 3) (60:40)
Flow rate	1.0 mL/min
Detection wavelength	210 nm
Injection volume	20 µL
Run time	10 min

EXPERIMENTAL SECTION

QUALITATIVE ANALYSIS OF RAMIPRIL TABLET

Description

Ramipril tablet is an oral solid dosage form containing Ramipril, which is an angiotensin-converting enzyme (ACE) inhibitor used mainly for the treatment of hypertension (high blood pressure), heart failure, and to reduce the risk of myocardial infarction and stroke.

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3. Strengths Available

- 1.25 mg
- 2.5 mg
- 5 mg
- 10 mg

TABLET

IMAGE OF RAMIPRIL TABLET

Specification

The retention time of principle peak of ramipril of sample preparation as obtained in the assay

Assay Of Ramipril Tablet

Assay is a quantitative test used to determine the amount (strength or content) of the active pharmaceutical ingredient (API) present in a dosage form (like tablet, capsule, injection, etc.).

Purpose of assay:

- To confirm correct drug strengt
- To ensure product quality and uniformity
- To meet pharmacopoeial standards

A tablet is labeled Ramipril 5 mg, assay determines whether it really contains 5 mg of Ramipril (within acceptable limits).

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ASSAY OF 2.5 mg RAMIPRIL TABLET

RAMIPRIL -2.5MG TABLET ASSAY

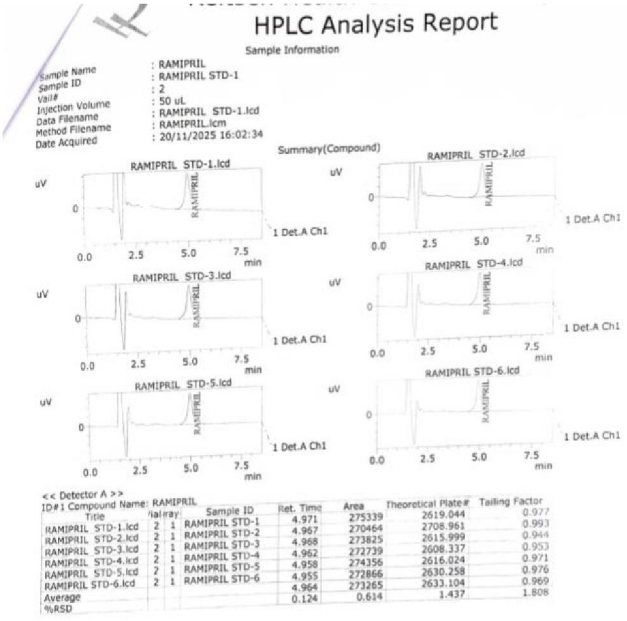
HPLC ID	QC002
BATCH NO.	255402K

DATE-	20.11.2025	
RAMIPRIL		
S.NO.	STD. AREA	SPL. AREA
1	275339	265121
2	270464	264948
3	273825	
4	272739	
5	274356	
6	272866	
AVERAGE	273264.8	265034.5
STD.DEV.	1678.50	86.5
RSD	0.61	0.03

COMP.NAME:	RAMIPRIL		
LABEL CLAIM	2.5		
STD AREA:	273264.8		
SAMPLE AREA:	265034.5		
FACTOR	1		
STD DILUTION	25.3	2	1
	100	200	1
SAMPLE DILUTION	1435.0	2	
	100	200	

STD wt. (mg):	25.3
SAMPLE wt.:	1435.0
COMP.PURITY	98.82
AVG.WT	143.7

CONTENT	2.43
ASSAY	97.13



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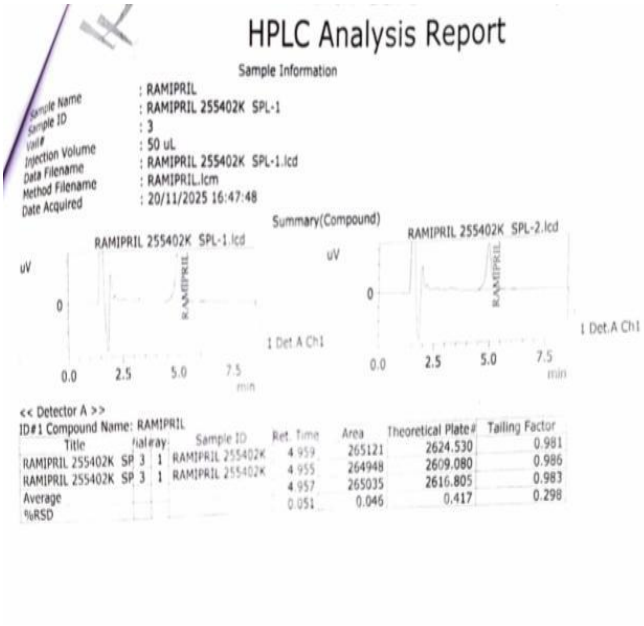

Dissolution Of Ramipril Tablet

Dissolution is a test that measures how fast and how much of the drug is released into solution from a dosage form under specified conditions.

Purpose of dissolution:

- To predict drug release and absorption
- To ensure consistent drug performance
- To check batch-to-batch consistency

It checks how much Ramipril dissolves in the medium within a fixed time (e.g., 30 or 45 minutes).

Dissolution Parameters

- **Apparatus :Paddle**
- **Medium :0.1 M Hydrochloric acid**
- **Volume : 500ml**
- **Time. : 45 minutes**
- **Speed : 75RPM**
- **Temperature: 37°**

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DISSOLUTION OF 2.5 mg RAMIPRIL TABLET

RAMIPRIL -2.5MG TABLET

DISSOLUTION

INS ID	QC 002
BATCH NO.	255402K

DATE	20.11.2025
RAMIPRIL	

S.No.	STD SREA
1	275339
2	270464
3	273825
4	272739
5	274356
6	272866
AVG	273264.8
STD.DEV	1678.5
RSD	0.61

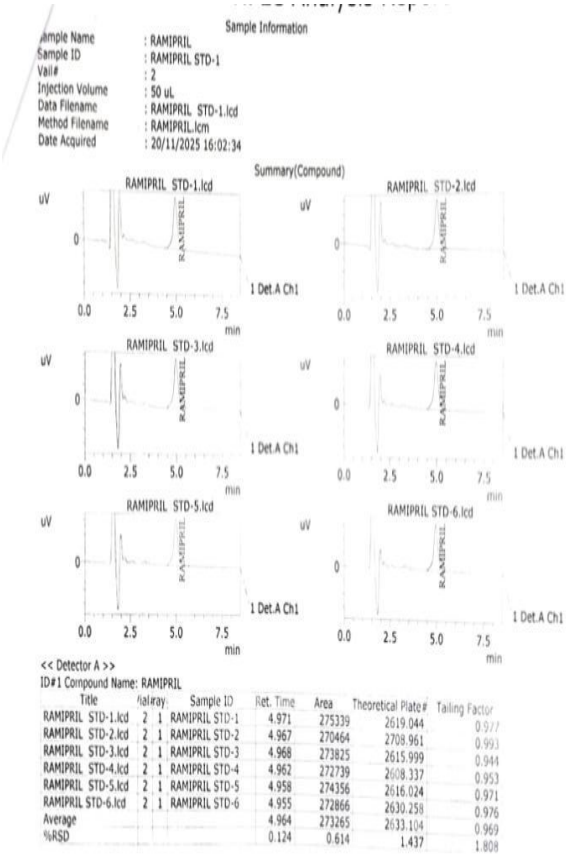
COMP. NAME	RAMIPRIL				
DURATION	45 MIN	0.1M HCL	75 RPM	PADDLE	37.0°C
LABEL CLAIM	2.5	TAB. NO.	SAMPLE AREA	CONTENT	% RELEASE
STD AREA	273264.8	1	259702	2.38	95.04
STD WT	25.3	2	270073	2.47	98.84
DISSO. VOLUME	500	3	296144	2.71	108.38
COMP. PURITY	98.82	4	262196	2.40	95.96
FACTOR	1	5	262329	2.40	96.00
		6	258537	2.37	94.62

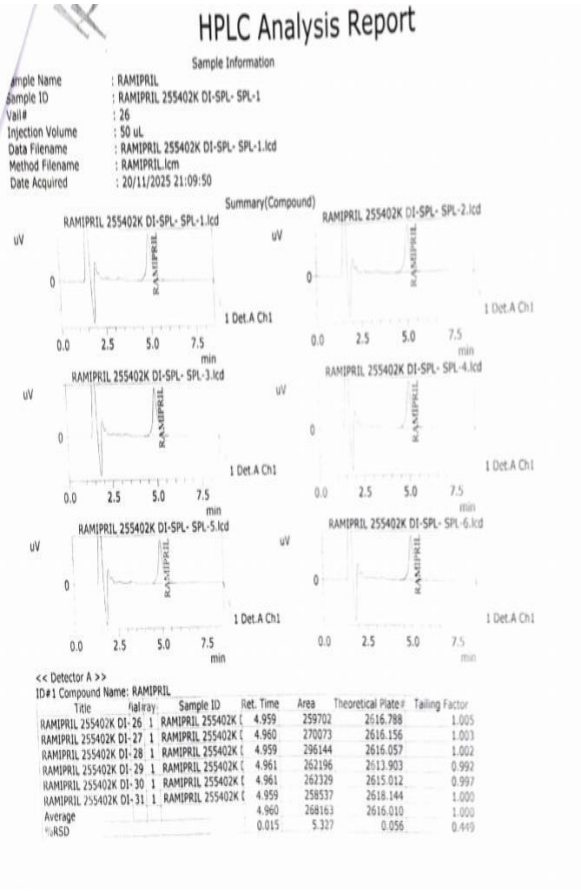
STD DILUTION	25.3	2	1
	100	200	1

SPL DILUTION	1	5
	500	10

LIMIT	NLT 70.0%
AVG %	98.14

HPLC ANALYSIS REPORT





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Average mass /weight variation

Weight of 20 tablet = 2.815g/20

Average weight. =0.1408g

Limit

Minimum:0.1302g **Minimum:0.1515g**

Maximum:0.135g **Maximum:0.152g**

0.135	**0.138**	**0.143**	**0.143**	**0.138**
0.141	**0.140**	**0.141**	**0.141**	**0.142**
0.140	**0.140**	**0.139**	**0.139**	**0.135**
0.137	**0.138**	**0.139**	**0.152**	**0.139**

Uniformity Of Ramipril Tablet

Uniformity of dosage units ensures that each Ramipril tablet contains the same amount of active drug within specified limits, so patients receive a consistent and accurate dose.

Materials Required

- Ramipril tablets
- Mobile phase / suitable solvent (e.g., Acetonitrile : Buffer)
- Volumetric flasks (50 mL, 100 mL)
- Pipettes
- Sonicator
- Whatman filter paper / 0.45 µm membrane filter

Procedure

Selection of Tablets

- Randomly select 10 tablets.

Weighing

- Weigh each tablet individually and record the weight.

Transfer

- Place one whole tablet into a 100 mL volumetric flask.

Addition of Solvent

- Add about 60–70 mL of mobile phase / suitable solvent.

Sonication

- Sonicate for 15–20 minutes to dissolve the drug completely.

Volume Make-up

- Cool if necessary and make up the volume to 100 mL with the same solvent.

Filtration

- Filter through 0.45 µm membrane filter (discard first few mL).

Dilution (if required)

- Further dilute to obtain working concentration (e.g., 10–50 µg/mL).

Analysis

- Inject into HPLC system (or measure absorbance in UV method).

Repeat

- Repeat the same procedure individually for each of the 10 tablets.

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Calculation

$$\frac{\text{Minimum weight} - \text{average weight}}{\text{Average weight}} \times 100 = 0.140\text{-}0.1437/0.1437\times 100 = (-)2.37\%$$

$$\frac{\text{Minimum weight} - \text{average weight}}{\text{Average weight}} \times 100 = 0.152\text{-}0.1437/0.1437\times 100 = (+)\ 5.77\%$$

Uniformity content

RAMIPRIL -2.5MG TABLET

UNIFORMITY OF CONTENT

INS ID	QC 002
BATCH NO.	255402K

DATE	20.11.2025

RAMIPRIL	
S.NO.	STD. AREA
1	275339
2	270464
3	273825
4	272739
5	274356
6	272866
AVERAGE	273264.8
STD.DEV.	1678.50
RSD	0.61

Comp.Name:	RAMIPRIL
Label Claim:	2.5
STD Area:	273264.8
STD wt. (mg):	25.3
Eqt.Factor:	1
Comp.Purity	98.82

STD Diluton	25.3	2
	100	200

Sample Dilution	1	5
	100	50

SAMPLE AREA	% CONTENT
267743	97.99
269822	98.75
269193	98.52
246665	90.27
267026	97.72
265636	97.21
265946	97.33
267531	97.91
262985	96.24
256801	93.98

MAXIMUM%	98.75
MINIMUM%	90.27
AVG%	96.59

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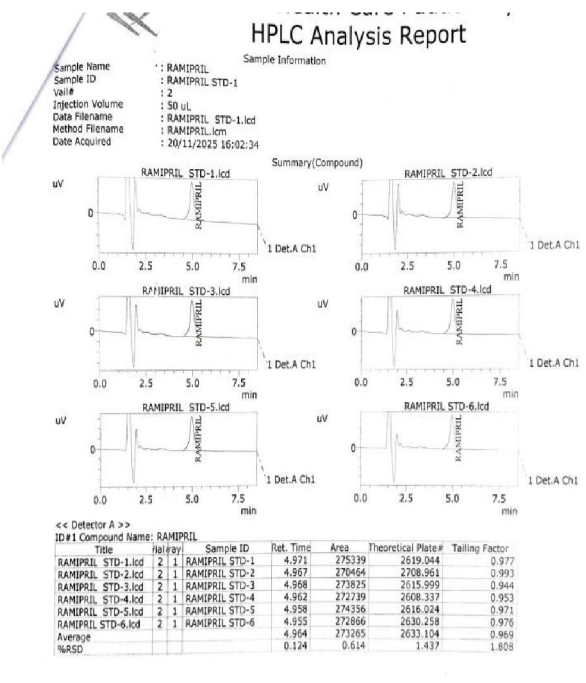
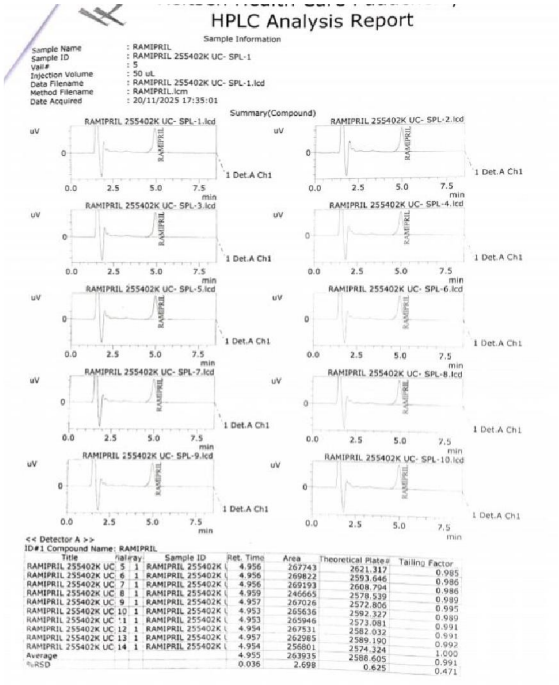
HPLC REPORT FOR UNIFORMITY



Title	Vial#	Injection Volume	Sample ID	Ret. Time	Area	Theoretical Plate#	Tailing Factor
RAMIPRIL STD-1.lcd	2	1	RAMIPRIL STD-1	4.971	275339	2619.044	0.977
RAMIPRIL STD-2.lcd	2	1	RAMIPRIL STD-2	4.967	270464	2708.961	0.993
RAMIPRIL STD-3.lcd	2	1	RAMIPRIL STD-3	4.968	273825	2615.999	0.944
RAMIPRIL STD-4.lcd	2	1	RAMIPRIL STD-4	4.962	272739	2608.337	0.953
RAMIPRIL STD-5.lcd	2	1	RAMIPRIL STD-5	4.958	274356	2616.024	0.971
RAMIPRIL STD-6.lcd	2	1	RAMIPRIL STD-6	4.955	272866	2630.258	0.976
Average				4.964	273265	2633.104	0.969
%RSD				0.124	0.614	1.437	1.808



Title	Vial#	Injection Volume	Sample ID	Ret. Time	Area	Theoretical Plate#	Tailing Factor
RAMIPRIL 255402K UC- 5 .lcd	5	1	RAMIPRIL 255402K UC- SPL-5	4.956	267743	2621.317	0.985
RAMIPRIL 255402K UC- 6 .lcd	6	1	RAMIPRIL 255402K UC- SPL-6	4.956	269822	2593.646	0.986
RAMIPRIL 255402K UC- 7 .lcd	7	1	RAMIPRIL 255402K UC- SPL-7	4.956	269193	2608.704	0.986
RAMIPRIL 255402K UC- 8 .lcd	8	1	RAMIPRIL 255402K UC- SPL-8	4.959	246665	2578.539	0.989
RAMIPRIL 255402K UC- 9 .lcd	9	1	RAMIPRIL 255402K UC- SPL-9	4.957	267026	2572.806	0.989
RAMIPRIL 255402K UC 10 .lcd	10	1	RAMIPRIL 255402K UC- SPL-10	4.953	269636	2592.327	0.995
RAMIPRIL 255402K UC 11 .lcd	11	1	RAMIPRIL 255402K UC- SPL-11	4.953	265946	2573.081	0.989
RAMIPRIL 255402K UC 12 .lcd	12	1	RAMIPRIL 255402K UC- SPL-12	4.954	267531	2582.032	0.991
RAMIPRIL 255402K UC 13 .lcd	13	1	RAMIPRIL 255402K UC- SPL-13	4.957	262985	2589.190	0.991
RAMIPRIL 255402K UC 14 .lcd	14	1	RAMIPRIL 255402K UC- SPL-14	4.954	256861	2574.324	0.992
Average				4.955	263935	2588.605	1.000
%RSD				0.036	2.698	0.625	0.991
							0.471

Hardness

Hardness of a Ramipril tablet is the measure of the crushing strength needed to break the tablet under controlled conditions, usually expressed in kg/cm² or Newton (N).

Purpose of Hardness Testing:

- To ensure adequate mechanical strength
- To prevent tablet breakage or chipping
- To maintain uniform drug release and dissolution
- To confirm good manufacturing quality.

3	3	3	3	3

Hardness tester

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Thickness

Thickness of a Ramipril tablet is defined as the perpendicular distance between the upper and lower surfaces of the tablet, measured using a vernier caliper or digital thickness gauge, to ensure uniformity in tablet size, proper packaging, and consistent drug content.

The thickness of a Ramipril tablet is the vertical measurement from one face of the tablet to the opposite face, used as a quality control parameter to maintain tablet uniformity.

Purpose

- Ensures uniform tablet dimensions
- Helps in proper packing (blister / bottle)
- Maintains consistent tablet weight and hardness.

Sample	Thickness (in mm)
Table1	3.67
Table 2	3.60
Table 3	3.64
Table 4	3.68
Table5	3.65
Average	3.65

Thickness Range for Ramipril Tablets

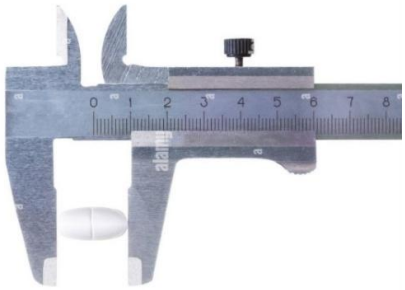
- Typical range: 2.5 mm – 5.0 mm
- Most commonly: 3.0 mm – 4.5 mm

Tablet thickness depends on:

- Tablet strength (e.g., 1.25 mg, 2.5 mg, 5 mg, 10 mg)
- Tablet diameter
- Compression force
- Formulation and excipients
- There is no fixed pharmacopoeial limit for thickness.
- Manufacturer sets in-house specifications to ensure:
- Uniformity
- Proper packaging (blister fit)
- Mechanical strength
- Patient acceptability

Typical In-house Limits (Example)

- Target thickness: 3.5 mm
- Acceptance criteria: ± 5% →3.33 – 3.68 mm



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Friability

Friability is the percentage weight loss of tablets after subjecting them to mechanical stress (shock and abrasion) in a friabilator. It indicates the mechanical strength and durability of tablets during handling, packaging, and transportation.

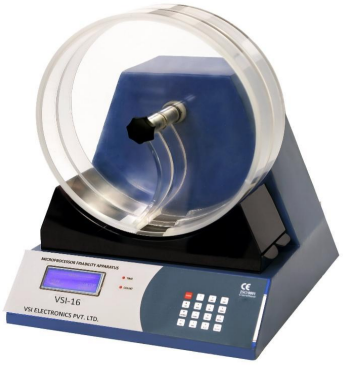
Apparatus

- Friabilator (Roche Friabilator)
- Balance (accuracy ± 0.1 mg)

Test Procedure (IP / USP Method)

- Take 10 tablets (if average weight ≤ 650 mg)
- Or 6.5 g of tablets (if average weight > 650 mg)
- Weigh the tablets (W_1).
- Place tablets in the friabilator.
- Rotate at 25 rpm for 4 minutes → 100 revolutions.
- Remove tablets, dedust, and reweigh (W_2).

Friability= 6.645-6.6540/6.645×100=0.07%



RESULT AND DISCUSSTION

RAW Material

S.No	Test	Specifications	Results
1.	Description	A white to almost white crystalline powder.	A white crystalline powder.
2.	Solubility	Freely soluble in methanol, sparingly soluble in water.	Freely soluble in methanol, sparingly soluble in water.
3.	Identification (by IR)	Compare the spectrum with that obtained with in Ramipril IPRS or with the reference spectrum of Ramipril.	Complies
4.	Appearance and solutions	The solution is clear and colourless.	Complies
5.	Specific optical rotation	+32.0°to +38.0°	+34.3°
6.	Related substances (by HPLC) Any other individual impurity Total impurities	Not more than 0.5% Not more than 1.0%	Below discregard Below discregard
7.	Sulphated ash	Not more than 0.1%	0.07%
8.	Loss on drying	Not more than 0.2%	0.13%
9.	Assay:(By titration on dried basis)	Not less than 98.0% and not more than 101.0%	Such basic:100.39% On dried basis:100.52%

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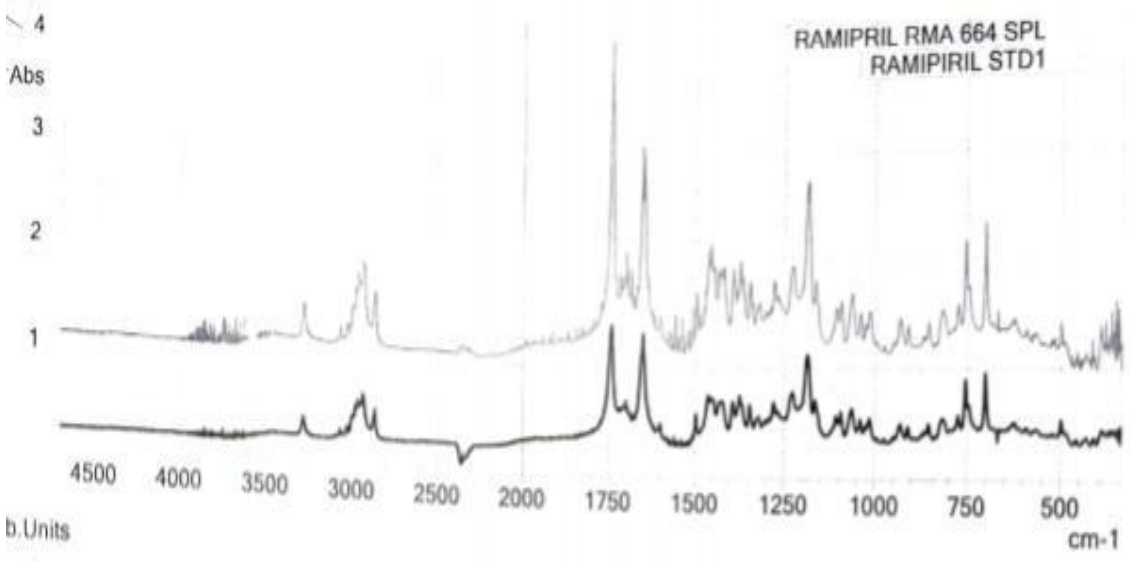
ANALYTICAL WORK RECORD FOR SEM FINISHED PRODUCT

S.NO	Test	Specifications	Results
1.	Description	Yellow colour circular shaped slightly bioconvexed flim coated tablet having plain on both side	**Complies**
2.	Identification (by HPLC)	The retention time of principal peak of Ramipril of sample preparation corresponds to that of standard preparation,as obtained in the assay.	**Complies**
3.	Average weight	0.143g+or – 7.5%(0.132gto 0.154g)	**0.1408g**
4.	Uniformity of weight l	Individual weight of tablet doesn't deviate by more than+or – 7.5%form the average weight	**(-)2.57%to (+)5.77%**
5.	Thickness	3.50mm+or-0.3mm(3.20mm to 3.80)	**3.65mm**
6.	Hardness	3	3
7.	Disintegration time	Not more than 30minutes	24 seconds
8.	Dissolution	Not less than 2.000mg	Average:98.14% Minimum:95.04% to maximize:108.38%
9.	Assay	2.250mg to 2.750mg	2.43mg(97.13%)
10.	Friability	6.645-6.640/6.645×100	0.07%

Spectrum of staPndard Ramipril raw material



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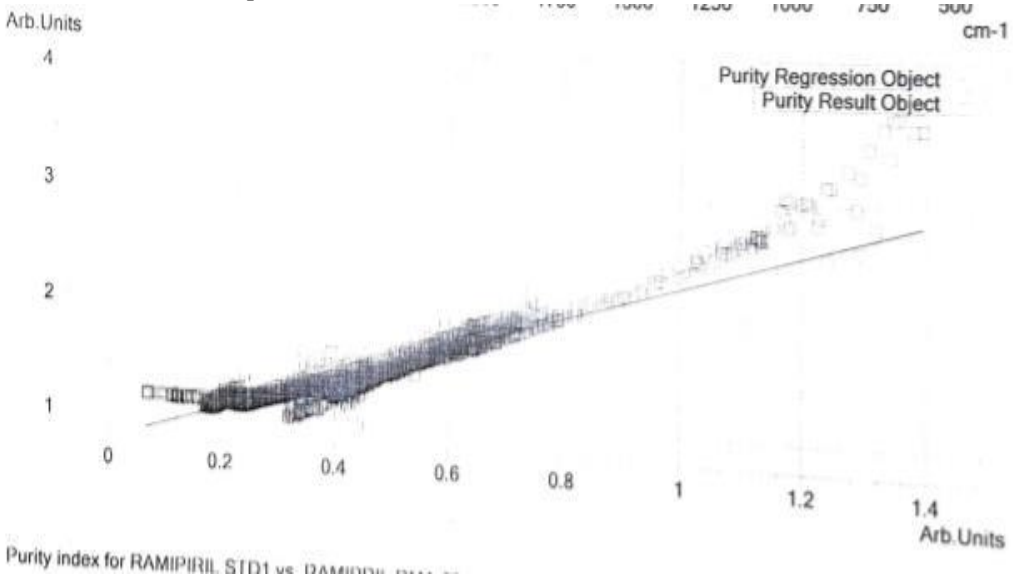
Spectrum of raw material sample



II. CONCLUSION

The quality control analysis of Ramipril tablets was successfully performed using standard pharmacopoeial methods. All evaluated parameters, including physical appearance, average weight, weight variation, thickness, hardness, friability, disintegration time, dissolution, and assay, were found to be within the acceptable pharmacopoeial limits.

The uniformity of dosage units confirmed consistent drug distribution, ensuring accurate dosing. The dissolution study demonstrated satisfactory drug release, indicating good bioavailability. The assay results confirmed that the active pharmaceutical ingredient content complies with the specified limits, ensuring potency and therapeutic efficacy.

Overall, the results indicate that the Ramipril tablets meet quality, safety, and efficacy requirements as per official standards (IP/USP/BP). Therefore, the analyzed batch is suitable for patient use and market distribution.

REFERENCES

[1]. Indian Pharmacopoeia, Vol. I & II, Government of India, Ministry of Health and Family Welfare, Ghaziabad.
[2]. United States Pharmacopeia–National Formulary, United States Pharmacopeial Convention, Rockville, MD.
[3]. British Pharmacopoeia, The Stationery Office, London.
[4]. European Pharmacopoeia, Council of Europe, Strasbourg.
[5]. Aulton's Pharmaceutics: The Design and Manufacture of Medicines, Elsevier, London.
[6]. Lachman, Lieberman and Kanig's Theory and Practice of Industrial Pharmacy, CBS Publishers, New Delhi.
[7]. Remington: The Science and Practice of Pharmacy, Pharmaceutical Press, London.
[8]. Pharmaceutical Analysis, Himalaya Publishing House, Mumbai.
[9]. Textbook of Pharmaceutical Analysis, Elsevier, India.
[10]. Instrumental Methods of Chemical Analysis, Himalaya Publishing House.
[11]. Modern Pharmaceutics, Marcel Dekker Inc., New York.
[12]. Pharmaceutical Dosage Forms: Tablets, Marcel Dekker Inc.
[13]. Quality Assurance of Pharmaceuticals, WHO Publications, Geneva.
[14]. World Health Organization, Technical Report Series: Quality Control Methods for Medicinal Products

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