



FORMULATION AND EVALUATION OF LISINOPRIL ORAL DISINTEGRATING TABLETS USING NATURAL SUPER DISINTEGRANTS

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ABSTRACT

The present study focuses on the formulation and evaluation of oral disintegrating tablets (ODTs) of Lisinopril using natural super disintegrants to enhance patient compliance, especially among geriatric and pediatric populations. Lisinopril, an ACE inhibitor used to treat hypertension, was formulated into ODTs via direct compression using natural disintegrants—Aloe vera powder, Isabgol husk, and Locust Bean Gum (LBG)—at varying concentrations (4%, 8%, and 12%). Pre-compression parameters such as bulk density, tapped density, Carr's index, Hausner's ratio, and angle of repose indicated good flow properties. Post-compression evaluations included weight variation, thickness, hardness, friability, disintegration time, wetting time, drug content, and in vitro dispersion and dissolution studies. Among all formulations, F9 containing 12% LBG showed superior performance with a rapid disintegration time of 15 ± 3 seconds and 99% drug release within 8 minutes. The study concluded that LBG at higher concentrations significantly enhances the disintegration and drug release profiles compared to other natural disintegrants, making it a promising excipient for Lisinopril ODTs. The use of natural super disintegrants offers a cost-effective, biocompatible, and eco-friendly alternative to synthetic agents, promoting sustainable pharmaceutical practices.

KEYWORDS: Lisinopril, Oral Disintegrating Tablets, Natural Super Disintegrants, Locust Bean Gum, Direct Compression, Dissolution Rate.

INTRODUCTION

Oral disintegrating tablets (ODTs) have gained significant attention in recent years due to their convenience, especially for pediatric and geriatric patients who face difficulties in swallowing conventional tablets.^[1] Lisinopril, an angiotensin-converting enzyme (ACE) inhibitor used primarily for hypertension, can benefit from this dosage form.^[2] The use of natural super disintegrants in formulating ODTs offers advantages such as biodegradability, non-toxicity, and cost-effectiveness.

Natural super disintegrants are preferred over synthetic ones due to their biocompatibility, availability, and safety. Commonly used natural super disintegrants include, Fenugreek Seed Mucilage Known for its rapid water absorption and swelling capacity, fenugreek mucilage has been shown to reduce disintegration time significantly.^[3,4] Dehydrated Banana Powder is Rich in pectin, this disintegrant enhances drug release and provides nutritional benefits.^[5,6] Plantago Ovata Mucilage acts as an effective binder and disintegrant, improving tablet properties.^[7] Mango Peel Pectin:

Derived from mango peels, this disintegrant is cost-effective and enhances solubility of poorly water-soluble drugs.^[8,9] Gum Karaya, A natural adhesive obtained from the sap of the Sterculia tree, it is chemically inert and improves tablet disintegration.

Natural super disintegrants function primarily through by following mechanisms. In Swelling and Hydration mechanism, these agents absorb water, swell, and hydrate, leading to the breakdown of the tablet matrix and rapid drug release.^[10,11] By Wicking Action, the disintegrants draw water into the tablet, facilitating disintegration and dispersion.^[4] In Particle Repulsion, the hydrated particles repel each other, further accelerating the disintegration process.^[4]

ODTs are particularly beneficial for patients with dysphagia, offering a convenient and safe mode of drug administration.^[12] Natural super disintegrants enhance drug solubility and bioavailability, particularly for poorly water-soluble drugs^[4,5]. The use of natural disintegrants reduces production costs and environmental impact, making them a sustainable choice.^[9,11]

The development of ODTs using natural super disintegrants contributes to the advancement of patient-friendly drug delivery systems. Academically, it promotes research into novel excipients and formulation techniques. Industrially, it offers a cost-effective and sustainable alternative to synthetic disintegrants, aligning with global trends towards green pharmaceuticals. Natural super disintegrants offer a promising approach in the formulation of Lisinopril ODTs, combining safety, efficacy, and environmental benefits. Their ability to enhance drug release and reduce disintegration time makes them a valuable component in modern pharmaceutical formulations. Future research should focus on exploring additional natural sources and optimizing their properties for improved drug delivery systems.

The aim of the present study was to prepare and evaluate Lisinopril oral disintegrating tablets using natural super disintegrants. The objectives were to evaluate the flow property of powder blend, prepare lisinopril fast disintegrating tablets by direct compression method

using natural super disintegrants and to perform post compression test of the prepared tablets.

MATERIALS AND METHOD

Preparation of standard graph of Lisinopril in Phosphate buffer

Accurately weighed amount (100mg) of the drug was dissolved in 100ml of Phosphate buffer in 100ml volumetric flask. From this stock solution 10 ml is withdrawn in to volumetric flask, made the volume up to 100ml with Phosphate buffer. From this second stock solution(100Mg/ml), concentrations of 2,4,6,8,10 µg/ml solutions were prepared and the corresponding absorbance was measured at 223 nm in a UV\Visible spectrophotometer.

Formulation of Lisinopril oral disintegrating tablets

Lisinopril oral dispersible tablets were formulated by using direct compression method. Drug and all the excipients were weighed accurately according to the formula, mixed in motor and pestle, passed through 100 sieve followed by compression into tablet using 6mm punch on rotary punching machine. (Table 1).

Table 1: Formulation Composition of Lisinopril oral disintegrating tablets.

Formulation Composition(mg)	Formulation codes								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Lisinopril	10	10	10	10	10	10	10	10	10
Alove vera powder	4	8	12	---	---	---	---	---	---
Isabgol husk powder	---	---	---	4	8	12	---	---	---
Locust bean gum	---	---	---	---	---	---	4	8	12
Micro crystalline cellulose	40	38	36	40	38	36	40	38	36
Mannitol	40	38	36	40	38	36	40	38	36
Magnesium stearate	1	1	1	1	1	1	1	1	1
Aerosol	2	2	2	2	2	2	2	2	2
Talc	3	3	3	3	3	3	3	3	3
Total weight (mg)	100	100	100	100	100	100	100	100	100

Pre compression parameters

Pre compression tests like angle of repose, bulk density, tapped density, compressibility index and hausner ratio were performed to determine the flow property of powder blend.

EVALUATION OF TABLETS^[13-19]

A) Weight Variation Test

To evaluate the consistency in tablet weight, the method outlined in the Indian Pharmacopoeia (IP, 1996) was followed. Ten tablets were randomly selected from each formulation batch. Their total weight was recorded using a digital balance, and the average weight was calculated. Each tablet was then weighed individually, and the standard deviation was determined to assess batch uniformity.

B) Tablet Thickness

Tablet thickness was measured using a calibrated dial caliper. Five tablets were randomly picked from each batch, and their thickness was measured individually to ensure dimensional consistency across the formulations.

C) Tablet Hardness

The mechanical strength of the tablets was assessed using a Monsanto hardness tester. Five tablets were randomly selected from each batch, and their hardness values were recorded. The average and standard deviation were then calculated to evaluate the consistency in hardness.

D) Friability

Friability measures a tablet's ability to withstand physical stress during handling. The Roche Friabilator was used for this test. Ten tablets were weighed initially (W_1) and placed into the friabilator, which was rotated at 25 rpm for 4 minutes or 100 revolutions. After the process, the tablets were reweighed (W_2), and the percent friability was calculated using the formula:

$$\% \text{ Friability} = [(W_1 - W_2) / W_1] \times 100$$

A friability value below 1% indicates acceptable mechanical strength.

E) Drug Content Uniformity

To assess drug content, three tablets (equivalent to 100 mg of lisinopril) were crushed and transferred into a 100 ml volumetric flask. Ten milliliters of phosphate buffer (pH 6.8) were added, and the mixture was shaken for 10 minutes. The volume was then made up to 100 ml with the same buffer. After filtration, 1 ml of the filtrate was further diluted and analyzed using a UV spectrophotometer at 223 nm to determine drug concentration.

F) Wetting Time

The time taken for the tablets to absorb water and begin to disintegrate was measured using a standard method. Each tablet was placed in a petri dish (6.7 cm in diameter) containing 10 ml of water. The time required for the tablet to become completely wet was recorded as the wetting time.

G) Disintegration Time

Disintegration time was determined using a USP disintegration apparatus containing 900 ml of phosphate buffer and a disk. The buffer was maintained at controlled conditions, and the time taken for the tablets to fully disintegrate without leaving residue on the mesh was noted in seconds.

H) In-vitro Drug Release Studies

The release of the drug from the tablets was studied using a USP Type-II dissolution apparatus (paddle method). The test was conducted in 900 ml of phosphate buffer (pH 6.8), maintained at $37 \pm 0.5^\circ\text{C}$, and the paddle speed was set to 50 rpm. At two-minute intervals, 5 ml samples were withdrawn and replaced with fresh medium. The amount of drug released was quantified by measuring absorbance at 223 nm using a UV spectrophotometer.

RESULTS AND DISCUSSION**Standard calibration curve of Lisinopril**

Lisinopril was dissolved in few ml of phosphate buffer and further dilutions were made using phosphate buffer. The method obeyed Beer-Lambert's law in the concentration of 2-10 $\mu\text{g/ml}$ with regression coefficient of 0.999 (Table 2, Figure 1).

Table 2: Standard Graph of Lisinopril in phosphate buffer at 223nm.

Concentration ($\mu\text{g/ml}$)	Absorbance (nm)
0	0.0
2	0.018
4	0.036
6	0.054
8	0.071
10	0.628
12	0.9

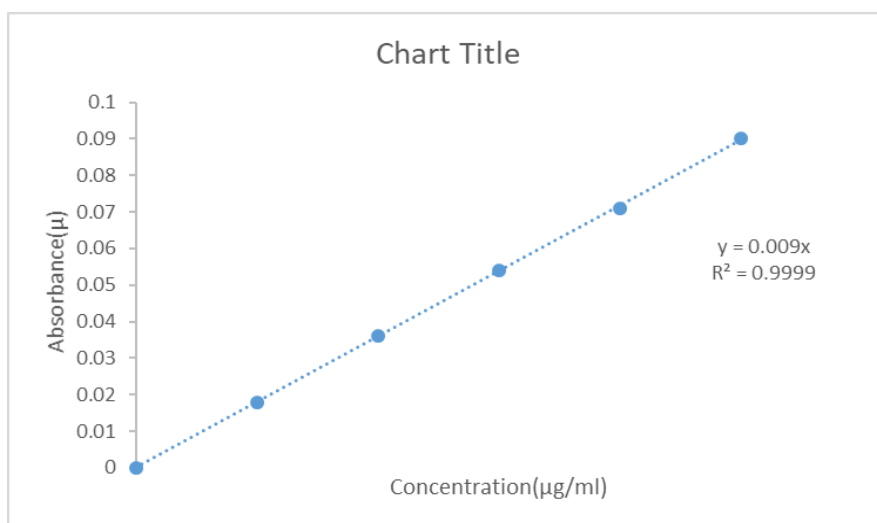


Fig. 1: Standard calibration curve of Lisinopril in phosphate buffer.

The present research was undertaken to formulate the ODTs of lisinopril through direct compression technique with various super disintegrant with various concentrations and keeping other excipients the same. Three different super disintegrants were used i.e. alovera powder, isabgol husk powder, and locust beam gum powder. The primary requirement for all the dosage forms is to disintegrate quickly.

PRE-COMPRESSION PARAMETERS

The analysis of flow properties of blended powders incorporates Bulk Density, Tapped Density, Carr's Index,

Hausner's Ratio, and Angle of Repose. These properties are critical for understanding the compressibility and volumetric behavior of powders, which is essential in numerous sectors such as pharmacy, food science, and chemicals. Each of the parameters has unique significance which is explained in the subsequent paragraphs.

According to the results presented in Table 3, the evaluated values of pre-compression parameters showed good flowing property due to the defined limits for pre-compression parameters.

Bulk density or loose bulk density defines the ratio of the mass of a powder blend to its bulk volume and in most cases is given as g/mL. It is well known that bulk density is a measure of how packed the particles of the blend are. More bulk density indicates better packing of the particles and elevated flowability of the powder. It is a key parameter determining the powder's handling, transportation, and storage. For each formulation, blends were prepared and evaluated for various Precompression parameters. The bulk density of all formulations was found to be in the range of $(0.505 \pm 0.03$ to $0.568 \pm 0.05)$.

Tapped density refers to the density a powder blend achieves after being gently tapped or vibrated to remove trapped air and allow the particles to pack more tightly. Because of this compacting effect, tapped density is usually greater than the initial bulk density. This measurement helps us understand how well a powder can be packed, which is important during processes like tablet pressing and capsule filling. In this study, the tapped density of all formulations was found to range from 0.606 ± 0.02 to 0.709 ± 0.02 g/cm³.

Carr's Index also known as the compressibility index, Carr's index evaluates how easily a powder reduces in volume under pressure. It's calculated by comparing the difference between tapped and bulk densities to the tapped density, expressed as a percentage. A lower Carr's index suggests better powder flow, whereas a higher value indicates poor flow and potential handling issues during manufacturing. In this case, Carr's index values ranged from 13.846 ± 0.2 to 20.787 ± 0.5 , reflecting excellent flowability across all formulations.

Hausner's ratio is another indicator of powder flowability and is determined by dividing tapped density by bulk density. This ratio gives insight into how much friction or cohesion exists between the particles. A value close to 1 points to free-flowing powder with minimal interparticle resistance, while higher ratios suggest poor flow. For the tested formulations, Hausner's ratios ranged between 1.161 ± 0.001 and 1.262 ± 0.002 , which also supports good flow properties.

The angle of repose measures the steepest angle at which a powder pile remains stable without sliding, which is indicative of its flow characteristics. It is determined by allowing the powder to form a conical mound via funnel flow. This angle is affected by factors such as particle size, shape, and texture. Lower angles suggest better flow, while steeper angles imply more cohesive powders. All the formulations showed excellent flowability, with angle of repose values falling between 24.28° and 28.5° .

POSTCOMPRESSION PARAMETERS

Results of post compression parameters were shown in (Table 4). All post-compression parameters for the formulated oral disintegrating tablets (ODTs) were

assessed and found to be within the acceptable limits specified by the Indian Pharmacopoeia.

Weight variation testing helps ensure dose uniformity by confirming that each tablet in a batch has a consistent weight. This is essential for delivering an accurate and consistent amount of both the active drug and excipients in every tablet. Across all formulations, the average tablet weight ranged between 120.1 ± 2.5 mg and 122.5 ± 2.5 mg. The results showed that all tablets complied with the pharmacopoeial limit of $\pm 7.5\%$, indicating uniformity in tablet weight. The standard deviation values also confirmed the consistency across batches.

Tablet thickness is a key factor in patient compliance and the efficiency of disintegration. Uniform thickness ensures proper handling and fast disintegration in the mouth, enhancing the user experience. In the tested formulations, tablet thickness was found to be between 2.1 ± 0.02 mm and 2.4 ± 0.05 mm, reflecting good control during the manufacturing process.

The hardness of a tablet indicates its mechanical strength and resistance to breakage during handling, packaging, and transportation. For ODTs, it's important to strike a balance between strength and rapid disintegration. The hardness of all tested tablets ranged from 3.3 ± 0.6 to 3.7 ± 0.4 kg/cm², demonstrating sufficient durability while still being suitable for oral disintegration.

Friability testing evaluates how easily a tablet can be broken or chipped under mechanical stress. Since ODTs are designed to disintegrate quickly, maintaining structural integrity until administration is vital. The friability of the tablets ranged from 0.4% to 0.9%, which is well below the acceptable threshold of 1%, indicating good resistance to abrasion and excellent mechanical properties.

Ensuring consistent drug content in each tablet is critical for therapeutic effectiveness and patient safety. All formulations exhibited drug content uniformity within the range of $98.5 \pm 0.7\%$ to $99.8 \pm 0.6\%$, confirming accurate dosing and uniform distribution of the active pharmaceutical ingredient (API) in the tablets.

Wetting time refers to how quickly the tablet absorbs moisture and begins to disintegrate upon contact with saliva. For ODTs, a shorter wetting time leads to faster disintegration and improved bioavailability. All the formulations demonstrated rapid wetting, indicating their potential for quick onset of action and enhanced patient convenience.

Wetting time in all the formulations were found between 42 ± 17 to 220 ± 15 sec. Comparing three super disintegrants and natural mixtures, we found that (LBG) in concentration (12%) show the best disintegration than other super disintegrants.

In vitro disintegration time measures the time it takes for a oral-disintegrating tablet to break down into smaller particles or disintegrate in a simulated physiological environment. oral disintegration is crucial for rapid drug release and absorption in the oral cavity. Monitoring disintegration time helps ensure that the tablets effectively disintegrate to promote quick drug dissolution and absorption.

In vitro dispersion time measures the time required for a oral-disintegrating tablet to disperse into fine particles when placed in a suitable liquid medium. It is particularly important for orally disintegrating tablets that are intended to be swallowed without water. Rapid dispersion ensures easy ingestion and quick dispersion of the tablet, improving patient convenience and compliance.

Rapid disintegration within few minutes was observed in all the formulations. The in-vitro disintegration time of oral dissolving tablets were found to be 15 ± 3 to 116 ± 8 secs, which is in the range of fulfilling the official requirements. By the addition of super disintegrants the disintegration time increased significantly tablets prepared. All the results were given in Table 4. The formulations F9 containing 12% w/w of natural super disintegrants (LBG) was found to be promising and has shown an in-vitro dispersion time of 32 ± 4 sec, wetting time of 42 ± 17 and disintegrating time 15 ± 3 sec. The

formulation F8 containing 8% w/w of natural super disintegrants (LBG) has shown an in-vitro dispersion time of 58 ± 6 sec, wetting time of 78 ± 15 and disintegrating time 32 ± 5 sec. The formulation F7 containing 4% w/w of natural super disintegrants (LBG) has shown an in-vitro dispersion time of 87 ± 5 sec, wetting time of 123 ± 10 and disintegrating time 54 ± 8 sec. Formulation F6 containing 12% w/w of natural super disintegrants (Isabgol) has shown an in-vitro dispersion time of 91 ± 6 sec, wetting time of 115 ± 11 and disintegrating time 78 ± 6 sec.

The dissolution of lisinopril from the tablets shows t50% and t90% of the release profiles. These values changed with change of formulations. Among all formulations F9 showed 99% drug release within 8 mins. F9 exhibited quick disintegration and improved drug dissolution. Formulation F1 to F3 showed complete drug release in between 28 to 24 min. Formulation F4 and F6 showed complete drug release in between 20 to 16 min. Formulation F7 and F8 containing locust bean gum showed complete drug release in 12 and 10 mins respectively. It was observed that as the concentration of natural super disintegrants was increased the parameters like disintegration time decreased and drug release were increased. The results revealed that natural super disintegrant's exhibited superior properties. It can be concluded that natural super disintegrants of LBG were superior to aloe vera and isabgol.

Table 3: Pre compression parameters of Lisinopril oral disintegration tablets.

Formulation codes	Pre-Compression Parameters				
	Bulk density (g/ml)	Tapped density (g/ml)	Carrs Index (%)	Hausners ratio	Angle of repose (θ)
F1	0.549 ± 0.02	0.667 ± 0.05	17.582 ± 0.3	1.213 ± 0.003	26.12
F2	0.505 ± 0.03	0.606 ± 0.02	16.667 ± 0.4	1.200 ± 0.004	27.16
F3	0.535 ± 0.04	0.641 ± 0.06	16.578 ± 0.3	1.199 ± 0.003	25.31
F4	0.541 ± 0.04	0.641 ± 0.06	15.676 ± 0.2	1.186 ± 0.002	25.36
F5	0.513 ± 0.02	0.595 ± 0.04	13.846 ± 0.2	1.161 ± 0.001	24.28
F6	0.513 ± 0.04	0.610 ± 0.03	15.897 ± 0.6	1.189 ± 0.001	25.24
F7	0.568 ± 0.05	0.680 ± 0.04	16.477 ± 0.6	1.197 ± 0.005	26.45
F8	0.562 ± 0.04	0.709 ± 0.02	20.787 ± 0.5	1.262 ± 0.002	28.51
F9	0.565 ± 0.05	0.720 ± 0.06	22.846 ± 0.6	1.282 ± 0.006	29.56

Table 4: Post compression parameters of Lisinopril oral disintegration tablets F4 to F6.

Post compression parameters	Formulation codes								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
weight variation	120.2 ± 1.4	120.1 ± 2.5	120.4 ± 2.1	120.3 ± 2.2	120.5 ± 1.1	120.4 ± 2.6	120.3 ± 2.4	120.5 ± 2.6	122.5 ± 2.5
Thickness	2.2 ± 0.03	2.2 ± 0.02	2.3 ± 0.03	2.4 ± 0.04	2.1 ± 0.02	2.4 ± 0.05	2.3 ± 0.04	2.2 ± 0.03	2.4 ± 0.05
Hardness	3.6 ± 0.3	3.4 ± 0.2	3.7 ± 0.4	3.5 ± 0.2	3.2 ± 0.4	3.4 ± 0.5	3.5 ± 0.3	3.3 ± 0.4	3.3 ± 0.6
% Friability	0.7	0.5	0.6	0.5	0.4	0.6	0.7	0.8	0.9
Drug content	98.5 ± 0.7	98.6 ± 0.5	99.1 ± 0.4	98.4 ± 0.6	99.2 ± 0.2	99.3 ± 0.2	99.1 ± 0.3	98.7 ± 0.4	99.8 ± 0.6
Disintegration time	116 ± 8	95 ± 6	80 ± 3	104 ± 4	92 ± 5	78 ± 6	54 ± 8	32 ± 5	15 ± 3
Wetting time	220 ± 15	181 ± 11	145 ± 12	193 ± 10	156 ± 8	115 ± 11	123 ± 10	78 ± 15	42 ± 17
In vitro dispersion time	134 ± 7	106 ± 5	95 ± 3	114 ± 8	105 ± 3	91 ± 6	87 ± 5	58 ± 6	32 ± 4

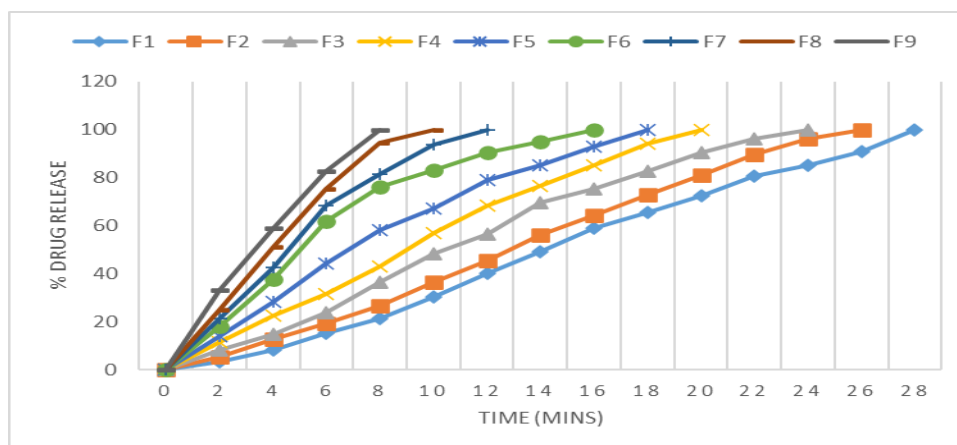


Fig 2: Percentage drug release profile of Lisinopril oral disintegration tablets.

CONCLUSION

Lisinopril is a angiotensin- converting enzyme inhibitor, used for the treatment of hypertension and heart failure, high blood pressure either alone or with other antihypertensive drugs like thiazide diuretics. In the present work, oral disintegrating tablets of Lisinopril were prepared using natural super disintegrant's aloe vera powder, ispaggol and locust bean gum at 4%, 8% and 12% concentration. Lisinopril tablets containing natural super disintegrants exhibit quick disintegration and improved drug dissolution. It can be concluded from the present work that tablets prepared with natural super disintegrants locust bean gum exhibited superior properties when compared to tablets prepared with aloe vera powder and ispaggol.

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CONFLICT OF INTEREST

Authors of this publication declare no conflict of interest.

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