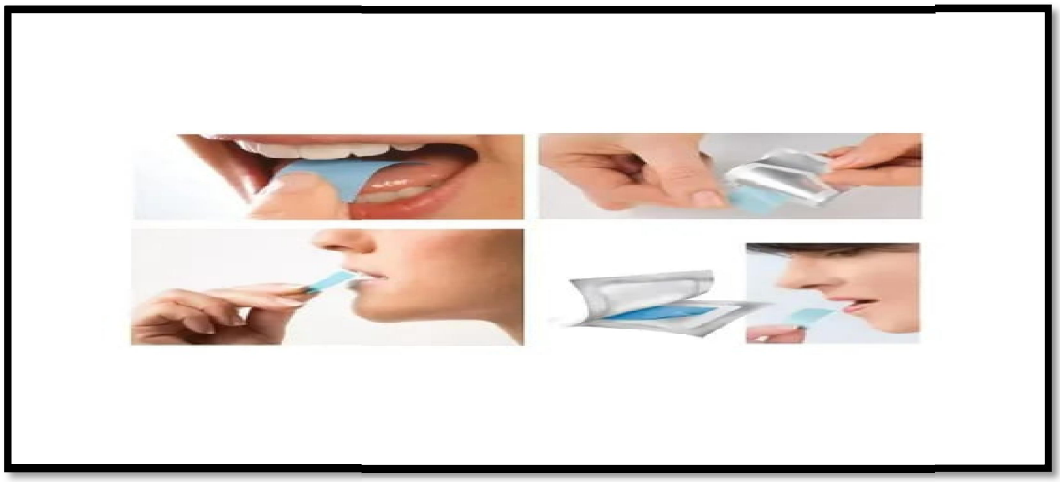
IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 8, May 2025
Impact Factor: 7.67

Formulation and Evaluation of Oral Thin Film of Lidocaine

Shamal Prakashrao Kadam and Deepak J. Kare
Nootan College of Pharmacy, Kavthe Mahankal

Abstract: *The easiest, safest, and ulmost applicable system of administration is buccal delivery. Fast-dissolving medicine- delivery systems were first developed in the late 1970s. This research aims to give an about the preparation, formulation techniques and the recent technologies used in the ODF formulations. Oral films (OFs) are used as a unique approach, because it dissolves quickly in the mouth and directly reaches to the systemic circulation. The solvent casting method is the widely used technique in the preparation of thin films. Creating and developing oral presto- disintegrating flicks with lidocaine to treat mouth ulcers was the thing of the current study. lidocaine (LH)is anesthetic drug and improve its local effect. In the evaluation of the formulations, different parameters such as structure, thickness, degree of swelling, moisture content, drug content, texture profile analysis, release kinetics according to the in vitro drug release, and cytotoxicity evaluation were taken into consideration. The solvent casting method is the widely used technique in the preparation of thin films.*

Keywords: Buccal film, local anesthesia, lidocaine, Severe oral pain, Film casting



I. INTRODUCTION

A novel oral delivery system, oral dissolving films were prepared based on transdermal patch technology. A thin oral strip is prepared and is placed on the patient's mucosal cavity where it is wetted by saliva making it adhere to the surface. Polymeric films have shown great potential in delivering medications into oral cavity. It's preferred by patients who have medical conditions that make it difficult for them to swallow or chew other solid oral dosage form [1]. This delivery consists of a thin mouthpiece that is simply placed on the patient's tongue or oral tissue and immediately wetted with saliva, as well as a rapid video that quickly moistens and adheres to the application site. It is then rapidly broken down and dissolved, allowing the drug to be absorbed by the oral mucosa, or modified to maintain rapid solubility, allowing gastrointestinal absorption when swallowed[2]. A dissolvable oral film medication offers a convenient and patient-friendly solution for mentally ill disabled and uncooperative individuals, providing ease of administration without the need for water, overcoming unpleasant taste, leaving minimal residue in the mouth and

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 8, May 2025
Impact Factor: 7.67

allowing for rapid disintegration and release of the medication [3]. The formulation offers immediate relief by rapidly releasing the drug into the bloodstream upon ingestion, making it beneficial for patients experiencing severe pain or discomfort associated with oral cancer or other mouth conditions that may alter taste perception or pose challenges in tolerating certain medications, with the inclusion of nonsteroidal anti-inflammatory drugs (NSAIDs) commonly used for managing severe cancerous pain and dental pain [4]. Mouth ulcer may be treated symptomatically by smoothing or removing the local cause of trauma. The local anesthetics can be the choice of medications for releasing pain of mouth ulcers. Due to the fast onset of action and the intermediate duration of efficacy of lidocaine, it is usually used as a local anesthetic in dental surgeries [5]. Lidocaine has been used to treat the mouth ulcers due to its excellent local anesthetic effect that leads to relieve the pain of the mouth ulcer [6].

Lidocaine (LC), one of the local anesthetics, is frequently utilized as a topical agent due to its immediate onset and mild duration of action [7]. Local anesthetics can reversibly block nerve endings without damage because of their binding with sodium channel of skin layers. Hence the nervous impulse is not propagated as a result of blocking of sodium ions influx[8]. One of these is lidocaine, which is an amide-type local anesthetic fundamentally used in mucosal, dermal, and topical dosage forms[9]. These films release lidocaine very rapidly at the site of action. Moreover, these films are very easy to be used and are suitable for geriatric, pediatric, bedridden patients [10]. Lidocaine hydrochloride is a widely used medication in oral healthcare, with a chemical formula of C14H22N2O and a molecular weight of 234.3373 grams/mole. It is a white crystalline solid that melts at a temperature of 68.5°C. LH serves as a drug of choice in various oral conditions such as tooth decay, periodontal disease, tooth loss, and lip and oral cavity cancer[11]. Lidocaine in pastes, creams, and ointment are the safest and most convenient mode of application for topical drug delivery system but these can be easily removed by wetting, movement, and contact, which is the main pitfall of these systems. So the newormulation strategy with bioadhesive preparation incorporated with enhanced local anesthetic effects is requested for the topical administration[12].

Advantages

1. Ease of Organization: ODFs break down rapidly in the mouth without The require for water, making them helpful for people with Trouble gulping or those on the go.
2. Quick Onset of Activity: The film's fast deterioration permits for Speedier retention of the dynamic fixings, driving to a faster onset of Helpful effects.
3. Made strides Understanding Compliance: ODFs are regularly more tasteful than conventional Dose shapes, possibly improving understanding adherence to endorsed regimens.
4. Accurate Dosing: The films are typically pre-dosed, minimizing the risk of Dosing errors associated with traditional oral forms like tablets or capsules.

Disadvantages

1. Eating and drinking can be prohibited.
2. High doses cannot be incorporated.
3. Excessive bitter drugs are not feasible.

II. MATERIALS AND METHODS

All the pharmaceutical materials used in the study had analytical grades. Lidocaine(Hindustan Chemicals and Pharmaceuticals Mumbai), HPMC, Glycerol, Citric acid, Sodium lauryl sulphate, Sucrose, Titanium dioxide, Water.

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 8, May 2025
Impact Factor: 7.67

DRUG PROFILE
LIDOCAINE

Chemical Formula: C14H22N2O
Molecular weight: 234.33 gm/mol
History: Lidocaine was first made in 1943 and initially was used for local anesthesia.
Uses: used as a local anesthesia that prevent the pain.
It is used for topically or locally pain
Also used in mouth ulcer and throat irritation.

FORMULATION OF LIDOCAINE ORAL DISPERSED FILM

1. Oral dispersed film of lidocaine was prepared by solvent casting method.
2. Solution 'A' was prepared by dissolving lidocaine in 5 ml water.
3. Solution 'B' was prepared by adding HPMC, Citric acid, Sucrose, Sodium lauryl sulphate, Titanium dioxide,Glycerol.
4. Remove all air bubbles entrapped and keep them aside.
5. The solution 'A' and 'B' were mixed and stirred for 30 min .
6. And cast the solution on the petri plate.
7. Dry the film by placing it in the hot air oven at 60^0 c for 1 hr or 24hr at room temperature.
8. Peel it carefully and collect the film. [13]

TABLE1: COMPOSITION OF LIDOCAINE ORAL DISPERSED FILM

INGREDIENT	F1	F2	F3
Lidocaine	5mg	5mg	5mg
HPMC	30mg	35mg	40mg
Glycerol	1ml	1ml	1ml
Citric acid	10mg	10mg	10mg
Sucrose	5mg	5mg	5mg
Sodium lauryl sulphate	12mg	12mg	12mg
Colour	q.s	q.s	q.s
Water	q.s	q.s	q.s

DOI: 10.48175/568

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 8, May 2025
Impact Factor: 7.67

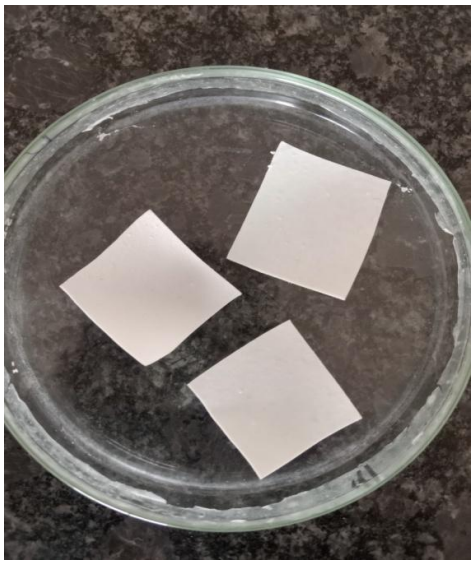


Fig No.2. Oral dispersed film of lidocaine

Evaluation parameter

Thickness

As the thickness of film is directly concern with drug content uniformity so it is necessary to as certain uniformity in the thickness of the film. It can be measured by micrometer screw gauge or calibrated digital Vernier Calipers at different strategic locations [14].

Physical Appearance and surface texture of film:

Films of each formulation were randomly selected and visually inspected for texture by feel or touch[15] .

Folding endurance

Folding endurance is determined by repeated folding of the strip at the same place till the strip breaks. The number of times the film is folded without breaking is computed as the folding endurance value[17].

Disintegration time

The disintegration time of oral dissolving film ranges from 5 to 30 seconds. Mostly Though there is no official method available for determining disintegrating of oral dissolving films. Two methods are carried out for determining the disintegration time of the film as follows .

Petri plate method:

Here in this method the film is placed on the petri dish and 2ml of distilled water is added to it, the amount of time taken by film to dissolve completely is called as the disintegration time[18].

Weight uniformity of films:

Three films of the size 2×2 cm2 were weighed individually using digital balance and the average weights were calculated[19].

Drug content uniformity study:

The films were tested for drug content uniformity by U.V-Spectrophotometric method. Films of 2×2 cm2 were each film was placed in 10 ml volumetric flask and diluted with phosphate buffer pH 6.8 up to 10 ml. The absorbance of the

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 8, May 2025
Impact Factor: 7.67

solution was measured at287nm using U.V visible spectrophotometer after suitable dilution. The percentage drug content was determined [20, 21]

Percentage of drug content = Observed value/Actual value × 100

III. RESULTS AND DISCUSSION

IR Spectrum:

For characterization of pure Lidocaine IR studies were carried out. The observed and reported indicating the presence of the drug in its original chemical form and IR spectrum is shown in (Fig.3).

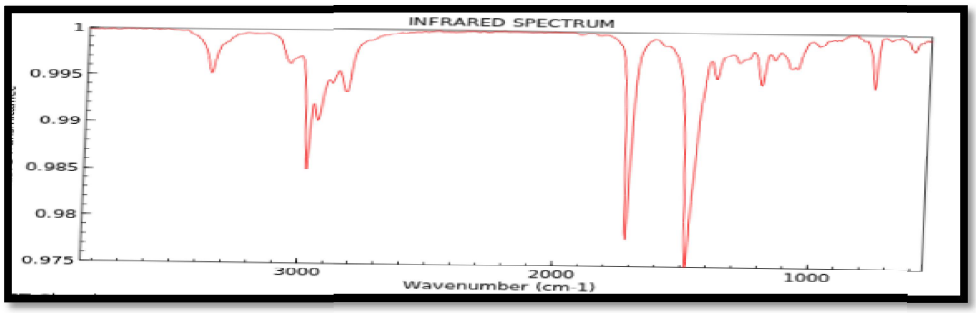


Fig. No. 3 IR Spectrum Of Lidocaine

IV. EVALUATION OF ORODISPERSIBLE FILMS

Thickness of films

Thickness of the film was found in increasing order. As polymer conc. increases the thickness of the film also increases. Film thickness of formulation F1- F3 was found in the range 0.26±0.02 to 0.30±0.05 mm. The thickness of the films was measured using Vernier calliper. Results of thickness are shown in table 2.

Physical appearance

This parameter was checked simply with visual inspection of films and evaluation of texture by feel or touch. The observation suggests that the films were having smooth surface.

Weight uniformity of films

Three films of the size 2×2 cm2 were weighed individually using digital balance and the average weights were calculated. Weight of the film was found in the increasing order. As the weight of polymer increases the weight of the film also increases. Weight of the films of F1- F3 was found in the range 19.04 mg to 22.1 mg. Weight of film was found uniform in all batches, ensuring uniform drug distribution among the prepared films. Result was shown in table 2

Folding endurance of films

The folding endurance of the films was determined by repeatedly folding a small strip of the films at the same place till it broke and the average folding endurance of all films was given in table2. The folding endurance of the film was found between 95 to 120. Among all batches, F1 batch shows higher folding endurance, while batch F3 showed lower folding endurance.

In vitro disintegration time of films

Disintegration time for all batch of Orodispersible film formulation (F1 to F3) was found in the range of 75 seconds to 110 seconds. Formulation F1 showed lowest disintegration time of 75 seconds, while batch F3 showed higher disintegration time of 110 seconds.

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 8, May 2025
Impact Factor: 7.67

Drug content uniformity study of films

Drug content uniformity for all formulation were shown in table 2. The prepared film formulations were analyzed for drug content and it was observed that all the formulation found to contain almost uniform quantity of drug as per content uniformity studies indicating reproducible technique. Drug content for all formulation was found to be in the range of 96.17 % to 98.07% which shows uniformity of drug content in all formulation. Batch F1 formulation showed highest 98.07 percent of drug content.

Batch no.	Thickness (mm)*	Folding Endurance*	Weight Variation (mg)*	DT (Sec)*	Drug content (%)*	Surface pH
F1	0.29± 0.01	120±1.93	19.4±0.03	75±0.64	98.07±0.82	6.8
F2	0.31±0.02	110±1.74	20.7±0.04	89±0.94	97.25±0.02	6.7
F3	0.32±0.03	95±0.93	22.1±0.06	110±1.13	96.17±1.08	6.6

V. CONCLUSION

From the present study following conclusion were observed. The orodispersible films of Lidocaine can be prepared by solvent casting method by using film forming agent HPMC. All the prepared formulations were showed satisfactory results required for the orodispersible type of products. Formulation F1 was consider as the ideal formulation which exhibited lowest disintegration time (75sec) and shows 98.07% drug release in 15 min. Future detailed investigation is required to established in vivo efficiency of orodispersible films of Lidocaine.

REFERENCES

[1] A Arya; A Chandra; V Sharma; K Pat hak. Int J Chem Tech Res. 2010, 2(1), 576-583.
[2] J.Naga Sowjanya, Dr.Manichandrika, Shilukuri Akhila, Varigonda Bhavya Sri, Formulation, and evaluation of Fast Dissolving Oral Films of Diphenhydramine Hydrochloride, IJPIR 2021 , 78 -79.
[3] Kshirsagar T, Jaiswal N, Chavan G, Zambre K, Ramkrushna S, Dinesh D. Formulation & evaluation of fast dissolving oral film. World Journal of Pharmaceutical Research. 2021 May 27;10(9):503-61.
[4] Peres MA, Macpherson LMD, Weyant RJ, Daly B, Venturelli R, Mathur MR, Listl S, Celeste RK, Guarnizo-Herreño CC, Kearns C, Benzian H, Allison P, Watt RG. Oral diseases: a global public health challenge. National Library of medicine . 2019 Jul 20;394(10194):249-260
[5] Ahmad J, Andrabi SIH, Rathore MA. Comparison of topical glyceryl trinitrate with lignocaine ointment for treatment of anal fissure: A randomised controlled trial. Int J Surg, 2007.5: 429-432.
[6] Rana A, Shereen A, Mutaz S &Alsayed S. Mucoadhesive Dosage form of Lidocaine Hydrochloride: I. Mucoadhesive and Physicochemical Characterization. Drug Dev Ind Pharm. 2007. 33(8):855-64.
[7] Brown, T. J., & Gupta, A. (2020). Management of cancer therapy–associated oral mucositis. JCO Oncology Practice, 16(3), 103-109. https://doi.org/10.1200/JOP.19.00652
[8] Beydoun A, Backonja MM. Mechanistic stratification of antineuralgic agents. J Pain Symptom Manage. 2003;25(5 Suppl):S18–S30.
[9] Ben-David B, Demeo PJ, Lucyk C, Solosko D. A comparison of minidose lidocaine-fentanyl spinal anesthesia and local anesthesia/propofol infusion for outpatient knee arthroscopy. Anesth Analg. 2001;93(2): 319–325.
[10] Chaudhary H, Gauri S, Rathee P, Kumar V. Development and optimization of fast dissolving oro-dispersible films of granisetronHCl using Box-Behnken statistical design. Bull Facul Pharm Cairo Uni, 2013.51: 193-201.
[11] Franz-Montan M, Baroni D, Brunetto G. Liposomal lidocaine gel for topical use at the oral mucosa: characterization, in vitro assays and in vivo anesthetic efficacy in humans. Journal of liposome research. 2015 Jan 2;25(1):11-9.
[12]Rode A. Nanocarriers: a novel approach for enhanced drug delivery through skin. Asian J Pharm. 2018;12(1).

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 8, May 2025
Impact Factor: 7.67

[13]Alves TF, Rios AC, da Silva Pontes K, Portella DL, Aranha N, Severino P, Souto EB, Gonsalves JK, de Souza Nunes R, Chaud MV. Bilayer mucoadhesive buccal film for mucosal ulcers treatment: Development, characterization, and single study case. Pharmaceutics. 2020 Jul 11;12(7):657

[14]Patel RA, Prajapati SD, Fast dissolving films (fdfs) as a newer venture in fast dissolving dosage forms. International Journal Drug Development & Research. 2(2): 2010: 232-246

[15] Dixit RP and Puthli SP, (2009), Oral strip technology: Overview and future potential. Journal of Controlled Release, 139(2): 94-107

[16] NK Verma; S Chaudhari; H Prasad; S Srivastava; V Chandra. Asian J Pharm Technol Innovation. 2013, 1(2), 1-10.

[17]Mahboob MBH, Riaz T and Jamshaid M, Oral films: a comprehensive review, International Current Pharmaceutical Journal, 2016; 5(12): 111-117.

[18]B Bhyan; S Jangra; M Kaur; H Singh. Int J Pharm Sci Rev Res. 2011, 9(2), 9-15.

[19] Khan S, Boateng JS, Mitchell J, Trivedi V. Formulation, characterisation and stabilisation of buccal films for paediatric drug delivery of omeprazole. AAPS PharmSciTech. 2015;16(4):800–10.

[20]Dwivedy, B.N.; Dabral, P.; Kumar, R. Preparation and evaluation of mouth dissolving film of pantoprazole sodium. World J. Pharm. Pharmceut. Sci. 2014, 3, 1564–1576.

[21] Speer, I.; Steiner, D.; Thabet, Y.; Breitkreutz, J.; Kwade, A. Comparative study on disintegration methods for oral film preparations. Eur. J. Pharm. Biopharm. 2018, 132, 50–61