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Formulation Development and Evaluation of Orodispersible Tablets of Proton Pump Inhibitor

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Abstract: *This study aimed to develop and evaluate Lansoprazole orodispersible tablets (ODTs) formulated by the direct compression method employing different superdisintegrants to enhance patient compliance and improve therapeutic efficacy in acid-related disorders. Lansoprazole calibration was established in 0.1 N HCl at λmax 281.5 nm. FTIR studies confirmed compatibility between Lansoprazole and selected excipients. Nine formulations (F1–F9) were prepared using crospovidone, sodium starch glycolate, and croscarmellose sodium at varying concentrations. Pre-compression parameters, including bulk density, tapped density, Carr's index, Hausner's ratio, and angle of repose, indicated satisfactory flow and compressibility. Post-compression evaluations demonstrated uniform thickness, acceptable hardness (3.37–4.23 kg/cm²), low friability (<1%), and consistent drug content (98.47–99.89%). In-vitro studies revealed varying disintegration times, with F3 exhibiting the shortest (~24 sec) and superior dissolution characteristics. Overall, formulation F3 proved most promising, achieving rapid disintegration, efficient drug release, and robust mechanical properties, supporting its potential as a patient-friendly dosage form for effective management of acid-peptic conditions.*

Keywords: Lansoprazole, orodispersible tablets, superdisintegrants, direct compression, disintegration time, dissolution, FTIR compatibility

I. INTRODUCTION

Lansoprazole is a widely used proton pump inhibitor (PPI) belonging to the benzimidazole class, which exerts its therapeutic action by irreversibly inhibiting the H^+/K^+-ATPase enzyme system at the surface of gastric parietal cells, thereby suppressing the final step of gastric acid production. This makes it highly effective in the treatment and management of acid-related gastrointestinal disorders such as gastroesophageal reflux disease (GERD), peptic ulcers, erosive esophagitis, and Zollinger–Ellison syndrome. Despite its efficacy, Lansoprazole is characterized by low aqueous solubility and is highly unstable in acidic environments, necessitating careful formulation approaches to protect it from gastric degradation and to enhance its bioavailability.

Traditional oral dosage forms like enteric-coated tablets and capsules are commonly employed to address these challenges. However, they are often associated with delayed onset of action and may be unsuitable for patients who experience dysphagia, including pediatric and geriatric populations. Orodispersible tablets (ODTs) have emerged as an innovative dosage form designed to disintegrate rapidly in the oral cavity without the need for water, thereby offering improved patient compliance and faster onset of therapeutic action. This is particularly advantageous for managing conditions requiring quick relief, such as acute episodes of acid reflux.

The rapid disintegration of ODTs is primarily facilitated by the incorporation of superdisintegrants, which swell upon contact with saliva, breaking the tablet matrix apart and releasing the drug for absorption. Commonly employed superdisintegrants such as crospovidone (CP), sodium starch glycolate (SSG), and croscarmellose sodium (CCS) differ in their swelling mechanisms and efficiencies, influencing the disintegration time and ultimately the drug release profile. The selection and optimization of these excipients are therefore critical to achieving desirable disintegration and dissolution characteristics.

In addition to enhancing patient convenience, ODTs offer potential pharmacokinetic benefits by promoting rapid drug dissolution in the oral cavity and upper gastrointestinal tract, which may translate into faster absorption and onset of action. This is especially relevant for Lansoprazole, which, after bypassing the acidic environment due to its buffering

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microenvironment created by excipients like sodium bicarbonate and potassium bicarbonate, can promptly reach its site of absorption in the small intestine.

Given these considerations, the present study was undertaken to develop and evaluate Lansoprazole ODTs using different superdisintegrants via the direct compression method, aiming to identify the optimal formulation with superior disintegration, mechanical strength, and dissolution characteristics. The study also involved comprehensive pre-compression assessments (such as bulk density, tapped density, Carr's index, Hausner's ratio, and angle of repose) to ensure blend suitability for direct compression, and post-compression evaluations (including hardness, friability, weight variation, drug content, in-vitro buoyancy, swelling index, and dissolution testing) to confirm the quality, uniformity, and performance of the final tablets. Compatibility studies using FTIR spectroscopy were performed to ascertain the absence of potential interactions between Lansoprazole and formulation excipients, ensuring formulation stability.

This systematic investigation not only aims to address the formulation challenges associated with Lansoprazole but also to offer an improved patient-centric dosage form capable of delivering prompt therapeutic effects with enhanced convenience, thereby improving treatment outcomes in acid-related gastrointestinal conditions.

II. MATERIALS AND METHODS

A standard calibration curve of Lansoprazole sodium in 0.1 N hydrochloric acid was prepared by first dissolving 1 g of sodium bicarbonate in a 100 mL amber volumetric flask using a small quantity of 0.1 N HCl. To this, 100 mg of Lansoprazole sodium dissolved in 2–5 mL water was added, and the volume was adjusted with 0.1 N HCl to obtain a standard stock solution of 1000 µg/mL (SS-I). From SS-I, 1 mL was further diluted to 100 mL to get 10 µg/mL (SS-II). Aliquots of 2, 4, 6, 8, and 10 mL of SS-II were each diluted to 10 mL with 0.1 N HCl to yield concentrations of 2, 4, 6, 8, and 10 µg/mL, respectively. Scanning these solutions in the UV range (200–800 nm) using 0.1 N HCl as blank revealed a λmax of 281.5 nm, and the absorbance of each was recorded at this wavelength (UV-1800 Shimadzu) to establish the calibration curve. Additionally, FTIR studies were performed to assess compatibility between Lansoprazole sodium and excipients, including superdisintegrants, by recording spectra of the pure drug, individual excipients, their physical mixtures, and the optimized formulation using the KBr pellet technique on a Shimadzu 8400S instrument, ensuring no significant chemical interaction occurred upon formulation.

Preparation of Lansoprazole Orodispersible Tablets:

Lansoprazole orodispersible tablets were prepared by the direct compression method using the superdisintegrant addition technique. All ingredients were first sieved individually through a 60# mesh to ensure uniform particle size, then accurately weighed and mixed with the drug in geometrical order to achieve a homogeneous blend. This mixture was gently shaken for a few minutes to guarantee uniform distribution of all components. The final blend was compressed into tablets of 1300 mg weight using compression machine fitted with flat-faced oval punches.

Preparation of Lansoprazole Orodispersible Tablets

Sr. No	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
1.	Lansoprazole	20	20	20	20	20	20	20	20	20
2.	CP	-	13	39	65	-	-	-	-	-
3.	SSG	-	-	-	-	13	39	65	-	-
4.	CCS	-	-	-	-	-	-	-	13	39
5.	Aspartame	52	52	52	52	52	52	52	52	52
6.	Mannitol DC	77. 5	64.5	38.5	12. 5	64. 5	38. 5	12.5	64. 5	38. 5
7.	Talc	26	26	26	26	26	26	26	26	26
8.	SSF	13	13	13	13	13	13	13	13	13
9.	Sodium Bicarbonate	585	585	585	585	585	585	585	585	585

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10.	Potassium Bicarbonate	520	520	520	520	520	520	520	520	520
11.	Flavour	6.5	6.5	6.5	6.5	6.5	6.5	6.5	6.5	6.5

Evaluation of Pre-Compression and Tablet Parameters:

The pre-compression parameters of the prepared Lansoprazole blends were thoroughly evaluated to ensure suitability for direct compression. Bulk density and tapped density were measured to understand powder packing and compressibility, with Carr's Index and Hausner's Ratio calculated to assess flow properties, alongside angle of repose for flow behavior classification, all critical for optimizing die filling and uniform tablet weight. The tablets were then evaluated for general appearance to ensure aesthetic quality Mechanical strength was assessed through hardness testing using a Monsanto tester, while uniformity in tablet weight was confirmed by comparing individual weights against the average, ensuring compliance with pharmacopeial standards Friability tests determined resistance to abrasion. Drug content analysis validated uniform distribution of Lansoprazole within tablets In-vitro buoyancy studies measured floating lag time (FLT) and total floating time (TFT), highlighting the gastroretentive capability. Swelling index studies monitored hydration behavior, important for sustained release, while in-vitro dissolution studies using USP-II apparatus in 0.1N HCl assessed drug release profiles over time, with absorbance measured at 281.5 nm to ensure efficient and predictable drug release .

III. RESULTS AND DISCUSSION

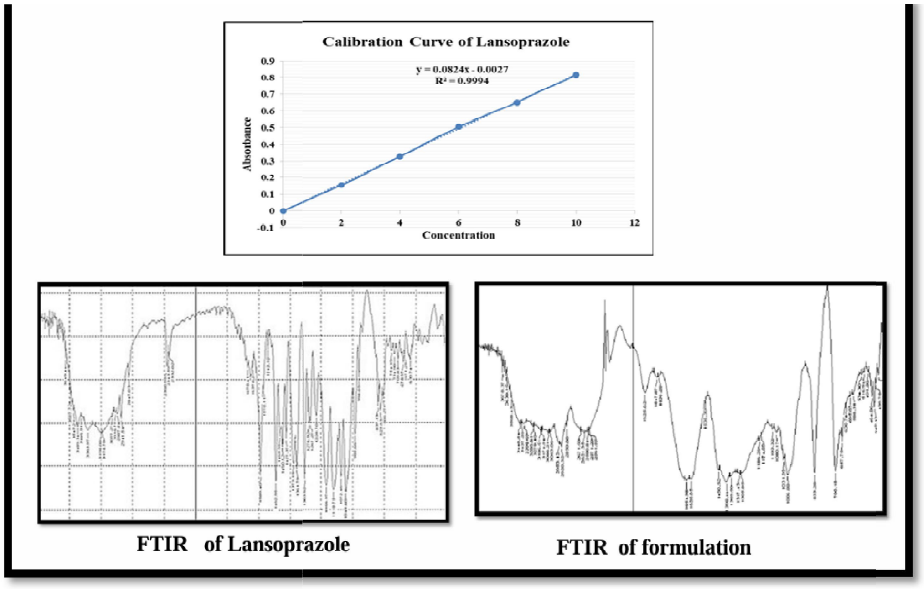

Fig 1: Preliminary evaluation of drug

The pre-compression evaluation of granules revealed satisfactory flow and packing properties across all formulations, which is essential for achieving uniform die filling and consistent tablet weight during compression. The angle of repose ranged from 24.28° to 29.51°, indicating good to acceptable flowability. Formulations F3 and F7 showed the lowest angles of repose, suggesting excellent flow, which was supported by their relatively low Carr's Index values (11.32% and 12.50%, respectively) and Hausner's Ratios (1.13 and 1.14), all well below the critical threshold of 1.25, signifying minimal interparticulate friction and good compressibility. Slightly higher values observed in F5, F6, F8, and F9 (Carr's Index ~14–15% and Hausner's Ratio ~1.17) still indicated acceptable flow for direct compression.

Post-compression evaluations demonstrated that all chewable tablet batches exhibited consistent thickness, uniform hardness ranging from 3.37 to 4.23 kg/cm², and very low friability values (<1%), reflecting adequate mechanical strength to withstand handling. Weight variation was minimal and within pharmacopeial limits for all batches,

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affirming uniform die filling and compression. Drug content uniformity ranged between 98.47% and 99.89%, indicating efficient blending and homogenous distribution of Saxagliptine.

Significant differences were observed in disintegration times, a critical attribute for chewable tablets. F3 displayed the fastest disintegration (~24 sec), followed by F7 (~87 sec), while formulations such as F1, F5, and F8 showed prolonged disintegration times (above 180 sec), likely due to higher binder or lower disintegrant efficiency. These disintegration profiles directly impacted dissolution behaviors; notably, F3 and F7 exhibited rapid onset of drug release in earlier in vitro studies, aligning with their faster disintegration. Meanwhile, harder tablets like F8 and F9, despite higher hardness (~4.2 kg/cm²), maintained acceptable disintegration (<180 sec) due to optimized excipient ratios.

Collectively, these findings validate that the chosen formulation and process parameters effectively produced chewable tablets with desirable mechanical properties, excellent drug content uniformity, and tailored disintegration characteristics. Among them, F3 stood out as the most promising formulation, balancing rapid disintegration, optimal hardness, minimal friability, and superior dissolution—thereby ensuring prompt drug availability for managing postprandial glucose spikes in diabetic patients

Table 2: Pre compression evaluation parameters

Formulation	Angle of repose	Bulk Density (gm/cm^3)	Tapped Density (gm/cm^3)	Carr's Index (%)	Hausner's Ratio
F 1	25.82	0.71	0.81	12.84	1.15
F 2	27.35	0.70	0.80	12.50	1.14
F 3	24.28	0.72	0.81	11.32	1.13
F4	25.11	0.69	0.79	12.73	1.15
F 5	29.05	0.69	0.81	14.53	1.17
F 6	26.76	0.70	0.82	14.55	1.17
F 7	25.12	0.68	0.78	12.50	1.14
F 8	25.29	0.71	0.83	14.55	1.17
F 9	29.51	0.69	0.80	14.29	1.17

Table 3: Post-compression evaluation parameters

Formulation	Uniformity of Thickness(mm)	Hardness (kg/cm^2)	Friability %	Weight Variation (mg)	*In- vitro* disintegration time(Seconds)	Drug Content (mg)
F 1	6.98±0.04	3.37±0.15	0.30±0.13	1303±2.15	Above 180 sec	98.52 ± 0.36
F 2	7.01±0.025	3.57±0.06	0.58±0.35	1315.5 ± 5.78	96.67 ± 5.03 sec	98.88 ± 0.38
F 3	6.89±0.32	3.43±0.06	0.44±0.43	1293.5 ± 4.68	24.33 ± 3.79 sec56	99.89 ± 0.33
F4	7.01±0.03	3.57±0.06	0.35±0.24	1295± 8.75	.33 ±5.03 sec	98.96 ± 0.34
F 5	6.89±0.071	3.77±0.06	0.30±0.08	1306.5±5.33	Above 180 sec	98.75 ± 0.41
F 6	6.86±0.04	4.2±0	0.61±0.34	1303.5±5.18	166.67 ± 10.41 sec	98.47 ± 0.35
F 7	6.95 ± 0.03	3.47±0.06	0.43±0.19	1309±3.45	87 ± 3.06 sec	99.19 ± 0.50
F 8	6.96±0.03	4.17±0.06	0.52±0.19	1296.5±4.83	Above 180 sec	99.62 ± 0.44
F 9	6.96±0.03	4.23±0.06	0.17±0.11	316.5±=3.58	172.33 ± 2.52 sec	99.14 ± 0.60

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IV. CONCLUSION

The study successfully formulated Lansoprazole orodispersible tablets employing superdisintegrants through a direct compression technique, achieving desirable physicochemical and mechanical properties. FTIR analysis confirmed no significant drug–excipient interactions, ensuring formulation stability. Pre-compression assessments confirmed excellent flow and compressibility necessary for uniform die filling. Post-compression tests validated consistent hardness, low friability, precise weight variation, and uniform drug content across formulations. Notably, F3, containing crospovidone at higher concentration, demonstrated the fastest disintegration and optimal dissolution profile, positioning it as the best candidate for immediate release, enhancing patient convenience and therapeutic efficacy in treating acid-related disorders. These findings underscore the formulation's suitability as an effective orodispersible dosage form, promising improved patient compliance and prompt onset of action.

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