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DESIGN, COMPARISON, AND EVALUATION OF LIDOCAINE HYDROCHLORIDE ORAL THIN FILMS USING NATURAL AND SYNTHETIC POLYMERS

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ABSTRACT
Oral thin films (OTFs) have emerged as a promising alternative to conventional oral dosage forms due to their rapid disintegration, ease of administration, and improved patient compliance, particularly in pediatric and geriatric populations. The present study aimed to design, compare, and evaluate fast-dissolving oral thin films of Lidocaine Hydrochloride using natural and synthetic polymers. Lidocaine Hydrochloride, a widely used local anesthetic, was selected to achieve rapid onset of action and localized drug delivery in the oral cavity while bypassing first-pass metabolism. Oral thin films were prepared by the solvent casting method using hydroxypropyl methylcellulose (HPMC) as a synthetic polymer and sodium alginate as a natural polymer in different ratios. The prepared films were evaluated for physicochemical and mechanical properties including appearance, thickness, folding endurance, percentage elongation, surface pH, disintegration time, drug content uniformity, and in-vitro drug release. Preformulation studies confirmed the purity and compatibility of Lidocaine Hydrochloride with selected excipients. Among the various formulations, formulation F4 containing an optimized combination of HPMC (0.72 g) and sodium alginate (0.92 g) exhibited desirable mechanical strength, rapid disintegration, acceptable surface pH, and maximum drug release within a short duration. The study demonstrates that the combination of natural and synthetic polymers can effectively enhance film performance and drug release characteristics. Oral thin films of Lidocaine Hydrochloride prepared using optimized polymer combinations can serve as an efficient, patient-friendly dosage form for rapid local anesthetic action.
Keywords: *Lidocaine Hydrochloride, Oral thin films, Solvent casting method, Natural polymers, Synthetic polymers, In-vitro drug release.*

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INTRODUCTION

The oral route remains the most preferred route of drug administration due to its convenience, safety, and cost-effectiveness. However, conventional oral solid dosage forms such as tablets and capsules present swallowing difficulties in pediatric, geriatric, and dysphagic patients, leading to poor patient compliance [1-4]. To overcome these limitations, fast-dissolving drug delivery systems such as oral thin films have gained significant attention. Oral thin films are ultra-thin polymeric strips that rapidly hydrate, disintegrate, and release the drug upon contact with saliva, without the need for water [5,6].

Oral thin films offer several advantages including rapid onset of action, improved bioavailability through partial avoidance of first-pass metabolism, accurate dosing, and enhanced patient acceptability. Lidocaine Hydrochloride is a commonly used local anesthetic in dentistry and minor oral procedures, characterized by rapid onset and intermediate duration of action. Conventional dosage forms of Lidocaine may result in delayed onset or systemic exposure, whereas oral thin

films provide localized delivery and faster therapeutic action[7-9].

Polymers play a crucial role in determining the mechanical strength, disintegration behavior, and drug release profile of oral thin films. Both natural polymers such as sodium alginate and synthetic polymers such as hydroxypropyl methylcellulose (HPMC) have been widely investigated due to their film-forming ability, safety, and biocompatibility [10-14]. The present study focuses on the formulation and comparative evaluation of Lidocaine Hydrochloride oral thin films using natural and synthetic polymers to identify an optimized formulation with desirable physicochemical and release characteristics.

MATERIALS AND METHODOLOGY

Materials

Lidocaine Hydrochloride was obtained as a gift sample from Jeel Enterprises, Bharuch. Hydroxypropyl methylcellulose (HPMC), sodium alginate, sodium starch glycolate, polyvinylpyrrolidone (PVP), sodium lauryl sulphate (SLS), glycerin, citric acid, ethanol, and distilled water were procured from the Laboratory of the School of Pharmacy, PU. All chemicals and reagents used in the study were of analytical grade.

Pre-Formulation Studies

Pre-formulation studies were carried out to evaluate the physicochemical properties of Lidocaine Hydrochloride and formulation excipients to ensure their suitability for oral thin film development[15-18].

Solubility Studies

Solubility studies of Lidocaine Hydrochloride and excipients were conducted in water and ethanol. An excess amount of each substance was added to the respective solvent and observed visually to determine solubility. The solubility data were used to guide the selection of solvents and polymers for formulation.

Melting Point Determination

The melting points of Lidocaine Hydrochloride and excipients were determined using standard procedures to confirm purity and physical stability. The observed melting points were compared with reported literature values.

Preparation of Calibration Curve of Lidocaine Hydrochloride

A calibration curve of Lidocaine Hydrochloride was prepared using a UV–visible spectrophotometer at a wavelength of 263 nm. A stock solution (1 mg/mL) was prepared in phosphate buffer pH 6.8 and serially diluted to obtain concentrations ranging from 5 to 30 µg/mL. The absorbance of each solution was measured, and a calibration curve was plotted to establish linearity[16-18].

Formulation of Lidocaine Hydrochloride Oral Thin Films

Oral thin films of Lidocaine Hydrochloride were prepared by the solvent casting method. Accurately weighed quantities of polymers and excipients were dissolved separately in distilled water or ethanol according to their solubility. Both solutions were mixed thoroughly, followed by the addition of Lidocaine Hydrochloride under continuous stirring using a magnetic stirrer for 20–30 minutes. The resulting solution was sonicated to remove entrapped air bubbles and cast onto petri dishes and glass slides. Drying was carried out either in a hot air oven at 60 °C or at room temperature, depending on polymer composition, and the dried films were carefully peeled.

Evaluation Parameters of Oral Thin Films

Organoleptic Evaluation

Since oral thin films disintegrate directly in the oral cavity, acceptable organoleptic properties are essential for patient compliance. The prepared films were visually examined for color, transparency, surface texture, and overall appearance. Taste and mouthfeel were also evaluated to ensure palatability [19].

Thickness Measurement

Film thickness is an important parameter as it directly affects dose accuracy and uniformity. The thickness of each film was measured using a micrometer screw gauge at five different strategic locations. The mean thickness value was calculated and reported [20].

Folding Endurance

Folding endurance was determined to evaluate the mechanical strength and flexibility of the films. A single film was repeatedly folded at the same place until it broke. The number of folds the film withstood without breaking was recorded as the folding endurance value[21].

Percentage Elongation

Percentage elongation was measured to assess the elasticity and tensile properties of the films. It was calculated using the following formula:

$$\% \text{ Elongation} = \frac{\text{Extension of film} - \text{Original length}}{\text{Original length}} \times 100$$

In-Vitro Disintegration Time

In-vitro disintegration time was determined visually by placing the film in a glass dish containing 10 mL of distilled water. Gentle swirling was performed every 10 seconds. The disintegration time was noted as the time required for the film to start breaking or disintegrating completely [22].

In-Vitro Drug Release Study

In-vitro drug release studies were carried out using distilled water maintained at 37 ± 0.5 °C. Four beakers corresponding to formulations F1–F4 were taken, each containing 30 mL of dissolution medium. Films of size 2 × 3 cm^2 were placed in the respective beakers. At predetermined time intervals (1, 3, 5, and 10 minutes), 3 mL samples were withdrawn and analyzed using a UV–visible spectrophotometer at 254 nm [23].

Surface pH Determination

Surface pH was measured to ensure that the films would not cause irritation to the oral mucosa. Each film was moistened with a small amount of distilled water, and a combined pH electrode was placed in contact with the film surface. The pH value was recorded. Measurements were carried out on at least six films, and the mean ± SD was calculated [24].

Dryness and Tack Tests

Dryness and tack tests were performed to assess the handling and storage characteristics of the films. Various stages of drying, such as set-to-touch, tack-free, dry-to-touch, dry-hard, and dry-through, were considered. Tack refers to the adhesive tendency of the film when in contact with another surface, such as paper. Although these tests are commonly applied to paint films, they were adapted for evaluating pharmaceutical oral thin films [25].

RESULTS AND DISCUSSION

Solubility Profile

The solubility behaviour of Lidocaine Hydrochloride and formulation excipients in water and ethanol is presented in Table 01. Lidocaine Hydrochloride was found to be very soluble in water and freely soluble in ethanol, which is favourable for solvent–casting–based oral thin film preparation.

Table 01: Solubility Profile of Ingredients

Ingredient	Water	Ethanol
Lidocaine HCL	Very soluble	Freely soluble
Sodium starch glycolate	Soluble	Soluble
Sodium alginate	Soluble	Insoluble
Sodium lauryl sulphate	Soluble	Soluble
HPMC	Soluble	Insoluble
Glycerine	Soluble	Soluble
Citric acid	Soluble	Soluble
PVP	Soluble	Soluble

Melting Point Analysis

The melting points of Lidocaine Hydrochloride and formulation excipients are summarised in Table 02. The melting point range of Lidocaine Hydrochloride (74–77 °C) was consistent with reported literature values, confirming the purity and identity of the drug.

Table 02: Melting Points of Ingredients

Ingredient	Melting Point (°C)
Lidocaine HCL	74–77
Sodium starch glycolate	75
Sodium alginate	>300
Sodium lauryl sulphate	206
HPMC	225–254
Glycerine	290
Citric acid	153
PVP	150

Calibration Curve of Lidocaine Hydrochloride

The calibration curve of Lidocaine Hydrochloride was constructed using UV–visible spectrophotometry at 263 nm, and the results are presented in Table 3, while the graphical representation is shown in Figure 1. A concentration-dependent increase in absorbance was observed in the range of 5–30 µg/mL, demonstrating good linearity of the analytical method. This confirms the reliability of the UV spectrophotometric method for quantitative estimation of Lidocaine Hydrochloride in further evaluation studies.

Table 03: Standard Calibration Curve Data of Lidocaine Hydrochloride

Concentration (µg/mL)	Absorbance
0	0.000
5	0.104
10	0.217
15	0.311
20	0.411
25	0.512
30	0.607

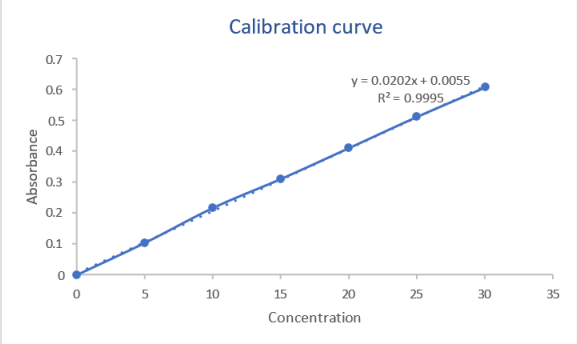

Figure 01: linear relationship between concentration and absorbance,

Batch-Wise Formulation Outcome of Lidocaine Hydrochloride Oral Thin Films

Lidocaine Hydrochloride oral thin films were prepared using different combinations of synthetic and natural polymers to evaluate their film-forming ability and physical characteristics. The composition of all formulations (F1–F6) is presented in Table 04.

Table 04: Formulation Table of Lidocaine Hydrochloride Oral Thin Films

Ingredients	F1	F2	F3	F4	F5	F6
HPMC (g)	1.5	2.0	0.72	0.72	–	–
Sodium Alginate (g)	–	–	0.96	0.92	0.75	0.75
Citric Acid (g)	0.4	0.4	0.096	0.096	0.4	0.4
Sodium Starch Glycolate (g)	–	–	–	–	–	0.75
PVP (g)	0.072	0.072	0.072	0.072	0.072	0.072
SLS (g)	0.072	0.072	0.072	0.072	0.072	0.072
Glycerin (mL)	2.5	2.5	0.48	0.48	2.5	2.5
Ethanol (mL)	10	10	10	10	10	10
Water (mL)	10	10	10	10	10	10
Lidocaine HCL (g)	1.6	1.6	1.6	1.6	1.6	1.6

Figure 02: Lidocaine Hydrochloride Oral Thin Films of different films

Evaluation Parameters of Lidocaine Hydrochloride Oral Thin Films

As shown in Table 05, all formulations demonstrated good folding endurance, indicating adequate mechanical strength, with F2 showing the highest flexibility. Percentage elongation values confirmed the acceptable elasticity of the films. Disintegration time ranged from 28–42 seconds, with F4 showing the fastest disintegration, which is desirable for rapid drug action. Uniform thickness across formulations indicates consistent dose distribution, while surface pH values close to neutrality suggest good mucosal compatibility.

Table 05: Evaluation Parameters of Lidocaine Hydrochloride Oral Thin Films

Sr. No	Evaluation Tests	F1	F2	F3	F4
1	Folding Endurance (times)	263	322	288	280
2	% Elongation (%)	11.4	12.1	13.6	12.3
3	Disintegration Time (sec)	30	42	33	28
4	Thickness (mm)	0.04	0.05	0.05	0.04
5	Surface pH	6.9	6.8	7.0	7.2

In-Vitro Drug Release Study

The data in Table 06 and Figure 03 indicate a time-dependent increase in drug release for all formulations. Formulations F2 and F4 exhibited significantly higher drug release, achieving more than 90% release within 10 minutes. The enhanced release from F4 may be attributed to its faster disintegration and optimised polymer composition. In contrast, F1 and F3 showed comparatively slower release, possibly due to denser polymer matrices.

Table 06: In-Vitro Drug Release Study of Lidocaine Hydrochloride Oral Thin Films

Time (min)	F1 (%)	F2 (%)	F3 (%)	F4 (%)
0	0	0	0	0
1	11.11	4.72	7.23	22.96
3	18.73	49.23	16.39	25.11
5	34.63	63.98	46.39	62.59
10	53.59	93.52	70.05	96.95

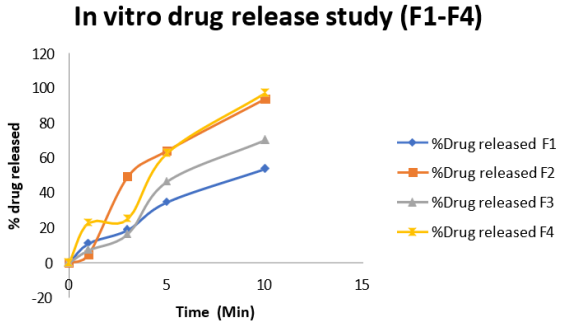

Figure 03: %Drug Release of F1-F4 formulations of LH OTF

CONCLUSION

Lidocaine Hydrochloride is a widely used local anesthetic employed to prevent and relieve pain during various medical procedures. It has a relatively short half-life of 1.5–2 hours, undergoes extensive hepatic metabolism, and exhibits low oral bioavailability of approximately 35%. To overcome these limitations and enhance bioavailability and therapeutic efficacy, fast-dissolving oral thin films of Lidocaine Hydrochloride were developed. The prepared films demonstrated desirable film characteristics, including uniform thickness, good folding endurance, rapid disintegration, acceptable surface pH, and efficient in-vitro drug release. All formulations were found to be flexible and uniform, with formulation F4 showing the most promising performance by releasing 96.95% of the drug within 10 minutes, which is favorable for rapid absorption. These results indicate good formulation stability and suitability for fast drug delivery. The present study concludes that oral thin film formulation represents an innovative and promising drug delivery approach for Lidocaine Hydrochloride, offering improved bioavailability, enhanced dissolution rate, and effective local anesthetic action. This dosage form is particularly advantageous for pediatric and geriatric patients, as well as for the general population. The combination of synthetic polymer HPMC and natural polymer sodium alginate proved to be effective in achieving improved therapeutic performance.

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CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest regarding the publication of this paper. Acknowledgment

AUTHOR CONTRIBUTIONS

K. Sushma conceived and supervised the study and drafted the manuscript. Konatham Teja Kumar Reddy contributed to data collection, analysis, and manuscript

preparation. All authors reviewed and approved the final manuscript.

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