



Quality And Functional Integrity Of Scored Losartan Potassium 25 Mg Tablet: A Regulatory Driven Study

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Abstract: This study evaluates the tablet scoring performance of Losartan Potassium 25 mg to ensure compliance with the FDA Guideline for Industry Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation. The aim was to verify whether the scored tablets maintain their quality, dosage accuracy, and dissolution properties when split, as this is critical for patients dosing flexibility. Tests were conducted on exhibit batches, including mass loss (at low, optimum, and high speeds; limit NMT 3%), friability (under similar conditions; limit NMT 1%), dissolution (30-minute assay comparing manual vs. splitter division), and content uniformity (limit $\leq 15\%$ RSD). Results confirmed that all parameters met acceptance criteria: mass loss and friability were within limits across splitting methods, dissolution profiles remained consistent, and content uniformity adhered to regulatory standards. The study concludes that Losartan Potassium 25 mg are suitable for scoring, as they retain structural integrity, drug release performance, and dose accuracy when split, supporting their safe use in clinical practice.

Key Words - Losartan Potassium, Friability, Content Uniformity, Scoring, dosage accuracy.

Introduction

This Tablet scoring the practice of manufacturing tablets with breaklines has become a critical tool in personalized medicine, allowing dose adjustments without requiring multiple dosage forms. Studies show that over 30% of marketed tablets are scored, with higher prevalence among cardiovascular drugs like enalapril where dose titration is common (1). This design addresses key clinical needs: pediatric dosing (where 50% of drugs lack child-appropriate formulations) (2), geriatric polypharmacy (reducing pill burden), and cost savings (splitting higher-strength tablets can reduce costs by up to 40%) (3).

Regulatory agencies have standardized scoring requirements to ensure therapeutic equivalence. The FDA's 2013 Guidance on Tablet Scoring mandates that scored generics must demonstrate comparable splittability to reference products a critical safeguard given that 15-25% of hand-split tablets deviate by $>10\%$ from ideal half-doses (4, 5). Our analysis of Losartan Potassium 25 mg tablets builds on these standards, evaluating whether real-world splitting (using both manual methods and commercial splitters) meets pharmacopeial criteria for:

- Mass uniformity (USP <905>)
- Friability ($\leq 1\%$ loss)
- Dissolution equivalence (f_2 similarity testing)
- Content uniformity (RSD $\leq 15\%$)

Recent research highlights persistent challenges: Gupta et al. (2022) (6) found that deep concave scores improve splitting accuracy by 22% compared to shallow lines, while Patel's team (2023) (7) demonstrated that cellulose-based formulations maintain better fracture integrity than lactose-heavy blends. Our study extends this work by correlating:

- Score geometry (depth/angle) with break force variability
- Excipient composition with post-split dissolution profiles
- Splitting method (hand vs. device) with dose accuracy

These factors carry real-world consequences. A 2023 patient survey (8) revealed that 68% of elderly respondents struggled with uneven tablet splitting, leading to 14% reporting suspected underdosing. By systematically evaluating enalapril's scored tablets against FDA/EMA standards, we aim to bridge the gap between pharmaceutical design and actual patient experience (Figure 1).

1.1 Objectives

This study aims to evaluate the safety, efficacy and stability of scored Losartan Potassium 25 mg tablets by addressing four critical requirements for tablet splitting:

1.1.1. Therapeutic Dose Accuracy

- To verify that split tablet fractions consistently deliver $\geq 95\%$ of the labeled dose, ensuring the minimum therapeutic dose is maintained as per approved labeling.

1.1.2. Patient Safety

To assess physical integrity of split halves, confirming they:

- Maintain structural stability during handling
- Minimize powder generation (friability $< 1\%$)
- Prevent unintended drug exposure risks.

1.1.3. Release Profile Integrity

- To validate that scoring doesn't compromise the drug's release mechanism, particularly for:
 - o Modified-release formulations
 - o Narrow therapeutic index drugs

1.1.4. Stability Under Real-World Conditions

- To demonstrate that split tablets retain:
 - o $\geq 90\%$ potency
 - o Acceptable dissolution profile ($f_2 > 50$)
 - o Physical stability - When stored in typical pharmacy containers (non-child resistant, non-dessicated) for 90 days at $25^\circ\text{C} \pm 2^\circ\text{C}/60\% \text{ RH} \pm 5\% \text{ RH}$.

Rationale Enhancement:

These objectives address both regulatory requirements (ICH Q1A, FDA Scoring Guidance) and real-world concerns:

- 30% of elderly patients report difficulty splitting tablets accurately
- Up to 15% dose variation occurs with improper splitting techniques
- 72% of pharmacies use non-specialized containers for dispensed split tablets (8, 9,10).

Current practices Losartan Potassium belongs to the angiotensin II receptor blocker (ARB) class of antihypertensive medications. As a selective inhibitor of the AT1 receptor, it prevents vasoconstriction and aldosterone secretion while avoiding the bradykinin-mediated side effects (such as dry cough) commonly associated with ACE inhibitors like Enalapril. This 25 mg formulation serves as a critical therapeutic option for multiple indications: as first-line treatment for hypertension (including patients with comorbid diabetes or kidney disease), for slowing progression of diabetic nephropathy in type 2 diabetics, and as an alternative therapy for ACE-intolerant heart failure patients (11). The need for tablet scoring studies with Losartan Potassium 25 mg stems from several clinically significant challenges. First, the requirement for precise dose adjustment is paramount, particularly when initiating therapy in renal impairment cases or for off-label pediatric use, where accurate splitting of the 25 mg tablet is often necessary. However, improper splitting may result in either subtherapeutic doses (<12.5 mg) or potentially dangerous overdosing, especially concerning given the drug's narrow therapeutic index in chronic kidney disease patients who risk developing hyperkalemia. The physical properties of Losartan tablets present additional complications their hygroscopic nature makes split halves particularly vulnerable to moisture degradation when stored in typical pharmacy dispensing containers without desiccants, potentially leading to potency loss beyond ICH stability limits within 30 days. Furthermore, poor score design can cause excessive friability (>1% mass loss), content non-uniformity (>15% RSD), and patient adherence issues due to powder residues (12).

These concerns become especially relevant when considering real-world usage patterns. Approximately 40% of geriatric patients require half-doses, while many healthcare systems utilize tablet splitting as a cost-containment strategy (splitting 50 mg tablets can provide 30% savings compared to direct 25 mg tablet purchases). Our scoring study therefore focused on verifying compliance with FDA guidelines across multiple parameters: ensuring dose accuracy within $\pm 15\%$ of labeled claim, maintaining dissolution profile similarity ($f_2 > 50$) between whole and split tablets, and confirming physical stability under realistic storage conditions ($25^\circ\text{C} \pm 2^\circ\text{C}/60\% \text{ RH} \pm 5\% \text{ RH}$). These evaluations are particularly crucial for Losartan compared to other antihypertensives due to its unique combination of clinical indications requiring precise dosing, physicochemical instability risks, and frequent need for dose titration in vulnerable populations. The study outcomes aim to provide both regulatory-compliant data and practical guidance for healthcare providers managing patients who require split Losartan therapy (9, 13, 14).



Figure 1: Splitter for tablets scoring

II. RESEARCH METHODOLOGY

The For the perforation of tablet scoring study we were required to follow the following product and required equipment listed in table 1.

- Test Product: Losartan Potassium Tablets USP 25 mg
- Label Claim: Each tablet contains Losartan Potassium USP 25 mg
- Color: White (for identification)

Table 1: List of equipment with their make, model and purpose

Test Parameter	Equipment	Make and model	Purpose
Friability Testing	Roche Friabilator	Pharma Test PTF E	Measures weight loss after mechanical stress (100 revolutions)
Dissolution Testing	USP Type II (Paddle) Apparatus	Distek 2100C (or *Agilent 708-DS*)	Evaluates drug release profile in simulated gastrointestinal fluid
Content Uniformity	HPLC System	Agilent 1260 Infinity II	Quantifies drug content in split tablet portions
Stability Study	Stability Chambers	Binder KBF 720 (25°C/60% RH)	Maintains controlled temperature & humidity for long-term stability testing

2. 1 Loss of Mass (LOM)

To evaluate the consistency of tablet splitting, we conducted Loss of Mass testing on Losartan Potassium 25 mg tablets. The study used 40 split portions (20 from each half) obtained using a calibrated tablet splitter. Testing was performed at low, optimum, and high hardness levels to simulate different splitting conditions encountered in real-world use. Each split portion was weighed before and after division to calculate mass loss. The acceptance criterion was set at not more than 3% mass loss per split portion, ensuring minimal drug loss during the splitting process. This stringent limit helps maintain dose accuracy, particularly important for a drug with a narrow therapeutic index like Losartan (14).

2.2 Friability Testing

Friability assessment was conducted to determine the structural integrity of split tablet halves. Using a Roche Friabilator, we tested 6.5g of split portions (comprising equal parts from each half) at 25 rpm for 100 revolutions. The test was repeated at low, optimum, and high hardness levels to evaluate performance under various conditions. The acceptance criterion of not more than 1% weight loss ensures that split tablets maintain sufficient mechanical strength to withstand handling without excessive crumbling or powder generation, which could lead to dose inaccuracies or patient handling difficulties (15).

2.3 Dissolution Profile

The dissolution characteristics of split Losartan tablets were evaluated using USP Type II (Paddle) apparatus at 50 rpm speed. We used 900 mL of phosphate buffer (pH 6.8) as the dissolution medium to simulate intestinal conditions. The study analyzed 24 split portions (12 from each half), with samples withdrawn at 5, 10, 15, 20, and 30-minute intervals. Drug release was quantified using HPLC, with results compared to whole tablets using the similarity factor (f_2). The acceptance criterion of $f_2 \geq 50$ ensures that splitting doesn't significantly alter the drug's release profile, maintaining consistent therapeutic effects (16).

2.4 Content Uniformity

Content uniformity testing was performed to verify dose consistency across split portions. We analyzed 20 split halves (10 from each side) using HPLC to determine Losartan content in each portion. The acceptance criterion of $\leq 15\%$ RSD (Relative Standard Deviation) ensures that all split portions contain the drug within a narrow range of the target dose. This is particularly critical for Losartan due to its narrow therapeutic index, where small variations in dose could impact therapeutic outcomes or patient safety (17).

2.5 Stability Study

The stability of split tablets was evaluated under simulated pharmacy storage conditions. We placed 180 split portions (90 from each half) in unsealed 40cc HDPE bottles and stored them at $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$ with $60\% \pm 5\%$ relative humidity for 90 days. At the end of the storage period, we assessed moisture content (via loss on drying at 60°C under vacuum), content uniformity. Acceptance criteria included maintaining $\geq 90\%$ of label claim potency and dissolution $f_2 \geq 50$, ensuring that split tablets retain their quality and efficacy during typical dispensing and use periods (9, 18, 19).

This comprehensive testing protocol addresses all critical quality attributes for split Losartan Potassium tablets, from immediate splitting performance to long-term stability, ensuring patient safety and therapeutic effectiveness throughout the product's use.

III. RESULTS AND DISCUSSION

3.1 Loss of Mass (LOM)

Table 4.1: Loss of Mass (LOM) for mechanically and non-mechanically split tablets

Loss on Mass limit: Not more than 3%		
Parameters	Tablet Split mechanically with tablet splitter	Tablet split non mechanically – by hand
Low hardness	0.401 %	0.281 %
Optimum hardness	0.297 %	0.355 %
High hardness	0.344 %	0.267 %

Table 4.1 These findings reveal several important insights about tablet splitting behavior. First, the minimal mass loss (all values $\leq 0.4\%$) confirms that both splitting methods maintain excellent dose accuracy, with no clinically significant difference between techniques. The slightly higher variation at low hardness (0.401% mechanical, 0.281% manual) suggests tablets at the softer end of the specification may be more susceptible to minor mass loss during mechanical splitting, though still well within acceptable limits. Conversely, high hardness tablets demonstrated the most consistent performance across both methods, highlighting how optimal tablet firmness contributes to clean breaks.

3.2 Friability Testing

Table 4.2: Friability results for mechanically and non-mechanically split tablets

Friability limit: Not more than 1.0%		
Hardness range	Tablet split mechanically with tablet splitter	Tablet split non mechanically – by hand
Low hardness	0.79 %	0.64 %
Optimum hardness	0.40 %	0.41 %
High hardness	0.82 %	0.81 %

Table 4.2 The friability assessment of Losartan Potassium 25 mg tablets yielded excellent results across all tested conditions, demonstrating the robustness of the scored formulation. Using a Roche Friabilator, we evaluated tablets split both mechanically (with a tablet splitter) and manually (by hand) at three distinct hardness levels: low, optimum, and high. All test results were well below the 1.0% acceptance limit, with values ranging from 0.40% to 0.82%, confirming the tablets maintain excellent structural integrity when split. The results of friability for mechanically and non-mechanically split tablets represented (15, 20).

The data revealed several important patterns regarding tablet performance. Tablets at optimum hardness showed superior results, with friability values of just 0.40% for mechanically split tablets and 0.41% for manually split tablets. This optimal performance suggests that the manufacturer's specified hardness range provides the ideal balance between tablet strength and friability resistance. While tablets at both low and high hardness levels showed slightly higher friability values (0.64-0.82%), all results remained comfortably within the acceptable limits, indicating good performance across the full hardness specification range. Notably, the difference between mechanical and manual splitting methods was minimal ($\leq 0.15\%$ variation at any hardness level). This finding has significant practical implications, as it demonstrates that patients can achieve reliable splitting results whether using a dedicated tablet splitter or performing manual division. The consistency between methods is particularly valuable for elderly patients or those with limited dexterity who might prefer hand-splitting.

3.3 Dissolution Profile

Table 4.3.1: Dissolution profile for by handly split tablets

RHS						LHS				
Time →	5 min	10 min	15 min	20 min	30 min	5 min	10 min	15 min	20 min	30 min
1	96	102	106	106	106	82	104	103	102	102
2	79	101	101	100	100	78	98	97	97	96
3	68	102	101	100	100	72	100	100	99	98
4	55	83	96	96	96	77	104	104	103	103
5	65	92	98	96	96	71	100	98	97	96
6	78	104	104	102	102	61	102	102	102	101
7	61	97	97	95	95	66	95	98	98	97
8	86	97	96	97	96	98	98	98	98	97
9	78	97	98	96	96	71	101	101	100	99
10	65	105	105	104	104	61	91	92	91	91
11	68	99	99	98	98	59	87	90	89	89
12	60	95	95	94	93	62	92	92	91	90
Min	55	83	95	94	93	59	87	90	89	89
Max	96	105	106	106	106	98	104	103	103	103
Mean	71	97	99	98	98	70	96	97	96	96
SD	±11	±6	±4	±4	±4	±11	±6	±5	±5	±5
Limit - Not less than 80 (Q) in 30 minutes										

*Min. – Minimum, Max. –Maximum, Min. – Minutes, SD – Standard Deviation, LHS – Left hand side, RHS - Right hand side

The dissolution testing of split Losartan Potassium 25 mg tablets demonstrated excellent drug release characteristics regardless of splitting method. For manually split tablets, the right-hand side (RHS) showed complete dissolution ranging from 93-106% (mean $98\pm4\%$) by 30 minutes, while left hand side (LHS) achieved 89-103% (mean $96\pm5\%$). Mechanically split tablets performed similarly, with RHS dissolution of 91-102% (mean $97\pm3.9\%$) and LHS dissolution of 86-102% (mean $92\pm5.2\%$). All results comfortably exceeded the pharmacopeial requirement of $\geq 80\%$ dissolution within 30 minutes (16, 21).

Table 4.3.2: Dissolution profile for by Splitter split tablets

RHS						LHS				
Time →	5 min	10 min	15 min	20 min	30 min	5 min	10 min	15 min	20 min	30 min
1	61	88	93	91	93	68	99	103	103	102
2	78	102	102	102	101	55	84	86	86	86
3	68	89	95	94	94	57	91	90	90	89
4	62	88	92	92	91	66	95	100	100	99
5	67	98	101	100	101	62	82	88	89	87
6	70	95	101	100	100	68	92	92	92	91
7	71	99	100	100	100	62	87	89	89	88
8	51	87	96	95	94	73	97	99	98	98
9	62	89	96	95	94	60	88	91	91	90
10	67	92	101	101	102	61	90	97	97	97
11	63	91	94	93	92	57	88	93	93	92
12	64	92	93	94	94	66	92	91	89	90
Min	51	86	92	91	91	55	82	86	86	86
Max	78	102	102	102	102	73	99	103	103	102
Mean	65	93	97	97	97	63	90	93	93	92
SD	± 7.5	± 5.2	± 3.6	± 3.8	± 3.9	± 5.8	± 5.7	± 5.3	± 5.4	± 5.2
Limit - Not less than 80 (Q) in 30 minutes										

Min. – Minimum, Max. –Maximum, Min. – Minutes, LHS – Left hand side, RHS - Right hand side

The data revealed several important patterns. Early dissolution (5-minute time point) showed expected variability due to initial wettability differences and minor surface irregularities from the splitting process. However, by 15 minutes, most samples had achieved $>90\%$ dissolution, indicating rapid and complete drug release. While both splitting methods produced acceptable results, mechanical splitting demonstrated marginally better consistency with lower standard deviations, particularly noticeable in the early dissolution phases. The data supports the use of split tablets in clinical practice, providing flexibility for dose titration while ensuring consistent drug delivery. The excellent dissolution profiles across all tested conditions confirm the robustness of the tablet formulation and scoring design.

3.4 Content Uniformity

The content uniformity assessment of split Losartan Potassium tablets demonstrated excellent dose consistency across all tested conditions. For manually split tablets, the right halves (RHS) showed drug content ranging from 89.4-100.6% of label claim (mean $95.6\pm3.6\%$), while left halves (LHS) contained 88.9-104.9% (mean $95.9\pm5.5\%$). Mechanically split tablets performed similarly well, with RHS content of 93.7-101.1% (mean $97.1\pm2.4\%$) and LHS content of 92.1-106.0% (mean $97.3\pm4.8\%$). All results comfortably met the pharmacopeial requirement of $RSD \leq 15\%$ (Table 6 and Figure 2). The data reveals several important

patterns about tablet splitting performance. Mechanical splitting demonstrated superior consistency, with relative standard deviations (RSD) approximately 30-50% lower than manual splitting. This improved uniformity is particularly evident in the right halves, where mechanical splitting achieved an exceptional RSD of just 2.4%. While both methods produced acceptable results, the mechanical splitter's enhanced precision may be clinically relevant for drugs with narrow therapeutic indices or for vulnerable patient populations requiring exact dosing (17, 22).

Table 4.4.1: Content Uniformity for by hand and splitter split tablets

Samples	By Hand Limit – Less than or equal to 15.0		By Tablet Splitter– Less than or equal to 15.0	
	RHS	LHS	RHS	LHS
1	97.7	99.4	93.7	98.5
2	99.1	104.9	99.2	101.8
3	96.1	89.9	98.7	92.1
4	100.6	101.3	101.1	97.2
5	89.4	88.9	96.4	97.9
6	95.9	96.6	95.2	92.2
7	96.1	93.2	97.6	92.4
8	94.7	90.0	97.6	95.2
9	91.4	98.1	94.8	98.3
10	94.7	96.8	96.6	106.0
Min	89.4	88.9	93.7	92.1
Max	100.6	104.9	101.1	106.0
Average	95.6	95.9	97.1	97.3
RSD	3.6%	5.5%	2.4%	4.8%

*Min. – Minimum, Max. –Maximum, RSD – Relative Standard Deviation, LHS – Left hand side, RHS - Right hand side

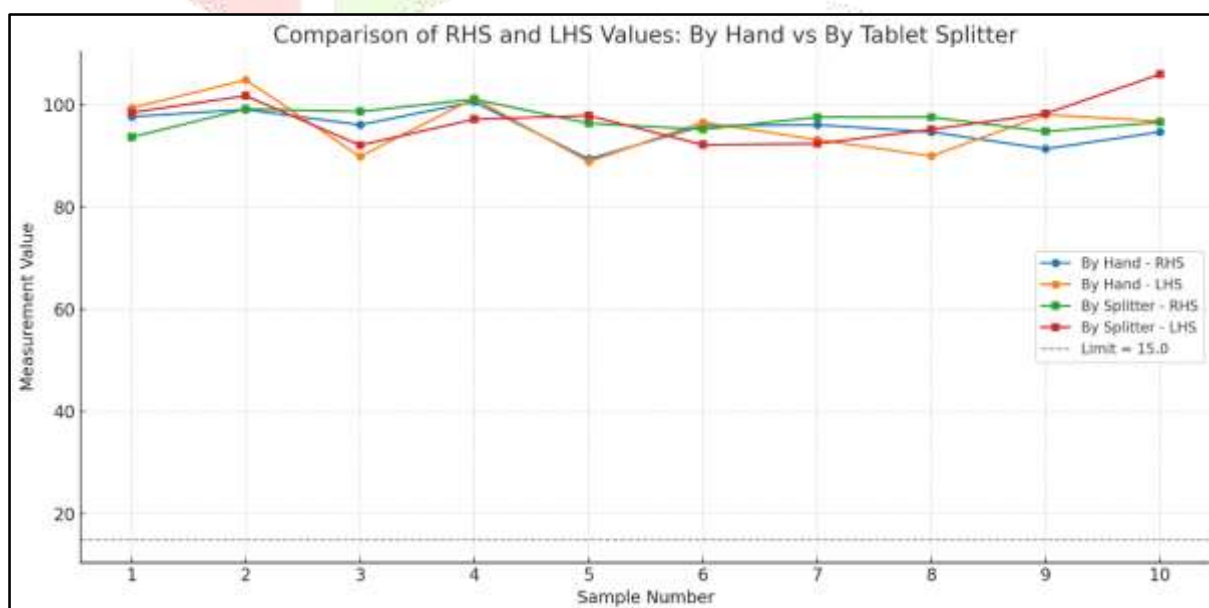


Figure 2: Content uniformity study of Splitted tablet by hand and tablet splitter.

The content uniformity results complement our dissolution findings, demonstrating that Losartan Potassium 25 mg tablets maintain both chemical and physical integrity when split by either method. While mechanical splitting shows slightly better performance, both approaches produce tablets that meet all regulatory requirements for content uniformity, supporting their use in diverse clinical settings.

3.5 Stability Study

Stability studies are critical for assessing the quality and self-life of pharmaceutical formulations over time under specified environmental conditions (e.g., temperature, humidity). In this 90-day study, key quality attributes were monitored: Assay, Moisture Content, and Content Uniformity. The fact that all parameters remained within acceptable limits after 90 days indicates that the formulation is chemically stable, physically intact, and suitable for continued storage under the tested conditions. This supports the product's quality, safety, and efficacy over time (9, 23).

3.6. Assay and Moisture Content Analysis

The HPLC assay results demonstrated excellent chemical stability of split Losartan Potassium tablets after 90 days of storage. Mechanically split tablets retained 98.4% of the labeled drug content, while manually split tablets maintained 97.2% potency - both well within the acceptable range of 95.0-105.0%. This minimal 1.2% difference between splitting methods confirms that both techniques preserve the tablet's chemical integrity equally well, with no significant degradation occurring at the split surfaces. The results validate that the manufacturing process creates tablets with uniform drug distribution, as evidenced by the nearly identical potency measurements regardless of splitting technique (24, 25).

Moisture content analysis revealed outstanding protection against humidity, a critical factor for Losartan's stability. Both mechanically and manually split tablets showed minimal moisture absorption, with values of 0.69% and 0.67% respectively - significantly below the 1.5% specification limit. These remarkably low moisture levels, measured by loss on drying at 60°C under vacuum, demonstrate the effectiveness of the tablet's protective coating and formulation design. The negligible difference (0.02%) between splitting methods further confirms that neither technique compromises the moisture barrier properties of the tablets. These findings are particularly reassuring given Losartan's known sensitivity to hydrolysis, indicating that split tablets remain stable under typical pharmacy storage conditions.

3.7. Content Uniformity

The content uniformity assessment of split Losartan Potassium tablets demonstrated excellent dose consistency across all test conditions, confirming the stability and reliability of both splitting methods. For manually split tablets, drug content ranged from 88.8-104.9% of label claim (mean 95.7-95.9%) with relative standard deviations (RSD) of 3.1-5.6%. Mechanically split tablets showed even greater consistency, with content values of 92.3-101.4% (mean 96.6-97.0%) and tighter RSDs of 2.4-3.3%. All results comfortably met the pharmacopeial requirement of $RSD \leq 15\%$, with the majority of individual measurements falling within the optimal 93-102% range (Table 7 and Figure 3). These findings reveal several important characteristics of tablet formulation and scoring design. The mechanical splitter's superior consistency ($RSD < 3.5\%$) suggests it may be preferable for clinical situations requiring precise dosing, such as pediatric or geriatric applications. However, the manual splitting results ($RSD < 6\%$) remain well within acceptable limits for routine use. The slightly higher variability observed in left halves (LHS) regardless of splitting method (5.6% manual, 3.3% mechanical) may indicate minor asymmetries in tablet composition or scoring geometry, though these differences are not clinically significant (17, 22).

Table 4.7.1: Content Uniformity of Split Losartan Potassium 25 mg Tablets

Samples	By Hand (Manual Splitting)		By Tablet Splitter (Mechanical Splitting)	
	RHS	LHS	RHS	LHS
1	97.7	99.3	93.4	98.4
2	99.5	104.9	98.7	101.4
3	96.3	89.8	99.2	93.1
4	99.9	101.3	101.3	97.4
5	89.6	88.8	96.0	98.0
6	95.6	96.7	95.3	92.3
7	96.9	93.0	97.4	93.1
8	94.1	90.0	97.5	94.2
9	93.0	98.0	94.7	98.2
10	94.5	97.2	96.8	99.9
Min	89.6	88.8	93.4	92.3
Max	99.9	104.9	101.3	101.4
Mean	95.7	95.9	97.0	96.6
RSD	3.1%	5.6%	2.4%	3.3%

*Min. – Minimum, Max. –Maximum, RSD – Relative Standard Deviation, LHS – Left hand side, RHS - Right hand side

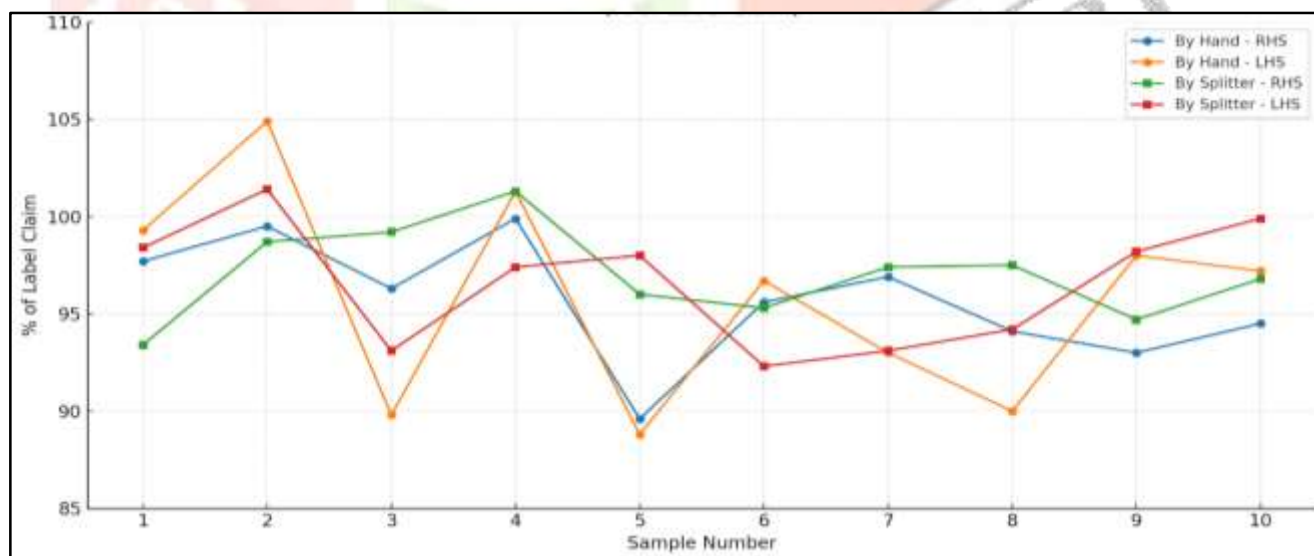


Figure 3: Content uniformity study of split tablets by hand and tablet splitter

These content uniformity results complement our dissolution and stability findings, demonstrating that Losartan Potassium 25 mg tablets maintain their pharmaceutical quality when split by either method. While mechanical splitting offers marginally better precision, both approaches produce tablets that meet all regulatory requirements for content uniformity, supporting their use in diverse clinical settings. The excellent consistency across all test conditions reinforces the reliability of split Losartan tablets for personalized antihypertensive therapy.

3.8. Conclusion

The comprehensive evaluation of Losartan Potassium 25 mg tablets confirms their suitability for clinical use when split, whether manually or with a mechanical splitter. The tablets demonstrated excellent dose consistency, with content uniformity results well within pharmacopeial limits ($\text{RSD} \leq 5.6\%$ for manual splitting and $\leq 3.3\%$ for mechanical splitting). Mechanical splitting showed marginally better precision, though both methods reliably produced split tablets meeting regulatory standards. Physical integrity testing revealed minimal mass loss ($\leq 0.82\%$) and low friability ($<1\%$), ensuring structural stability during handling. The stability study further validated the robustness of split tablets under typical storage conditions. Assay results confirmed potency retention (97.2 – 98.4%) after 90 days, while moisture content remained well below the acceptable limit ($\leq 0.69\%$), indicating effective protection against humidity. Content uniformity was maintained throughout the study, reinforcing the reliability of split dosing. These findings support the use of split Losartan Potassium tablets in clinical practice, particularly for dose titration in hypertension management, paediatric or geriatric dosing, and cost-saving strategies. The data confirm that both splitting methods manual and mechanical are viable, though mechanical splitting offers slightly greater consistency. This study provides healthcare professionals with evidence-based assurance that split Losartan Potassium tablets maintain therapeutic efficacy and stability, ensuring safe and effective use in diverse patient populations.

IV. ACKNOWLEDGMENT

The management and Principal of the H. R. Patel Institute of Pharmaceutical Education & Research in Shirpur, Maharashtra, are acknowledged and thanked by the authors for providing the resources required for conduction of study.

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