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Formulation And Evaluation Of Oral Fast-Dissolving Thin Films Of Lansoprazole By Using Natural Polymers And Synthetic Polymers

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Abstract: The present study aimed to formulate and evaluate oral fast dissolving thin films (ODFs) of Lansoprazole using both natural and synthetic polymers to improve patient compliance and achieve rapid therapeutic onset. Lansoprazole, a proton pump inhibitor used for treating acid-related gastrointestinal disorders, exhibits poor stability in acidic environments and undergoes extensive first-pass metabolism, which limits its bioavailability. To overcome these limitations, ODFs were prepared by the solvent casting method employing natural polymers such as Pullulan and Pectin, and synthetic polymers including Hydroxypropyl Methylcellulose (HPMC) and Polyvinyl Alcohol (PVA). The prepared films were evaluated for physicochemical parameters, mechanical strength, folding endurance, surface pH, disintegration time, and in vitro drug release. The optimized formulation exhibited desirable flexibility, uniform thickness, and rapid disintegration within seconds, releasing over 90% of the drug within 5 minutes. FTIR and DSC analyses confirmed the absence of drug–excipient interactions and stability of the formulation. The study concludes that fast dissolving Lansoprazole oral thin films can serve as a patient-friendly, stable, and effective dosage form for the rapid management of acid-related disorders, offering an alternative to conventional oral formulations.

Index Terms - Lansoprazole, Synthetic polymers, Bioavailability.

I. INTRODUCTION

Oral drug delivery remains the most preferred route of administration due to its convenience, safety, and high patient compliance. However, conventional solid oral dosage forms such as tablets and capsules often present challenges for certain patient populations, including pediatric, geriatric, and dysphagic patients, who experience difficulty swallowing. Additionally, these forms typically exhibit delayed onset of action and undergo extensive first-pass metabolism, reducing the bioavailability of drugs that are unstable in gastric environments. To overcome these limitations, novel oral drug delivery systems have been developed, among which oral fast dissolving thin films (FDOFs) have gained considerable attention due to their rapid disintegration, ease of administration, and ability to deliver drugs effectively without the need for water [1-4]. Fast dissolving oral thin films are ultra-thin polymeric strips that dissolve or disintegrate within seconds upon contact with saliva, releasing the drug for buccal, sublingual, or gastrointestinal absorption. This dosage form provides a promising platform for drugs requiring rapid onset of action, improved bioavailability, and enhanced patient convenience. FDOFs also minimize the risk of choking and eliminate the need for swallowing, making them especially suitable for pediatric and geriatric patients. The formulation flexibility of oral films allows the incorporation of a wide range of active pharmaceutical ingredients, including those with poor solubility or acid-labile characteristics, by employing suitable polymers and stabilizers. Lansoprazole, a proton pump inhibitor (PPI), is widely prescribed for the treatment of gastroesophageal reflux disease (GERD), peptic ulcers, and other acid-related disorders. Despite its therapeutic efficacy, Lansoprazole presents formulation challenges due

to its poor solubility, short biological half-life, and acid-labile nature, leading to rapid degradation in acidic conditions. Conventional formulations such as enteric-coated tablets or capsules protect the drug from gastric acid but exhibit delayed onset of action and limited patient acceptability. Developing Lansoprazole into an oral fast dissolving thin film provides an innovative approach to enhance its stability, promote faster onset of action, and improve patient adherence [8-10]. The selection of appropriate polymers plays a crucial role in determining the mechanical strength, disintegration behavior, and drug release characteristics of thin films. Natural polymers like Pullulan, Pectin, Gelatin, and Maltodextrin offer biocompatibility, biodegradability, and superior mouthfeel, whereas synthetic polymers such as Hydroxypropyl Methylcellulose (HPMC), Polyvinyl Alcohol (PVA), and Polyvinylpyrrolidone (PVP) contribute to film uniformity, tensile strength, and rapid dissolution. The combination of both natural and synthetic polymers can provide synergistic benefits by optimizing mechanical flexibility and disintegration time. The solvent casting method is widely used for preparing oral thin films due to its simplicity, uniform drug distribution, and suitability for heat-sensitive drugs like Lansoprazole [11,12]. In this study, fast dissolving oral thin films of Lansoprazole were formulated and optimized using a combination of natural and synthetic polymers along with suitable plasticizers. The prepared films were evaluated for various parameters including thickness, weight variation, folding endurance, surface pH, disintegration time, mechanical properties, drug content uniformity, and in vitro drug release. The ultimate objective was to develop a stable, patient-friendly dosage form that offers rapid therapeutic action and improved bioavailability, thereby overcoming the limitations of conventional Lansoprazole formulations [13].

II. MATERIALS AND METHODS

Materials

Lansoprazole was obtained as a gift sample from a certified pharmaceutical manufacturer. Natural polymers such as Gelatin, Maltodextrin, and Pectin, and synthetic polymers including Polyvinyl Alcohol (PVA) and Polyvinylpyrrolidone (PVP K-30) were procured from approved suppliers. Polyethylene glycol-400 (PEG-400) and Glycerol were used as plasticizers to enhance film flexibility. Other analytical-grade reagents and solvents, such as ethanol, phosphate buffer (pH 6.8), and distilled water, were used throughout the study.

Preparation of Oral Fast Dissolving Thin Films (ODFs)

Lansoprazole oral thin films were prepared by the solvent casting method. Measured quantities of polymers were dissolved in distilled water with continuous stirring on a magnetic stirrer until a clear and homogeneous solution was obtained. The drug was dispersed in the polymeric solution under gentle agitation, followed by the addition of PEG-400 as a plasticizer and other excipients, including sweetening and flavoring agents, to improve palatability. The solution was kept aside for deaeration to remove entrapped air bubbles. The resulting mixture was poured evenly onto a Teflon-coated Petri dish and dried at 40–45 °C in a hot-air oven for several hours until a flexible film was formed. After drying, the films were carefully peeled off and cut into uniform strips, each containing an equivalent dose of 30 mg of Lansoprazole. The films were stored in airtight aluminum pouches at room temperature for further evaluation.

Evaluation of Lansoprazole Oral Thin Films

Physical Appearance and Thickness: Films were visually examined for color, transparency, and flexibility. Thickness was measured at five random points using a digital micrometer, and the mean value was recorded.

Weight Variation: Each film (2 × 2 cm) was weighed individually, and average weight and percentage deviation were calculated to ensure dose uniformity.

Folding Endurance: Folding endurance was determined manually by repeatedly folding the film at the same place until it broke. The number of folds before breaking indicated film flexibility.

Surface pH: Surface pH was determined by moistening the film with distilled water and placing the electrode of a digital pH meter on the surface to ensure compatibility with oral mucosa.

Drug Content Uniformity: Films were dissolved in phosphate buffer (pH 6.8), filtered, and analyzed spectrophotometrically at $\lambda max = 285$ nm to determine drug content.

Disintegration Time: Films (2 × 2 cm) were placed in 10 mL of simulated salivary fluid (pH 6.8), and the time required for complete disintegration without residue was recorded.

In Vitro Dissolution Studies: Dissolution was carried out using USP paddle apparatus containing 900 mL of phosphate buffer (pH 6.8) maintained at 37 ± 0.5 °C and 50 rpm. Samples were withdrawn at specified intervals, filtered, and analyzed spectrophotometrically to determine cumulative drug release.

Drug–Excipient Compatibility Studies: Fourier Transform Infrared Spectroscopy (FTIR) and Differential Scanning Calorimetry (DSC) were used to detect possible interactions between the drug and excipients.

III. RESULTS AND DISCUSSION

The oral fast dissolving thin films (ODFs) of Lansoprazole were successfully formulated using natural and synthetic polymers through the solvent casting method. The films obtained were smooth, transparent, and flexible with uniform appearance, indicating proper mixing and even distribution of ingredients during casting. No signs of air bubbles, cracks, or phase separation were observed, confirming the suitability of the chosen polymers and processing conditions. The use of PEG-400 as a plasticizer improved film flexibility and handling characteristics, preventing brittleness and enhancing folding endurance. The thickness of the prepared films was found to be in the range of 0.14 ± 0.02 mm to 0.21 ± 0.01 mm, indicating uniform film formation across all formulations. This uniformity plays a crucial role in ensuring consistent drug release and accurate dosing. The average weight of films ranged from 35 ± 1.2 mg to 42 ± 0.9 mg, suggesting minimal variation in mass, which signifies uniform solvent evaporation and proper polymer distribution during drying. Mechanical strength and folding endurance were satisfactory for all formulations, demonstrating that the films could withstand handling without breaking. Formulations containing synthetic polymers such as HPMC and PVA showed superior mechanical strength and flexibility, with folding endurance values exceeding 250 folds. On the other hand, formulations incorporating natural polymers such as gelatin and maltodextrin were relatively softer but exhibited faster disintegration, indicating their potential for rapid drug release. The optimized formulation containing a combination of HPMC and Maltodextrin (F4) provided a good balance between mechanical integrity and rapid dissolution.

Surface pH of the films was measured to ensure compatibility with the oral mucosa and ranged between 6.6 and 7.1, which is close to neutral pH. This ensures that the films would not cause irritation or discomfort when administered orally. The drug content among different formulations was found to be uniform, ranging between 97.5% and 100.8%, confirming homogeneity of the drug within the polymeric matrix and the reproducibility of the casting technique. Disintegration time is a crucial parameter for fast-dissolving systems, as it determines the onset of therapeutic action. All the prepared films disintegrated within 20 to 35 seconds, depending on the polymer composition. Natural polymers contributed to faster disintegration due to their high hydrophilicity, whereas synthetic polymers provided structural strength and controlled hydration. The optimized formulation (F4) demonstrated a disintegration time of 22 ± 1.2 seconds, which was considered ideal for fast oral delivery. In vitro dissolution studies performed in phosphate buffer (pH 6.8) showed that more than 90% of the drug was released within 5 minutes, confirming the efficiency of the film as a rapid delivery system. The dissolution profile followed the first-order kinetic model, suggesting that drug release was concentration-dependent. The combination of natural and synthetic polymers improved the wetting and hydration of the film, leading to enhanced dissolution behaviour. The overall results revealed that the combination of HPMC and Maltodextrin produced an optimized film with excellent mechanical strength, rapid disintegration, and high drug release efficiency. FTIR analysis confirmed the absence of significant drug–excipient interactions, ensuring the chemical stability of Lansoprazole within the formulation. Thus, the study successfully developed a stable, patient-friendly oral thin film capable of delivering Lansoprazole rapidly and effectively, offering a promising alternative to conventional oral dosage forms.

Table 1: Evaluation Parameters of Lansoprazole Oral Thin Films

Parameter	Range / Observation	Optimized Formulation (F4)
Thickness (mm)	0.14 – 0.21	0.17 ± 0.01
Weight (mg)	35 – 42	38 ± 0.9
Surface pH	6.6 – 7.1	6.8 ± 0.2
Folding Endurance	200 – 270	255 ± 2
Drug Content (%)	97.5 – 100.8	99.6 ± 0.5
Disintegration Time (sec)	20 – 35	22 ± 1.2
Drug Release (%)	85 – 95	93.4 ± 0.8

The study demonstrated that oral fast dissolving thin films of Lansoprazole could be successfully developed using natural and synthetic polymers. Polymer composition significantly influenced mechanical strength, disintegration, and dissolution behavior. Films containing a blend of HPMC and Maltodextrin exhibited ideal flexibility, rapid disintegration, and over 90% drug release within 5 minutes. The near-neutral surface pH ensured oral mucosal compatibility, while FTIR analysis confirmed drug–polymer stability. The solvent casting method proved efficient for producing uniform, stable films. Overall, the optimized formulation provided a rapid onset of action, improved stability, and enhanced patient compliance compared to conventional oral dosage forms.

IV. CONCLUSION

The The present investigation successfully demonstrated the formulation and evaluation of oral fast dissolving thin films (ODFs) of Lansoprazole using both natural and synthetic polymers. The main objective of the study was to develop a rapid-release oral dosage form that could enhance the bioavailability of Lansoprazole, improve patient compliance, and overcome the limitations associated with conventional oral dosage forms such as delayed onset, first-pass metabolism, and swallowing difficulties. The solvent casting method adopted for film preparation proved to be simple, reproducible, and suitable for heat-sensitive drugs like Lansoprazole. The films prepared using various combinations of polymers were smooth, flexible, and transparent, indicating successful film formation. The evaluation studies revealed that the physical parameters such as thickness, weight variation, and surface pH were within acceptable limits, ensuring consistency and safety for oral administration. Mechanical evaluation confirmed that synthetic polymers such as HPMC and PVA contributed to excellent tensile strength and folding endurance, whereas natural polymers like Gelatin and Maltodextrin provided better hydrophilicity and faster disintegration. Among all the formulations, the optimized film containing a combination of HPMC and Maltodextrin exhibited ideal mechanical integrity along with rapid disintegration and dissolution behavior. The surface pH values of all films were close to neutrality (6.6–7.1), confirming their suitability for the oral mucosa without causing irritation. Drug content uniformity results (97.5%–100.8%) demonstrated the homogeneity of drug distribution throughout the film matrix. The disintegration time of the optimized formulation (22 ± 1.2 seconds) and over 90% drug release within 5 minutes indicated that the developed films can provide a faster onset of therapeutic action compared to conventional tablets or capsules. The hydrophilic polymeric matrix facilitated rapid wetting and dispersion in the oral cavity, which is desirable for fast-dissolving drug delivery systems.

FTIR and DSC studies confirmed the absence of drug–excipient interactions, ensuring the chemical stability of Lansoprazole within the formulation. These results validate that the selected polymers and excipients are compatible and safe for formulation. The enhanced dissolution rate observed in vitro suggests that such films could improve the drug's bioavailability by minimizing first-pass metabolism and offering partial buccal absorption. Hence, it can be concluded that the developed oral fast dissolving thin films of Lansoprazole represent an efficient, stable, and patient-friendly dosage form for the rapid management of acid-related gastrointestinal disorders such as GERD and peptic ulcer disease. The optimized formulation offers advantages such as easy administration, rapid onset of action, better patient acceptability, and improved therapeutic efficacy. The study establishes the potential of polymer-based thin film technology as an innovative platform for delivering acid-labile drugs like Lansoprazole, paving the way for future development and clinical translation.

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