

Formulation And Evaluation of Mouth- Dissolving Tablet of Losartan

Pushendra Kumar Tiwari¹ and Prof. Jai Deo Pandey^{2*}

1, 2* - Rajarshi Rananjay Singh College of Pharmacy, Amethi, Sultanpur, U.P.-227405

*Correspondence to Author : Prof. Jai Deo Pandey

Head, Department of Pharmaceutics, Rajarshi Rananjay Singh College of Pharmacy, Amethi, Sultanpur, U.P.,
227405, 9450169055, jaideo.p@gmail.com , pushpendratiwari9494@gmail.com

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ABSTRACT

The present investigation is centered on the development and evaluation of mouth-dissolving tablets (MDTs) of Losartan, a drug primarily used in the management of irritable bowel syndrome (IBS). Conventional oral dosage forms of Losartan may lead to delayed onset of action and reduced patient compliance, especially in individuals who experience difficulty in swallowing. Mouth-dissolving tablets provide an effective alternative by disintegrating rapidly in the oral cavity, thereby enhancing patient convenience and facilitating quicker drug absorption.

Losartan MDTs were formulated using the direct compression method with the incorporation of different superdisintegrants to promote fast tablet disintegration. Various formulations were prepared and assessed through pre-compression parameters such as bulk density, tapped density, angle of repose, and compressibility index to ensure good flow properties. The compressed tablets were further evaluated for post-compression characteristics including hardness ranged from 2.1 to 2.5 kg/cm²., weight uniformity, friability scores less than 1%, disintegration time, wetting time, drug content, and in vitro dissolution behavior.

The optimized formulation demonstrated rapid disintegration within a short duration and showed significant drug release in a limited time frame, complying with pharmacopeial specifications. Stability studies indicated that the prepared tablets maintained their integrity and performance under different storage conditions. Release kinetics analysis suggested a controlled drug release mechanism predominantly governed by diffusion.

Overall, the study confirms that mouth-dissolving tablets of Losartan can be successfully developed with improved patient acceptability, faster onset of therapeutic action, and enhanced bioavailability, making them a suitable alternative to conventional tablet formulations.

Keywords: Losartan, Mouth-Dissolving Tablets, Superdisintegrants, Direct Compression, Dissolution, Bioavailability, Irritable Bowel Syndrome

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1. INTRODUCTION

All of the methods for the basic or fundamental drug delivery system would have been investigated with the help of dose selection for the orally DDS. The oral route's high incidence of occurrence may be partly attributed to its ease of insertion or absorption as well as the common misconception that a drug taken orally is typically absorbed throughout the body like regular meals.

These patients include noncompliant patients, those who make sense in terms of their disease, and elderly and pediatric patients. Interest in measurements that are more consistently pleasurable has increased during the past 20 years. For children, the elderly, immobile, sick, or resistant patients, there are now feasible oral course dosage options thanks to recent advances. Recently, buccal drug delivery has emerged as a critical component of medication management. "A variety of bioadhesive mucosal measurement forms have been developed, such as gels, salves, patches, glue tablets,

and most recently, the use of polymeric film, sometimes referred to as mouth dissolving films, for buccal conveyance."

- Correctness of the dose given
- Quick response improved bioavailability
- concealing taste
- Minimal shipping costs
- Lack of fracture and leaking

However, the primary obstacle to the oral administration of medications as potentially useful experts is their substantial presystemic digestion, which causes insufficient and unpredictable oral absorption and shakiness in an acidic environment. Therefore, reducing all of the parental dose form's drawbacks should be a key component of the primary approach. Nevertheless, these standards are overly stringent, lead to decreased patient compliance, cause suffering inside the organization, and have other negative consequences related to this methodology.

Transmucosal and transdermal administration systems

*Author for Correspondence: : jaideo.p@gmail.com

have been investigated by pharmaceutical researchers worldwide during the past few decades. Out of all the transmucosal destinations that are accessible, the buccal pit mucosa demonstrated a number of advantages with regard to the approach and for gas-related problems and youngsters. This is due to its copious vascularization, comparatively stable smooth muscle region, recovery period after stretching, and near-complete lack of Langerhans cells. It also avoids the first pass digestion of medications, has a direct connection to the fundamental flow through the internal jugular vein, and produces great bioavailability.

Low enzyme movement, suitability for medications and excipients that gently and reversibly irritate or damage mucosa, ease of organization, simple medication withdrawal, the office's capacity to include chemical inhibitors, pH modifiers, or saturation enhancers in the detailing, and flexibility in planning as multidirectional or unidirectional discharge frameworks for nearby and foundational activities are some of the favorable conditions.

2. MATERIALS AND METHODS

2.1 PREFORMULATION STUDIES

The initial stage in creating a dosage form is Preformulation research. At this point, the drug's chemical and physical characteristics are examined both by itself and in conjunction with excipients. These investigations aid in the selection of appropriate ingredients and techniques for making a stable and potent losartan mouth dissolving tablet.

2.2 Identification Tests:

Organoleptic properties:

The drug's (losartan) physical characteristics, including its color, taste, and odor, were assessed. For the purpose of identifying the medicine, these features were visually evaluated and contrasted with conventional reference criteria.

a. Solubility Analysis:

Ten milliliters of various solvents, including phosphate buffer (pH 6.8 and 7.4), ethanol, methanol, acetone, chloroform, and hexane, were combined with an excess of losartan in separate conical flasks. To ensure adequate solubility, the solutions were constantly shaken for a whole day using a flask shaker. Following completion, the solutions were filtered using Whatman filter paper No. 1, and the drug's solubility behavior in various solvents was noted.

b. Melting point determination:

A digital melting point device was used to ascertain the losartan sample's melting point. The purpose of this test was to determine the drug's purity because any fluctuation in the melting point may be a sign of contaminants. The findings and discussion section contains the observed melting point value.

c. UV Spectral analysis:

1. To ascertain the wavelength of maximum absorbance (λ_{max}) of losartan and to create a standard calibration curve for quantitative drug measurement, ultraviolet (UV) spectral spectroscopy was performed. This approach is popular for analytical research since it

is straightforward, precise, and easy to apply.

2. To make Stock Solution I (1000 $\mu\text{g/ml}$), precisely weighed 100 mg of losartan was put into a 200 ml volumetric flask and dissolved in a buffered phosphate (pH 6.8). To create Stock Solution II, which has a concentration of 100 $\mu\text{g/ml}$, 10 ml of this solution was taken out and diluted to 100 ml using the same buffer solution.

3. Then, from Stock Solution II, various aliquots measuring 0.2, 0.4, 0.6, 0.8, 1.0, 1.2, 1.4, 1.6, 1.8, and 2.0 ml were separated and put into 10 ml volumetric flasks. Phosphate buffer pH 6.8 was used to modify the final volume in each flask, resulting in solutions with concentrations ranging from 2 to 20 $\mu\text{g/ml}$.

4. The prepared samples were scanned between 250–350 nm using a UV-visible spectrophotometer to identify the λ_{max} of losartan. Absorbance values for each concentration were recorded at the selected wavelength.

5. The obtained calibration curve was further employed for quantitative estimation of losartan during formulation development and evaluation studies. A linear relationship was observed between concentration and absorbance, confirming compliance with Beer–Lambert's law within the selected concentration range.

d. Infra-Red spectral analysis:

Losartan's identification and purity were verified using infrared (IR) spectroscopy. This method aids in locating the drug molecule's distinctive functional groups. About 2–4 mg of Losartan and 110–160 mg of KBr were precisely combined for the study. After that, the mixture was crushed into a thin, transparent pellet using a KBr press. The FTIR spectrophotometer's sample receptacle was carefully filled with the manufactured pellet. An FTIR spectrophotometer (Shimadzu) operating in the 4000–600 cm^{-1} wavelength range was used to record the infrared spectra. To verify the drug's identification and purity, the acquired spectrum was examined for distinctive absorption peaks that corresponded to the various functional groups of losartan and compared with standard reference spectra.

e. Compatibility Studies:

When losartan was combined with certain excipients, drug-excipient compatibility tests were first carried out by visual inspection to look for any physical changes, such as color, odor, or texture. Table 5.6 presents the observations. FTIR spectrum analysis was used to further validate compatibility. We recorded and analyzed the infrared spectra of individual excipients, pure losartan, and their physical combination. Losartan was compatible with the chosen excipients and appropriate for formulation development, according to the results, which revealed no discernible change in the drug's distinctive peaks.

FORMULATION AND DEVELOPMENT

Mouth dissolving tablets preparation:

1. The direct compression method was used to make Losartan mouth dissolving tablets in compliance with the formulation found in Table. To guarantee consistent particle size and appropriate mixing, each ingredient was individually run through a 60-mesh filter.

2. To create a consistent and homogenous mixture, losartan was first combined with microcrystalline cellulose in little amounts. To guarantee that the medication was evenly distributed throughout the mixture, this step was carefully executed. To ensure homogeneity, the remaining excipients were then precisely weighed and added to the medication mixture using the geometric dilution approach.

3. Finally, the generated blend powder was compressed into tablets using a Rimek tablet compression machine fitted with an 8 mm flat-faced round punch. The resulting tablets were appropriate for additional assessment research since they were consistent in size, weight, and appearance.

Table : Formulation Chart

Ing redients (mg)	Formulation								
	L	L	L	L	L	L	L	L	L
	S	S	S	S	S	S	S	S	S
	F	F	F	F	F	F	F	F	F
	1	2	3	4	5	6	7	8	9
Losartan	10	10	10	10	10	10	10	10	10
Dosage	4	7.5	10	-	-	-	-	-	-
SSG	-	-	-	4	7.5	10	-	-	-
Supra-D33	-	-	-	-	-	-	4	7.5	10
Aspartane	3	3	3	3	3	3	3	3	3
Talcum	1	1	1	1	1	1	1	1	1
MC	3	3	3	3	3	3	3	3	3
C	1	1	1	2	1	1	2	1	1
Mg stearate	1	1	1	1	1	1	1	1	1
D-Mannitol	50	46.5	45	49	45	45	49	45	45
Total	100	100	100	100	100	100	100	100	100

* Average of three determinations **Compendial and Non-Compendial Evaluation Parameters:**

1. Physical Appearance and Visual Elegance: The structural uniformity, surface smoothness, texture, base color, and absence of physical macro-defects (such as capping, lamination, or chipping) were checked visually across twenty randomly selected units.

2. Weight Variation Test: Compendial weight uniformity was checked by selecting twenty tablets at random from each batch and weighing them individually on an analytical electronic balance. The individual weights were compared against the calculated mean weight, and percentage deviations were determined:

$$\text{Percentage Deviation} = [(W_{\text{tablet}} - W_{\text{avg}}) /$$

$$W_{\text{tablet}}] \times 100$$

For tablets with an average weight ≤ 130 mg, official guidelines stipulate that not more than two individual tablets can deviate by more than $\pm 10\%$ from the mean weight, and none can deviate by more than double that limit.

3. Geometrical Thickness: The physical thickness of ten tablets selected at random from each operational batch was determined using a calibrated digital Vernier caliper. Mean values and standard deviations (\pm SD) were established.

4. Mechanical Hardness: Tablet diametral crushing strength was evaluated to verify structural durability. Ten tablets from each trial formulation were placed individually within an Erweka hardness tester. The force required to induce cross-sectional fracture was logged in units of kg/cm^2 .

5. Mechanical Friability: Tablet surface durability against physical friction and impact was evaluated using a Roche Friabilator. An accurately dusted sample of tablets weighing approximately 6.5 g (corresponding to W_0) was placed inside the internal chamber of the device. The apparatus was rotated at a constant speed of 25 rpm for a continuous duration of 4 minutes (totaling 100 revolutions), dropping the tablets from a height of 6 inches during each cycle. The tablets were removed, carefully dusted, and reweighed (W_1). The fractional weight loss was calculated via:

$$\text{Percentage Friability} = [(W_0 - W_1) / W_0] \times 100.$$

A friability value $\leq 1.0\%$ represents the standard validation threshold for industrial compliance.

6. In Vitro Disintegration Testing: The disintegration profile of six tablets per batch was evaluated using an automated USP disintegration tester (Electrolab model). The basket-rack assembly was fitted with a standard 10-mesh screen at its base. Each glass tube was charged with one tablet, and the apparatus was lowered into a 1-liter beaker filled with purified water maintained at a physiological temperature of $37 \pm 2^\circ\text{C}$. The assembly was reciprocated vertically at a frequency of 28 to 32 cycles per minute across a fixed distance of 5 to 6 cm. The exact timeframe required for each tablet matrix to undergo complete structural collapse and pass entirely through the lower mesh screen was logged. Minimum and maximum intervals were defined.

7. Blend and Content Uniformity: Ten tablets were randomly selected from each compression batch, crushed into fine powders, and dissolved in phosphate buffer (pH 6.8). After filtration, the samples were analyzed spectrophotometrically at 261 nm to determine the exact percentage of active drug present in each unit dose.

8. In Vitro Dissolution Testing: Comprehensive kinetic drug release analysis was performed using a USP Type-II (Paddle) dissolution apparatus at 50 rpm. The dissolution vessel was filled with 500 mL of freshly prepared phosphate buffer (pH 6.8), serving as simulated salivary fluid, maintained at a stable temperature of $37.0 \pm 0.5^\circ\text{C}$. At designated time intervals of 5, 10, and 15 minutes, a 10 mL sample was withdrawn from the medium and replaced with an equal

volume of fresh, pre-warmed buffer to maintain sink conditions. The collected samples were passed through 0.45- μm membrane filters and analyzed spectrophotometrically at 261 nm to compute the cumulative percentage of drug released over time.

RESULTS AND DISCUSSION

PRE-COMPRESSION PARAMETERS

Precompression parameters were applied to a powder that was ready for compression and contained a medicine and different excipients. This allowed for the examination of granule flow properties and the achievement of consistent tablet weight. Tables 3.5 provide the outcomes of each preformulation parameter.

Angle of Repose

The angle of repose of the prepared losartan powder blends was evaluated to determine flow properties. The outcomes were shown to be within the typical permissible range of 25° to 30°, indicating good flowability of the powder mixture suitable for direct compression. This suggests that the blend possessed adequate internal friction and was appropriate for uniform die filling during tablet compression.

Carr's Consolidation Index

Carr's consolidation index of the powder blends was found to be within the **standard range of 12%–18%**, indicating better to excellent flow properties. These values confirm that the prepared blends have satisfactory compressibility and are suitable for the direct compression technique used in the creation of tablets that dissolve in the mouth.

Bulk and Tapped Density

The packing qualities of the produced losartan powder blends were evaluated by measuring their tapped bulk density and loose bulk density. All formulations had LBD and TBD values that fell between 0.52 and 0.56 g/cm³ and 0.54 and 0.64 g/cm³, respectively. These findings show that the powder mix has strong packing ability and consistent flow properties, making it appropriate for the process of making mouth-dissolving tablets via direct compression.

Hausner's Ratio

"Better flow properties are indicated by a Hausner's ratio of 1.147 to 1.222 for the entire formulation."

Table : Precompression parameter

Form Code	Angle of repose	Compressibility index	Hausner ratio	Bulk Density	Tapped Density
LSF1	26°.24 ± 0.16	15.66 ± 0.12	1.174± 0.02	0.55± 0.003	0.62± 0.004
LSF2	28°.28 ± 0.15	16.88 ± 0.13	1.168± 0.03	0.54± 0.002	0.66± 0.001
LSF3	27°.88 ± 0.14	15.46 ± 0.14	1.222± 0.03	0.53± 0.003	0.65± 0.003
LSF4	26°.55 ± 0.15	15.65 ± 0.13	1.134± 0.04	0.56± 0.001	0.57± 0.002
LSF5	27°.32 ± 0.16	16.22 ± 0.13	1.206± 0.02	0.55± 0.002	0.59± 0.004
LSF6	24°.20 ± 0.19	16.34 ± 0.14	1.151± 0.03	0.53± 0.002	0.60± 0.003
LSF7	25°.33 ± 0.18	17.99 ± 0.13	1.147± 0.03	0.54± 0.003	0.62± 0.004
LSF8	28°.92 ± 0.17	17.33 ± 0.12	1.138± 0.04	0.53± 0.00	0.56± 0.005
LSF9	29°.67 ± 0.16	16.91 ± 0.13	1.146± 0.02	0.52± 0.003	0.63± 0.002

POST-COMPRESSION PARAMETERS:

Hardness:

Tablets prepared using both manufacturing methods exhibited hardness values ranging from 2.1 ± 0.02 to 2.5 ± 0.01 kg/cm². The average hardness values obtained for all formulations are presented in Table.

Weight Variation Test:

All developed formulations showed tablet weights within the range of 99 ± 5 mg to 105 ± 6 mg. The mean results of the weight variation study are summarized in Table. As the percentage deviation in weight remained within the pharmacopoeial limit of ±7.5%, all formulations successfully complied with the weight variation requirements.

Thickness:

The mean tablet thickness ranged from 2.31 ± 0.13 mm to 2.45 ± 0.12 mm and remained almost uniform across all three formulations. The calculated standard deviation confirmed that each formulation was within the acceptable range. Detailed thickness measurements are provided in Table.

Friability Test:

All formulations had friability values between 0.37% and 0.77%, which is less than the permissible limit of 1%. These results confirm adequate mechanical strength of the tablets. The complete friability data are presented in Table.

Time to Wet

The formulation composition had a noticeable influence on the wetting behaviour of the prepared tablets. Wetting time values obtained for different batches are presented in Table. With measured values ranging from 42.6 ± 1.42 to 48.6 ± 1.43 seconds, tablets made using direct compression and sublimation processes demonstrated quick wetting. The faster wetting behaviour indicated efficient penetration of the medium into the tablet matrix.

Water Absorption Ratio

The water absorption capacity of the formulations was affected by the concentration of superdisintegrant incorporated in the tablets. Batches containing lower concentrations of superdisintegrant exhibited comparatively reduced water uptake, whereas higher

concentrations promoted greater absorption of the medium. The observed water absorption ratio values were found within the range of $60 \pm 1.45\%$ to $82 \pm 1.15\%$. An increase in CCS concentration improved water uptake due to the swelling behaviour produced by cross-linked sodium CMC. The cross-linked structure assists rapid expansion after contact with moisture, thereby enhancing hydration of the tablet system. Table presents the detailed water absorption ratio results.

In Vitro Disintegration Time

The disintegration time represents the period necessary for a tablet to fragment into smaller pieces under specified experimental conditions. All prepared formulations exhibited quick disintegration behaviour within a short duration. The disintegration results are summarized in Table . Tablets prepared by direct compression showed disintegration times ranging from 14.12 ± 1.23 to 22.75 ± 2.05 seconds, which complied with acceptable limits for mouth dissolving tablets.

Drug Content:

To guarantee that losartan was distributed evenly across the tablet batches, drug content uniformity was assessed for each of the nine formulations. For each formulation, three individual samples were analysed spectrophotometrically and the average values were calculated. The percentage drug content was observed in the range of $96.5 \pm 6.78\%$ to $99.7 \pm 6.33\%$. The obtained values confirmed satisfactory mixing and uniform incorporation of the drug throughout the formulations.

Table : Post Compression Parameters

Formula Code	Diameter (mm)	Thickness (mm)	Hardness (kg/cm ²)	Weight Variation (mg)
LSF1	3.02 ± 0.011	2.45 ±0.12	2.1±0.02	101 ± 5
LSF2	4.03 ± 0.010	2.37 ±0.14	2.3±0.02	102 ± 5
LSF3	3.02 ± 0.011	2.41 ±0.12	2.5±0.01	103 ± 5
LSF4	3.04 ± 0.012	2.32 ±0.14	2.3±0.02	104± 5
LSF5	4.03 ± 0.010	2.39 ±0.15	2.4±0.01	99.6 ± 5
LSF6	3.04 ± 0.012	2.42 ±0.16	2.3±0.02	103 ± 5
LSF7	4.04 ± 0.010	2.38 ±0.13	2.5±0.05	99 ± 5
LSF8	3.03 ± 0.012	2.31 ±0.13	2.4±0.02	102 ± 5
LSF9	3.02 ± 0.010	2.352±0.12	2.3±0.02	101 ± 5

Table : Post Compression Parameters

Formulation	Friability	Wetting	Water	Disintegration	Drug
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Code	(%)	Time* (sec)	Absorption Ratio	time (sec)	Content * (%)
LSF1	0.65	44.5 ±1.32	80±1.42	18.12±1.76	97.9 ± 4.98
LSF2	0.76	48.5 ±1.34	78±1.34	14.12±1.23	99.5 ± 2.54
LSF3	0.58	42.6 ±1.42	75±1.62	13.12±1.56	99.7 ± 6.33
LSF4	0.63	45.6 ±1.42	78±1.43	21.23±2.03	98.8 ± 5.85
LSF5	0.73	44.2 ±1.05	82±1.15	22.75±2.05	96.5 ± 6.78
LSF6	0.65	45.6 ±1.24	73±1.22	19.34±1.78	98.5 ± 5.53
LSF7	0.34	48.6 ±1.43	76±1.23	20.54±2.11	99.6 ± 6.32
LSF8	0.53	45.3 ±1.25	60±1.45	22.11±2.21	98.6 ± 5.66
LSF9	0.72	44.2 ±1.24	68±1.34	17.46±1.62	97.5 ± 6.33

In Vitro Dissolution Studies:

Using a USP Type II paddle dissolution apparatus in accordance with USP XXIII standards, an in vitro dissolution research was conducted to assess the release behavior of Losartan from mouth dissolving tablets. The dissolving media was a 950 ml amount of phosphate buffer(6.8pH), and the speed of paddle was consistently kept at 55 rpm throughout the experiment.

The dissolution medium temperature was maintained at $38 \pm 0.5^\circ\text{C}$ to simulate physiological conditions. In each vessel one tablet was placed, and at predetermined time intervals, samples were withdrawn and immediately filtered to remove any particulate matter. The cumulative % release of drug was calculated and used to evaluate the dissolution profile of losartan mouth dissolving tablets.

The dissolution study profiles of all formulations are presented in Tables. It was observed that the drug release pattern varied depending on the method of tablet preparation and composition of the formulation. Formulations prepared using the sublimation technique showed comparatively rapid drug release than other methods. This improvement may be attributed to the porous structure created due to the sublimation of volatile components, which enhances water penetration into the tablet matrix.

The increased porosity, along with lower hardness, facilitates rapid swelling and disintegration, allowing quicker drug release. All formulations exhibited rapid

drug release ranging from $85.65 \pm 1.65\%$ to $99.10 \pm 2.92\%$ within a short time period. Among all batches (LSF1–LSF9), formulation LSF3 showed the highest drug release of $99.12 \pm 2.94\%$ within 10 minutes, indicating superior performance compared to other formulations.

All prepared tablets complied with acceptable limits for post-compression parameters. Based on the overall evaluation, formulation LSF3 demonstrated the best disintegration and dissolution profile and was identified as the optimized formulation.

Table: Release profile of Losartan MDT (LSF1-LSF3)

S. No.	Time in Min	% Cumulative Drug Release		
		LSF1	LSF2	LSF3
1	0	0.00	0.00	0.00
2	2	88.98±1.66	88.66±2.33	89.19±1.49
3	4	91.13±1.46	90.58±2.57	91.14±2.29
4	6	94.46±1.33	94.12±4.13	91.38±2.14
5	8	95.79±3.07	97.45±3.61	93.24±2.67
6	10	98.68±3.46	98.61±4.58	99.12±2.94

CONCLUSION

The present study successfully developed Losartan mouth dissolving tablets (MDTs) by the direct compression method using different superdisintegrants. All prepared formulations were evaluated for various pre-compression and post-compression parameters, including weight variation, hardness, friability, drug content uniformity, wetting time, water absorption ratio, in vitro disintegration time, drug–excipient compatibility, and in vitro drug release. The results demonstrated that all formulations complied with the acceptable pharmaceutical quality standards. The tablets prepared by direct compression showed satisfactory mechanical strength without any evidence of capping or chipping. The hardness and friability values were within acceptable limits, indicating good tablet integrity and handling characteristics. Drug content was found to be uniformly distributed in all formulations, confirming the reliability of the manufacturing process. FTIR studies revealed no significant interaction between Losartan and the excipients used, indicating good compatibility of the drug with formulation components. All formulations exhibited rapid disintegration and drug release characteristics suitable for mouth dissolving tablets. Among the tested formulations, LSF3 and LSF9 showed superior performance with shorter disintegration and wetting times along with higher water absorption ratios. The enhanced swelling ability of the superdisintegrants contributed to faster tablet disintegration and improved drug release. The percentage drug release of all formulations ranged from 85.65% to 99.10%, demonstrating efficient dissolution behavior.

Among all the formulations, LSF3 containing Doshion as the superdisintegrant exhibited the most promising results, showing the fastest disintegration and highest drug release profile. Therefore, LSF3 was identified as the optimized formulation and may serve as an effective mouth dissolving tablet of Losartan for rapid onset of action and improved patient compliance.

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