

Formulation and Evaluation of Losartan Potassium Cr Tablets by Okra Gum as a Binder

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I. INTRODUCTION

TABLET

A **tablet** is a small, flat, or slightly convex disc of medication that is typically composed of the active pharmaceutical ingredient (API) mixed with excipients (inactive ingredients such as fillers, binders, disintegrants, and lubricants). Tablets are designed for oral administration and can either be swallowed directly or dissolved in water (effervescent tablets) for easier consumption.

Types of Tablets:

- ✓ **Conventional Tablets (Regular Tablets):** Standard tablets that release the medication at a consistent rate when ingested.
- ✓ **Coated Tablets:**

Film-coated tablets: Tablets coated with a thin layer of polymer-based film that protects the tablet from moisture, improves taste, or controls the release of the drug.

Sugar-coated tablets: Tablets with a thick sugar coating to mask the taste and protect the drug.

- ✓ **Enteric-Coated Tablets:** Tablets coated with a substance that prevents the drug from dissolving in the stomach but allows it to dissolve in the small intestine. This is useful for drugs that may irritate the stomach or require absorption in the intestine.
- ✓ **Effervescent Tablets:** Tablets that contain ingredients that react with water to produce carbon dioxide, causing the tablet to dissolve rapidly and release the active drug in solution.
- ✓ **Extended-Release (ER), Sustained-Release (SR), or Controlled-Release Tablets:** Formulations that allow for the gradual release of the drug over an extended period, providing a prolonged therapeutic effect and reducing the frequency of dosing.
- ✓ **Chewable Tablets:** Tablets designed to be chewed before swallowing, typically used for

children or patients who have difficulty swallowing whole tablets.

✓ **Buccal and Sublingual Tablets:**

Buccal tablets: Placed between the cheek and gums, where the drug is absorbed through the mucous membranes.

Sublingual tablets: Placed under the tongue for absorption through the mucous membranes. These tablets dissolve quickly and allow for rapid onset of action.

✓ **Mouth-dissolving Tablets (ODTs):** Tablets that dissolve quickly in the mouth without the need for water, often used for patients with difficulty swallowing.

✓ **Dispersible Tablets:** Tablets that are designed to disperse in a small amount of water, making it easier for patients to swallow.

Advantages of Tablets in Pharmacy:

- ✓ **Convenience:** Easy to store, transport, and administer. Simple for patients to take, especially compared to injectable forms.
- ✓ **Accurate Dosage:** Tablets can be manufactured to deliver a precise dose of medication, ensuring consistency.
- ✓ **Cost-Effectiveness:** Tablets are generally more affordable compared to other dosage forms, such as injections or capsules, both in terms of production and distribution.
- ✓ **Variety of Formulations:** Tablets can be manufactured in various formulations, including controlled-release, effervescent, and chewable forms, to suit different patient needs.
- ✓ **Improved Patient Compliance:** Easier to swallow and incorporate into daily routines compared to more complicated dosage forms (e.g., injections).
- ✓ **Taste Masking:** Coating and specialized formulations (like chewable tablets or effervescent tablets) can mask the unpleasant taste of the drug.

Disadvantages of Tablets in Pharmacy:

- ✓ **Swallowing Difficulties:**Some patients, especially children or the elderly, may have difficulty swallowing tablets.
- ✓ **Slow Onset of Action:**Tablets generally take longer to dissolve and be absorbed compared to other dosage forms like injections or sublingual tablets, leading to slower onset of action.
- ✓ **Gastrointestinal Issues:**Some tablets, especially those with hard coatings or those that are not enteric-coated, can irritate the stomach lining or cause discomfort.
- ✓ **Dose Flexibility:**Once a tablet is made with a certain dose, it cannot be adjusted easily without breaking the tablet. Breaking tablets may sometimes alter the intended release rate or effectiveness of the drug.
- ✓ **Incompatibility with Certain Drugs:**Some medications may not be suitable for tablet formulation due to stability issues or the need for rapid absorption.
- ✓ **Potential for Overdose:**If a tablet is not taken as directed, there is a risk of accidental overdose, especially if tablets are broken or chewed when they should not be.

Okra gum, derived from the pods of the **Abelmoschus esculentus** plant, is a natural polysaccharide that has gained interest as a potential excipient in pharmaceutical formulations. It has been investigated for its gelling, binding, and

BLOOD PRESSURE:

Blood pressure is the force exerted by circulating blood on the walls of the arteries, the blood vessels that carry oxygenated blood from the heart to the rest of the body. It is an essential vital sign used to assess cardiovascular health.

ANTI-HYPERTENSION

Antihypertension refers to the prevention and treatment of high blood pressure (hypertension). This involves the use of medications, lifestyle changes, and other interventions aimed at lowering blood pressure to prevent complications like heart disease, stroke, and kidney damage.

AIM:

The aim of this study was to develop and evaluate formulation of Losartan Potassium tablets

- ✓ **Need for Proper Storage:**Tablets can be sensitive to environmental factors like moisture, light, and temperature, which can degrade the active ingredient or coating, reducing effectiveness.

LOSARTAN POTASSIUM

Losartan Potassium is an antihypertensive medication commonly used to treat high blood pressure, chronic kidney disease, and heart failure. It belongs to the class of angiotensin II receptor blockers (ARBs), which work by blocking the action of angiotensin II, a hormone that causes blood vessels to constrict. By inhibiting this action, Losartan helps relax blood vessels, lowering blood pressure, and improving blood flow.

In order to optimize the therapeutic effects of Losartan Potassium and improve patient compliance, controlled-release formulations are gaining attention. These formulations ensure that the drug is released slowly over time, allowing for sustained therapeutic effects, minimizing side effects, and enhancing convenience by reducing the frequency of dosage.

OKRA GUM

controlled-release properties. Okra gum is known for being biodegradable, biocompatible, and cost-effective, making it an attractive alternative to synthetic excipients like synthetic polymers..

using Okra gum as a binder .By utilizing Okra gum as a binder, the goal is to improve the tablet's physical properties, enhance drug release control, and explore the potential of a natural and biocompatible excipient.

OBJECTIVES:

- ✓ **To use of natural binding agent:**Okra gum as a binder, ensuring that it is safe, non-toxic, and compatible with Losartan Potassium.To study its effectiveness in comparison to synthetic binders in terms of tablet integrity and drug release characteristics.To determine if Okra gum as a binder can improve the bioavailability of Losartan Potassium compared to conventional formulations.
- ✓ **To treat blood pressure**
- ✓ **To increase patient compliance**

II. MATERIALS AND METHOD

FORMULATION F-I

S.NO	CHEMICAL NAME	NAME OF THE MANUFACTURER	QUANTITY REQUIRED
1.	Losartan potassium	Dr. Reddy's Laboratories	0.1g
2.	Okra Gum	Field visit	4%
3.	HPMC	Vasundhara Micro Mineral Infinite Pvt Ltd	30mg
4.	Magnesium stearate	Ratan Industries	1%
5.	Talc	Vasundhara Micro Mineral Infinite Pvt Ltd	1%
6.	Lactose	Shreeji Pharma International Vadodara, India	1%

TABULATION 01: LIST OF CHEMICALS FORMULATION F-I

7.1.2 FORMULATION F-II

S.NO	CHEMICAL NAME	NAME OF THE MANUFACTURER	QUANTITY REQUIRED
1.	Losartan potassium	Dr. Reddy's Laboratories	0.1g
2.	Okra Gum	Field visit	4%
3.	HPMC	Vasundhara Micro Mineral Infinite Pvt Ltd	30mg
4.	Magnesium stearate	Ratan Industries	1%
5.	Talc	Vasundhara Micro Mineral Infinite Pvt Ltd	1%
6.	Lactose	Shreeji Pharma International Vadodara, India	1%

TABULATION 02: LIST OF CHEMICALS FORMULATION F-II

7.1.3 FORMULATION F-III

S.NO	CHEMICAL NAME	NAME OF THE MANUFACTURER	QUANTITY REQUIRED
1.	Losartan potassium	Dr. Reddy's Laboratories	0.1g
2.	Okra Gum	Field visit	6%
3.	HPMC	Vasundhara Micro Mineral Infinite Pvt Ltd	90mg
4.	Magnesium stearate	Ratan Industries	1%
5.	Talc	Vasundhara Micro Mineral Infinite Pvt Ltd	1%
6.	Lactose	Shreeji Pharma International Vadodara, India	1%

TABULATION 03: LIST OF CHEMICALS FORMULATION F-III

COLLECTION OF OKRA GUM

The okra gum was collected from in and around Perambalur, collected okra gum as

authenticated by P.G Assistant in Botany, National college ,Trichy

FORMULATION & EVALUATION

FORMULATION	LOSARTAN POTASSIUM	OKRA GUM	HPMC	MAGNESIUM STEARATE	TALC	LACTOSE	TOTAL
F1	0.1g	4%	30mg	1%	1%	1%	100mg

F2	0.1g	5%	60mg	1%	1%	1%	100mg
F3	0.1g	6%	90mg	1%	1%	1%	100mg

TABULATION 04: PREPARATION OF TABLET

Procedure:

1. Losartan potassium, lactose and HPMC was weighed and triturated in mortar and mixed well
2. Okra Gum is added to batch, little by little until the stage cohesive mass. Forced the mass in pass through the sieve number 10 and then dried in hot air oven at 50 °
3. The dried granules are again passed through sieve no:16. Weight quantity of talc and magnesium stearate are added to batch and mixed well
4. The granules are composed and then stored in a well closed container.

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PREFORMULATION STUDIES:

ANGLE OF REPOSE

1. Weigh an adequate amount of Losartan potassium prepared granules.
2. Place the powder in a conical funnel. The idea is to allow the powder to flow freely and form a cone shape when poured onto a flat surface.
3. Gently release the powder from the funnel or container onto the flat surface. Allow the prepared granules to form a pile without disturbing it. The prepared granules will naturally form a cone shape as it piles up.
4. Once the pile has formed, use a ruler to measure the height of the cone (h) from the base to the top of the pile. Measure the diameter (D) of the base of the pile and Calculate the Angle of Repose (θ)

POROSITY

1. Measure Bulk Density:

Weigh a clean, dry graduated cylinder and record its weight. Gently fill the cylinder with the Losartan potassium prepared granules without compacting it. Allow the powder to settle naturally by tapping the cylinder lightly to eliminate air pockets. Weigh the graduated cylinder with the prepared granules inside and record the total weight.

2. Measure Tapped Density:

Fill the graduated cylinder with the same amount of prepared granules as used for bulk density measurement. Place the graduated cylinder on the tap density apparatus and tap it for a fixed number of taps (usually 100-1000 taps). This process compacts the prepared granules into the cylinder, reducing the volume it occupies. After tapping, measure the new volume of the prepared granules in the cylinder. Weigh the graduated cylinder with the compacted prepared granules inside. Once you have both the bulk density and tapped density, calculate the **porosity** of the Losartan potassium prepared granules. Perform the measurements multiple times to ensure accuracy and calculate an average value for bulk density, tapped density, and porosity.

ORGANOLEPTIC PROPERTIES

- General Appearance
- Size And Shape
- Colour
- Odour
- Taste

WEIGHT VARIATION

1. Take 20 tablets should be randomly selected from the batch.
2. Weigh Each Tablet Individually
3. Calculate the Average Weight: Calculate the average weight of the tablets by dividing the total weight by 20.
4. Compare Individual Tablet Weights with the Average Weight

FRIABILITY TEST

1. Weigh the sample of 20 tablets (record the total weight).
2. Place the 20 tablets in the drum of the friabilator.
3. Set the friabilator to rotate at a speed of 25 rpm (revolutions per minute). Allow the friabilator to rotate for 4 minutes (100 rotations).
4. After 4 minutes, remove the tablets from the friabilator.
5. Weigh the tablets again (final weight).

HARDNESS TEST

1. Select 6 tablets of Losartan Potassium for testing
2. Place a Losartan Potassium tablet horizontally between the two anvils of the hardness tester. The tablet should be positioned such that the force will be applied perpendicular to the tablet's face, ensuring accurate measurement.
3. The Monsanto hardness tester will gradually apply a force to the tablet until it breaks. Units are kilograms (kg), Newtons (N), or pounds (lb), depending on the model. Record the hardness value displayed on the tester.
4. Repeat the test on 3-6 tablets to get an average tablet hardness value for the batch.

DISINTEGRATION TEST

1. Prepare the disintegration medium as per the specification for Losartan Potassium tablets. Common options include:

- Water (for immediate-release tablets),
- Buffer solutions (Phosphate buffer for pH 6.8).

Ensure the medium temperature is maintained at $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$ (simulating human body temperature) throughout the test timer once the test starts. The tablets should break into small particles or dissolve completely within the disintegration medium.

3. Check at specified time intervals, typically every 3-5 minutes, to determine if the tablet has completely disintegrated. The test duration is typically 30 minutes, and the tablet should fully disintegrate by that time. If the tablet does not disintegrate within the specified time, it is considered a failure. Record the time at which each tablet completely disintegrates.

DRUG CONTENT UNIFORMITY

1. Select 10 tablets randomly from the batch.

2. Crush the selected tablets to a fine powder using a mortar and pestle, or an appropriate grinder. Mix the powder thoroughly to ensure uniform distribution of the active ingredient across the powder.

3. Weigh a specific amount of the powdered tablet mixture and transfer it to a volumetric flask or a suitable container. Add a specific volume of the solvent to the powdered tablet. The volume of solvent used depends on the solubility of the API. The mixture is then allowed to dissolve completely. If any insoluble particles are present after dissolving the powder, filter the solution to remove them.

4. After dissolution, measure the concentration of the active ingredient in the solution.

- Analyze the solution UV-Visible Spectrophotometry Commonly used for drugs with distinct absorbance peaks in the UV-Visible range.

DISSOLUTION TEST

1. Prepare the dissolution medium (typically 900 mL of phosphate buffer 6.5). Ensure the temperature of the medium is at $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ (the same temperature as the human body) during the test.

2. Place one Losartan Potassium tablet into each dissolution vessel.

3. Set the paddle speed to 50-75 rpm, depending on the specified method. Begin the test, and allow the dissolution process to occur.

4. At predetermined time intervals (e.g., 5, 10, 15, 30, 45, 60 minutes, etc.), withdraw samples of the dissolution medium (typically 10 mL). Replace the withdrawn sample with an equal volume of fresh medium to maintain the volume constant.

5. Analyze the samples by UV-Visible Spectrophotometry or High-Performance Liquid Chromatography (HPLC), as per the method specified in the Losartan Potassium monograph at 205nm. Find the absorbance. Measure the concentration of Losartan Potassium in the samples to determine the dissolution rate at each time point.

6. Plot the percentage of drug dissolved versus time to determine the dissolution profile of the Losartan Potassium tablet.

III. RESULTS AND DISCUSSION

PREFORMULATION STUDIES

ANGLE OF REPOSE

FORMULATION	ANGLE OF REPOSE
F1	21.70°
F2	25.32°
F3	47.72°

TABULATION 05: ANGLE OF REPOSE

Formulation F2 passes with good flow properties the Angle of repose and the I.P standards are

ANGLE OF REPOSE	FLOW PROPERTY
Less than 25 ⁰	Excellent Flow
25 ⁰ - 30 ⁰	Good Flow
30 ⁰ - 40 ⁰	Fair to passable flow
More than 40 ⁰	Poor flow

TABULATION 06: I.P STANDARDS OF ANGLE OF REPOSE

POROSITY

FORMULATION	POROSITY
F1	30.76%
F2	27.22%
F3	32.83%

TABULATION 07: POROSITY

Formulation F2 passes the porosity and the I.P standards are 10 to 30%

ORGANOLEPTIC PROPERTIES

GENERAL APPEARANCE

The appearance of a tablet its identity and general elegance is essential for consumer acceptance, for control of lot to lot uniformity and tablet-to-tablet uniformity The control of general appearance involves the measurement of size, shape, color, presence or odor, taste etc..

SIZE AND SHAPE

It can be dimensionally described and controlled. The thickness can be measured by micrometer or by other device. Tablet thickness should be controlled within a +5% variation of standard value.

COLOUR

Losartan potassium tablets are typically white or off-white in color.

ODOUR

Losartan potassium tablets do not have a noticeable or distinctive odor.

TASTE:

The taste of losartan potassium tablets is usually bitter or neutral, as is common with many medications.

WEIGHT VARIATION

Formulation F2 passes the weight variation test and Formulation F1 and F3 Fails the weight variation test.

The I.P standards are

1. less than 80 + or -10%

2. 80-250mg + or -7.5%

3. more than 250 + or -5%

9.3 FRIABILITY TEST

FORMULATION	INITIAL	FINAL	%
F1	1.05	1.03	1.9%
F2	1.05	1.04	0.9%
F3	1.05	1.02	2.85%

TABULATION 8: FRIABILITY

Formulation F2 passes the friability test and the I.P standards is less than 1%

HARDNESS TEST

FORMULATION	INITIAL	FINAL	HARDNESS (Kg/cm ²)
F1	0	3.9	3.9 Kg/cm ²
F2	0	4.2	4.2 Kg/cm ²
F3	0	3.8	3.8 Kg/cm ²

TABULATION 9: FORMULATION OF HARDNESS TEST

Formulation F2 passes the hardness test and the I.P standards is 4 to 10 Kg/cm²

DISINTEGRATION TEST

FORMULATION	INITIAL TIME	FINAL TIME	DISINTEGRATION TIME(MINS)
F1	0	10	10
F2	0	15	15
F3	0	20	20

TABULATION 10: FORMULATION OF DISINTEGRATION TEST

Formulation F2 passes the hardness test and the I.P standards is 15 MINS

WAVELENGTH(nm)	ABSORBANCE
205nm	0.455

TABULATION 11: CONTENT UNIFORMITY

CONTENT UNIFORMITY

Weight of tablet=0.1+0.10+0.11+0.10+0.9/5

$$=1.32/5$$

$$=0.052\text{gm}$$

Weight to be taken=average weight/label claim*weight equivalence

$$=0.052/0.1*0.9$$

$$=0.468\text{G}$$

Conversion factor=1/100

Dilution factor-200/2*100/10*100/10

%Purity=Absorbance/A1%*Dil.Factor*con.Factor*Avg.wt/L.C*100

$$=0.455/560*1/100*200/0.46*100/10*0.052/0.1*100$$

$$=93.4\%W/V$$

9.7 DISSOLUTION TEST

STANDARD CURVE OF LOSTARTAN POTASSIUM:

S.NO	CONCENTRATION (X) (µg/mL)	ABSORBANCE AT 276 nm(Y)
1	0	0
2	2	0.18
3	4	0.346
4	6	0.523
5	8	0.706
6	10	0.842

TABULATION12:STANDARD CURVE OF LOSTARTAN POTASSIUM

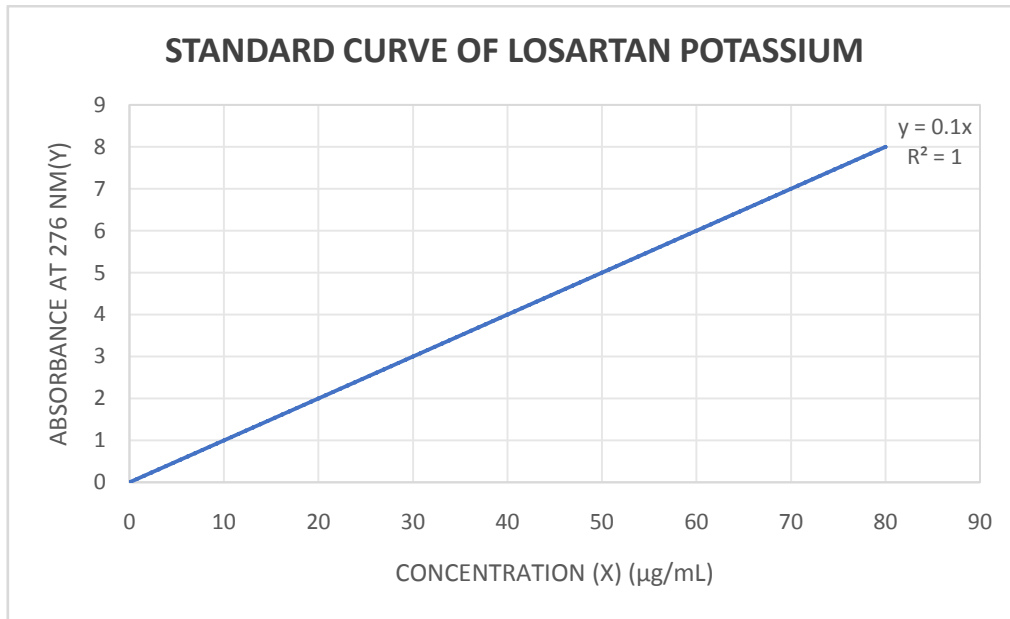


FIGURE 01: STANDARD CURVE OF LOSTARTAN POTASSIUM

FORMULATION I:

S.NO	TIME	ABSORBANCE	CONCENTRATION $X=Y-C/M$	AMOUNT FOUND(mg)	% DRUG RELEASE
1	0	0	0	0	0%
2	1	0.071	0.1326	1.938	1.19%
3	2	0.132	0.9107	8.1964	8.19%
4	3	0.191	1.6632	14.9693	14.96%
5	4	0.251	2.4285	21.8571	21.85%
6	5	0.306	3.1301	28.1709	28.17%
7	6	0.451	4.9795	44.8163	44.81%
8	7	0.524	5.9795	53.1964	53.19%
9	8	0.612	7.0331	63.2984	63.29%
10	9	0.742	8.6913	78.2219	78.22%
11	10	0.922	11.0892	98.88	98.88%
12	11	0.067	0.0816	0.7346	0.73%
13	12	0	0	0	0%

TABULATION13:FORMULATION I

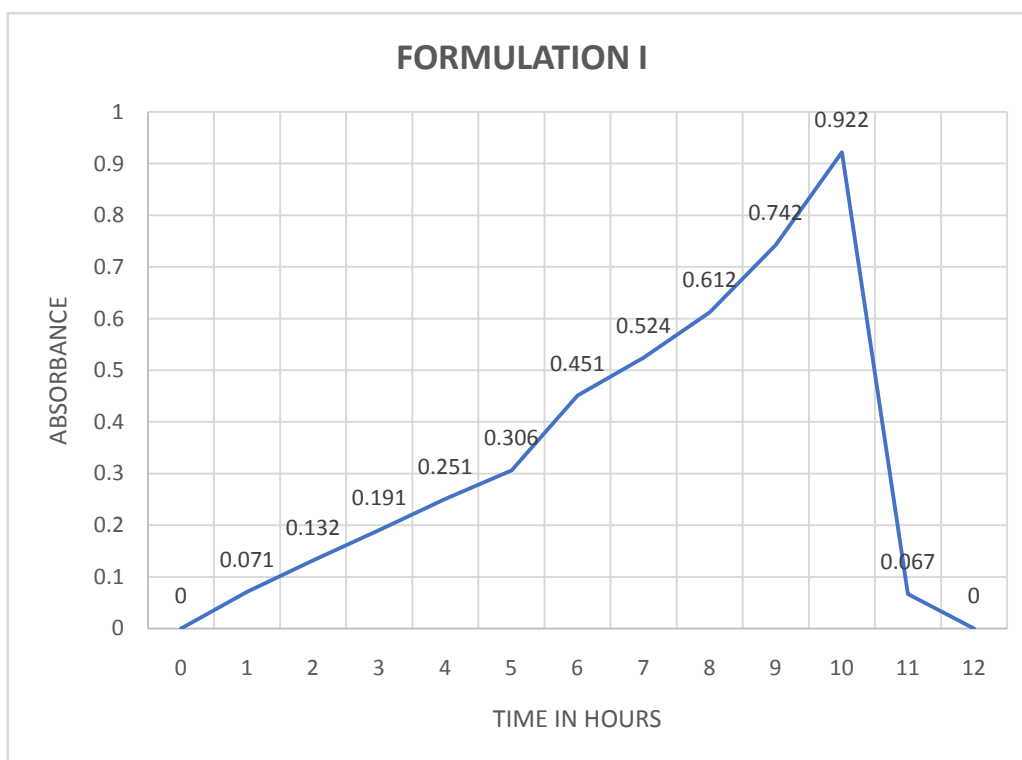


FIGURE2:FORMULATION I

FORMULATION II:

S.NO	TIME	ABSORBANCE	CONCENTRATION $X=Y \cdot C/M$	AMOUNT FOUND(mg)	% DRUG RELEASE
1	0	0	0	0	0%
2	1	0.108	0.6075	5.44	5.4%
3	2	0.192	1.6747	15.07	15.67%
4	3	0.223	2.0714	18.642	18.64%
5	4	0.299	3.0408	27.36	27.36%
6	5	0.357	3.7806	34.02	34.02%
7	6	0.382	4.0994	36.89	36.89%
8	7	0.442	4.86	43.783	43.78%
9	8	0.562	6.3954	57.55	57.55%
10	9	0.612	7.0331	63.29	63.29%
11	10	0.689	8.0153	72.13	72.13%
12	11	0.757	8.882	74.93	74.93%
13	12	0.931	11.1020	99.9183	99.91%

TABULATION 14:FORMULATION II

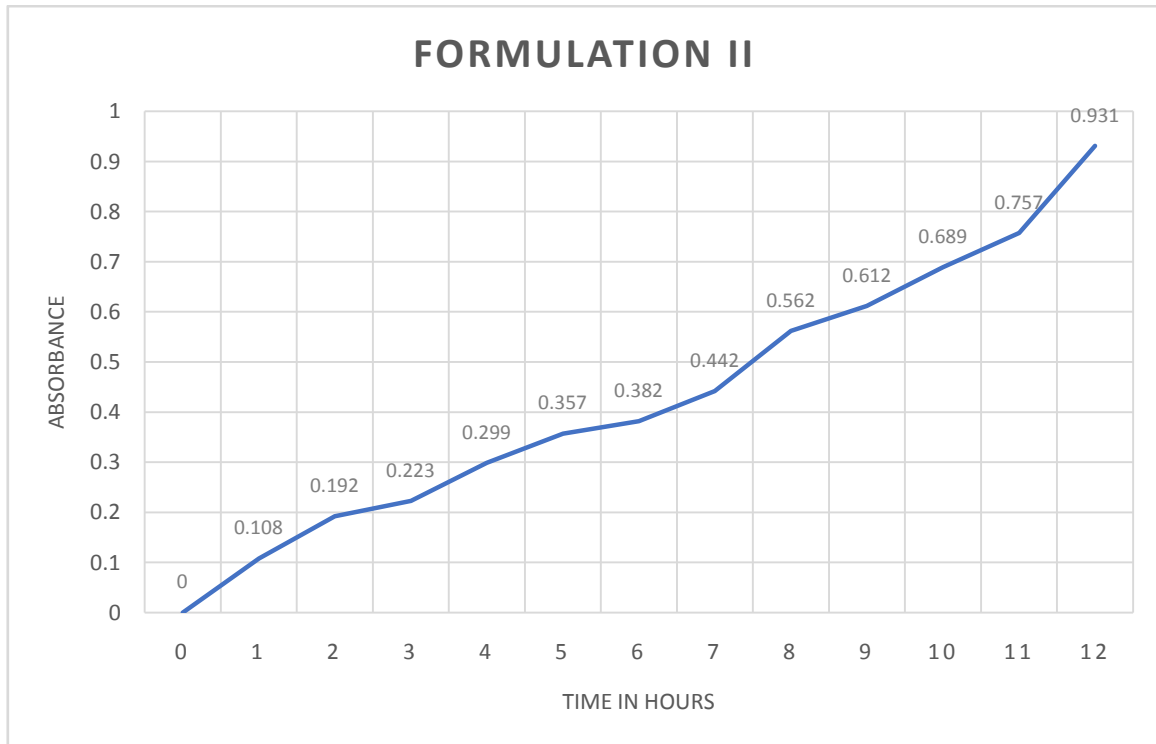


FIGURE 3:FORMULATION II

FORMULATION III:

S.NO	TIME	ABSORBANCE	CONCENTRATI ON X=Y-C/M	AMOUNT FOUND(mg)	% DRUG RELEASE
1	0	0	0	0	0%
2	1	0.132	0.9107	8.1964	8.19%
3	2	0.199	1.7653	15.8817	15.88%
4	3	0.258	2.5178	22.6607	22.66%
5	4	0.316	3.2576	29.31	29.31%
6	5	0.400	4.3290	38.9619	38.96%
7	6	0.489	5.4642	49.1785	49.17%
8	7	0.514	5.7831	52.04	52.04%
9	8	0.718	8.3852	75.46	75.40%
10	9	0.929	11.0765	99.68	99.68%
11	10	0.066	0.0688	0.6198	0.61%
12	11	0	0	0	0%
13	12	0	0	0	0%

TABULATION15:FORMULATION III

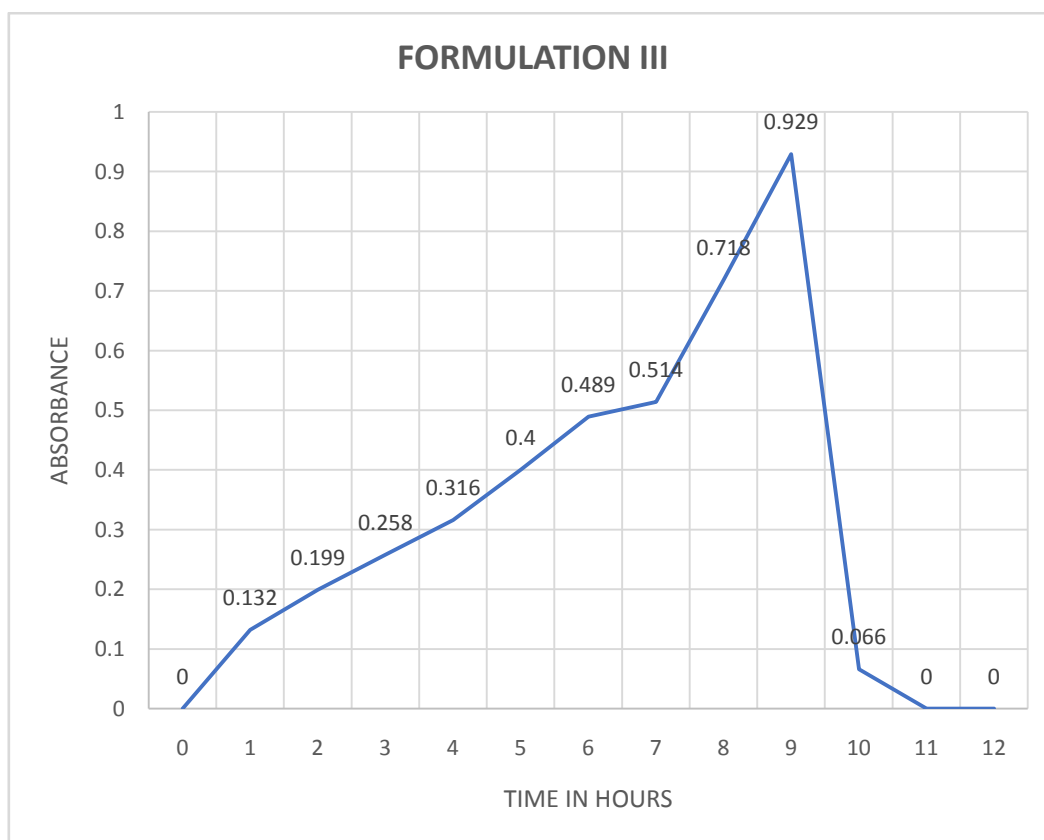


FIGURE 4:FORMULATION III

FORMULAT ION	TIME	ABSORBAN CE	CONCENTRA TION X=Y-C/M	AMOUNT FOUND(m g)	% DRUG RELEASE
F1	10	0.926	11.0382	99.3443	99.34%
F2	12	0.931	11.1020	99.9183	99.91%
F3	9	0.929	11.0765	99.6887	99.68%

TABULATION 16:OVERALL FORMULATION

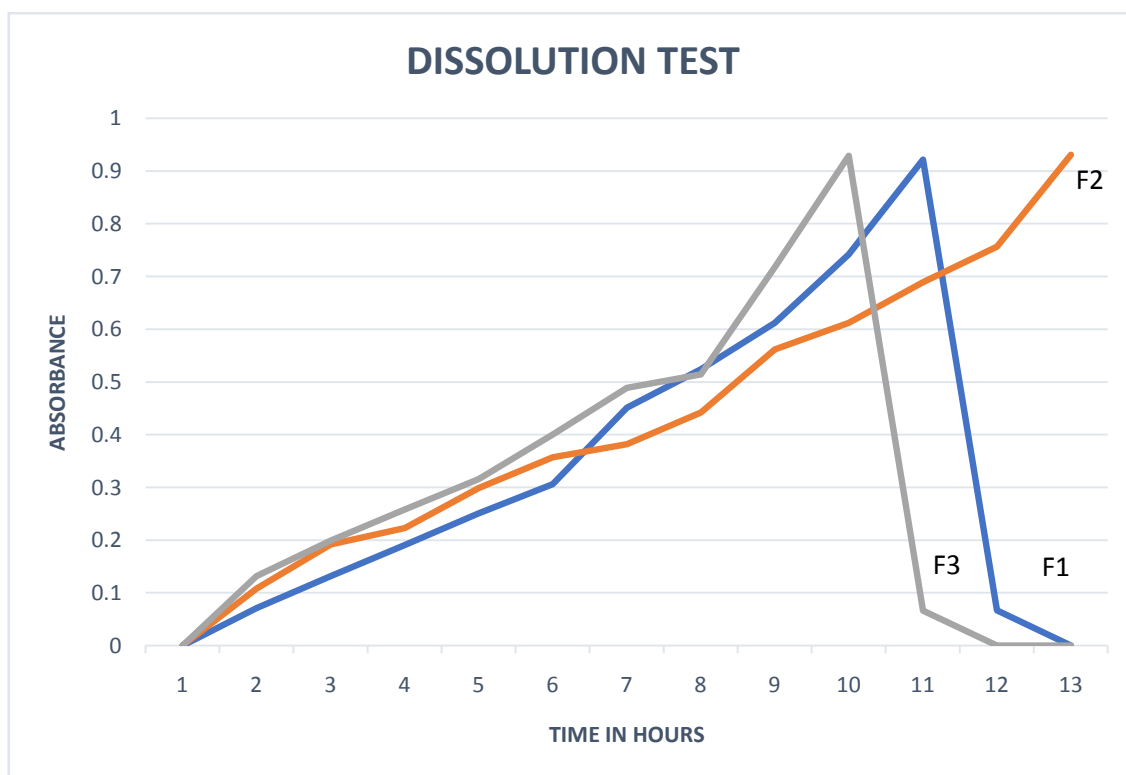


FIGURE 5:DISSOLUTION TEST

Formulation F1 And F3 % drug release within 10 hours .Formulation F2 passes the dissolution test and extend the % drug release within 12 hours

IV. CONCLUSION:

The present study shows that the tablets of Losartan potassium, prepared by using a Okra gum and other hydrophilic polymers like HPMC in various concentrations were able to retard the drug release and in spite of being hydrophilic in nature, they can prolong the therapeutic effect up to 12 hr, establishing its cognizance over similar dosage forms. The characterization demonstrated that the gum produces granules with good micromeritic properties and tablets with physicochemical properties. The best release pattern was obtained in Formulation F2, where 99.1% .

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