EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 12
Issue: 9
Year: 2025

FORMULATION AND EVALUATION OF FAST DISSOLVING ORAL FILMS OF LACOSAMIDE

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Article Received on 17/07/2025 **Article Revised on 07/08/2025** **Article Accepted on 27/08/2025**

ABSTRACT
This research paper focuses on the development and evaluation of fast-dissolving oral films (FDOFs) of Lacosamide, an antiepileptic drug used to treat partial onset seizures. The oral route of administration is preferred due to its convenience, non-invasiveness, and patient compliance, especially for pediatric and geriatric patients who have difficulty swallowing conventional tablets and capsules. FDOFs offer several advantages, including rapid onset of action, increased bioavailability by bypassing hepatic first-pass metabolism, and ease of use without water. The solvent casting technique was used to prepare the films, incorporating natural polymers such as HPMC, sodium alginate, guar gum, and xanthan gum. The prepared films were then evaluated for various parameters, including thickness, weight uniformity, folding endurance, and in vitro dissolution. The results demonstrate that the formulation successfully creates a fast-dissolving oral film that is a promising alternative for drug delivery.

KEYWORDS: Fast-dissolving oral films, Lacosamide, antiepileptic, bioavailability.

1. INTRODUCTION

Polymers are large molecular compounds made of repeating monomer units and are widely used in the pharmaceutical and biomedical industries. Natural polymers, sourced from plants and animals, are particularly important due to their biodegradability, non-toxicity, and cost-effectiveness compared to synthetic polymers. These polymers are utilized in various dosage forms, including films, beads, and nanoparticles, acting as binders, matrix formers, or drug-release modifiers(1-9).

Orally disintegrating films (ODFs), or thin films, are a type of drug delivery system that hydrates and dissolves rapidly on the tongue, releasing the active pharmaceutical ingredient (API). This technology is particularly beneficial for patients with dysphagia. FDOFs are known for their rapid absorption through the sublingual and buccal mucosa, leading to a quick onset of drug action. However, challenges such as dose uniformity and limited drug loading capacity (typically less than 75 mg) must be addressed (8-16).

2. MATERIALS AND METHODS

Lacosamide was obtained as a gift sample from Bioplus Life Science, Bangalore, while other excipients like Carbopol, sodium starch glycolate, and HPMC were sourced from Loba Chemie Pvt. Ltd.

2.1. Preformulation Studies

Preformulation studies were conducted to characterize the physical and chemical properties of Lacosamide. This included organoleptic evaluation, solubility in different solvents, identification using FTIR spectroscopy, and determination of moisture content and melting point (21-31).

2.2. Formulation of Films

Fast-dissolving oral films of Lacosamide were prepared using the **solvent casting technique**. Six formulations (F1-F6) were developed with varying concentrations of HPMC, sodium alginate, guar gum, and xanthan gum.

Table 1: Selection and optimization of film forming agents.

Name of ingredients (mg for 12 strips)	F1	F2	F3	F4	F5	F6
API	600	600	600	600	600	600
HPMC (mg)	400	600	800	400	600	800
PEG-400 (mg)	100	100	100	100	100	100
Sodium alginate (mg)	100	150	200	-	-	-
Guar Gum (mg)	-	-	-	100	150	200
Xanthan gum (mg)	150	200	250	150	200	250
Aspartame	25	25	25	25	25	25
Citric acid	50	50	50	50	50	50
DM water qs to (ml)	30	30	30	30	30	30

HPMC=Hydroxypropyl methylcellulose, PEG 400= Polyethylene glycol 400,

The process involved

1. Dissolving HPMC in distilled water to form a uniform polymeric dispersion.
2. Lacosamide was sonicated and dissolved separately in ethanol along with PEG-400 (plasticizer) and added to the polymer solution.
3. Additional film-forming agents and additives like aspartame (sweetener) and citric acid (salivating agent) were incorporated.
4. The solution was stirred, deaerated, and cast onto clean, flat glass molds.
5. The films were dried at a controlled room temperature for 48 hours.

3. Evaluation of Films

The prepared films were evaluated for the following parameters (17-26):

- **Thickness and Weight Uniformity:** Measured at three different places using a vernier caliper and digital electronic balance, respectively, to ensure consistency.
- **Folding Endurance:** Determined by the number of times a film can be folded without breaking, indicating its mechanical strength.
- **Moisture Content:** The percentage of moisture was calculated by weighing the films before and after keeping them in a desiccator for 24 hours.
- **Drug Content Analysis:** The amount of Lacosamide in each film was quantified using a UV spectrophotometer.
- **Disintegration Time:** Measured to ensure the films dissolve within a few seconds. The USP disintegration apparatus can be used, with a typical disintegration time ranging from 5 to 30 seconds.
- **In Vitro Dissolution Study:** Performed using the USP dissolution apparatus to assess the rate and extent of drug release.

4. RESULTS AND DISCUSSION

The specific results of the evaluation tests are not provided in the document. However, the aim was to improve the dissolution and bioavailability of Lacosamide.

The evaluation of the prepared Lacosamide fast dissolving oral films revealed that all formulations (F1–F6) exhibited a uniform translucent appearance, indicating proper dispersion of the drug and excipients within the polymeric matrix. The thickness of the films ranged from 54 ± 3 µm to 59 ± 7 µm, with F6 showing the lowest thickness and F1 the highest. These minor variations in thickness are attributed to the differing concentrations of film-forming agents used across formulations. The weight of the films was found to be within the range of 178 ± 3 mg to 192 ± 9 mg. Formulations containing sodium alginate (F1–F3) showed slightly higher weights, especially F3, which contained the highest amount of sodium alginate. In contrast, films prepared with guar gum (F4–F6) exhibited slightly lower weights and thicknesses, suggesting that guar gum may yield thinner and lighter films. The physical evaluation results demonstrate good uniformity, reproducibility, and acceptable film characteristics, supporting the effectiveness of the solvent casting method and the suitability of the selected film-forming agents in producing stable and consistent Lacosamide fast dissolving films.

Table 2: Results of Evaluation of prepared film.

Formulation code	General Appearance	Thickness (µm)	Weight (mg)
F1	Translucent	59±7	185±8
F2	Translucent	58±8	190±7
F3	Translucent	55±6	192±9
F4	Translucent	58±5	186±6
F5	Translucent	56±6	178±3
F6	Translucent	54±3	182±7

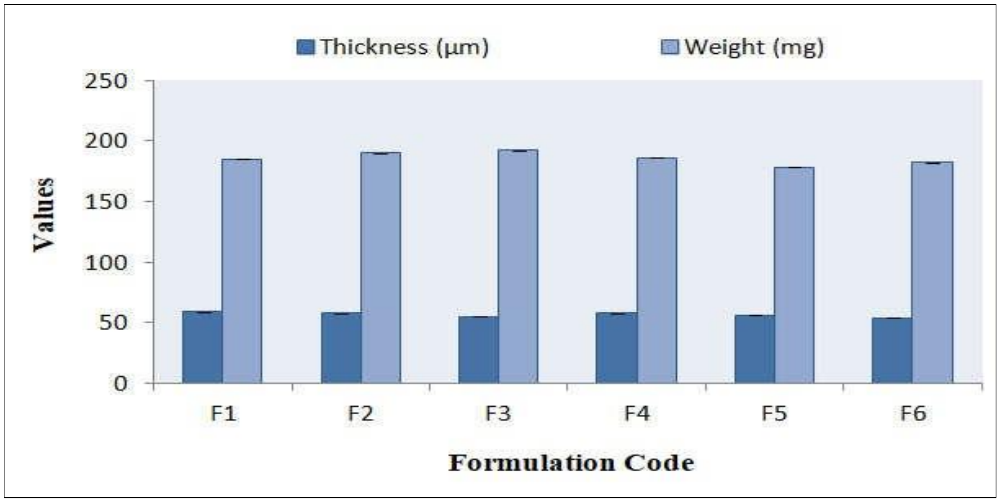

Figure 1: Thickness and weight of formulated films.

Result of folding endurance, disintegration time, tensile strength moisture content and assay of prepared film

The evaluation parameters of the prepared fast-dissolving oral films of Lacosamide revealed significant differences in mechanical strength, disintegration ability, moisture sensitivity, and drug content among the formulations.

Folding Endurance is a measure of the mechanical integrity and flexibility of the film. Among all formulations, F5 showed the highest folding endurance (245±4), indicating excellent flexibility and durability, which is essential for handling and packaging. Formulation F3 also showed relatively high endurance (210±5), while F1 had the lowest (165±8), suggesting brittle characteristics at lower polymer or plasticizer levels.

Disintegration Time is a crucial parameter for fast-dissolving films. Formulation F5 again performed best, with the shortest disintegration time of 52±3 seconds, ensuring rapid drug release in the oral cavity. This rapid disintegration correlates well with its lower moisture content and optimized film composition. On the other hand, F1 had the longest disintegration time (92±5 seconds), which may affect the onset of action in clinical use.

Tensile Strength values were comparable across formulations, ranging from 0.71 to 0.78 kg/cm², indicating adequate mechanical strength to withstand handling without breaking. F2 had the highest tensile strength, while F6 had the lowest. F5 exhibited slightly lower tensile strength (0.73±0.06), but it remained within acceptable limits, ensuring a balance between flexibility and strength.

Moisture Content varied from 1.85% to 2.74%, where F5 had the lowest value (1.85±0.14%), indicating better stability and less hygroscopicity, which enhances the shelf life of the film. Excessive moisture, as seen in F4 (2.74±0.36%), can lead to microbial growth and film deformation. % Drug Content (Assay) was highest in F5 (99.05±0.26%), reflecting uniform drug distribution and content accuracy. All other formulations showed acceptable drug content between 95.85% and 98.85%, adhering to pharmacopeial standards.

In conclusion, formulation F5 emerged as the most optimized film based on its superior folding endurance, rapid disintegration, adequate tensile strength, low moisture content, and highest drug content. These attributes confirm its suitability as a promising fast-dissolving oral delivery system for Lacosamide, with potential clinical advantages in terms of patient compliance and rapid onset of action.

Table 3: Result of folding endurance, disintegration time, tensile strength moisture content and assay.

Formulation code	Folding endurance	Disintegration time (min.)	Tensile strength (kg/cm2)	Moisture Content (%)	% Drug Content
F1	165±8	92±5	0.75±0.05	2.25±0.15	96.65±0.15
F2	185±6	85±4	0.78±0.08	2.45±0.32	98.85±0.32
F3	210±5	80±6	0.76±0.07	2.65±0.25	97.74±0.14
F4	186±7	78±5	0.75±0.09	2.74±0.36	96.12±0.36
F5	245±4	52±3	0.73±0.06	1.85±0.14	99.05±0.26
F6	195±6	69±2	0.71±0.07	2.15±0.52	95.85±0.36

***Average of three determinations (n=3)**

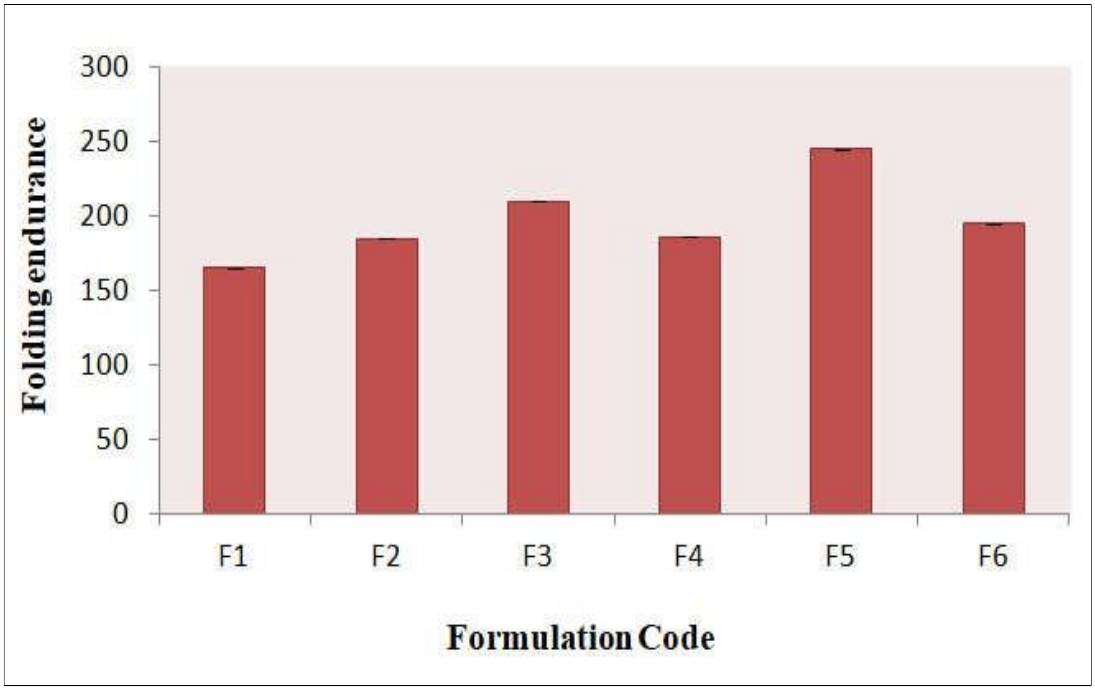

Figure 2: Graph of result of folding endurance.

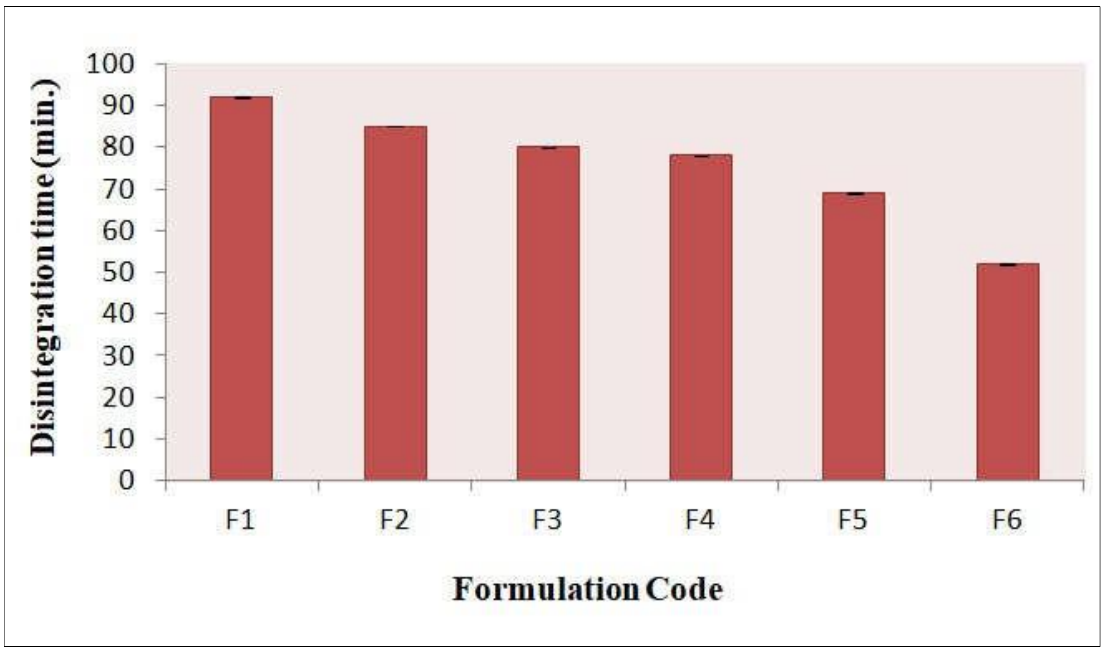

Figure 3: Graph of result of disintegration time.

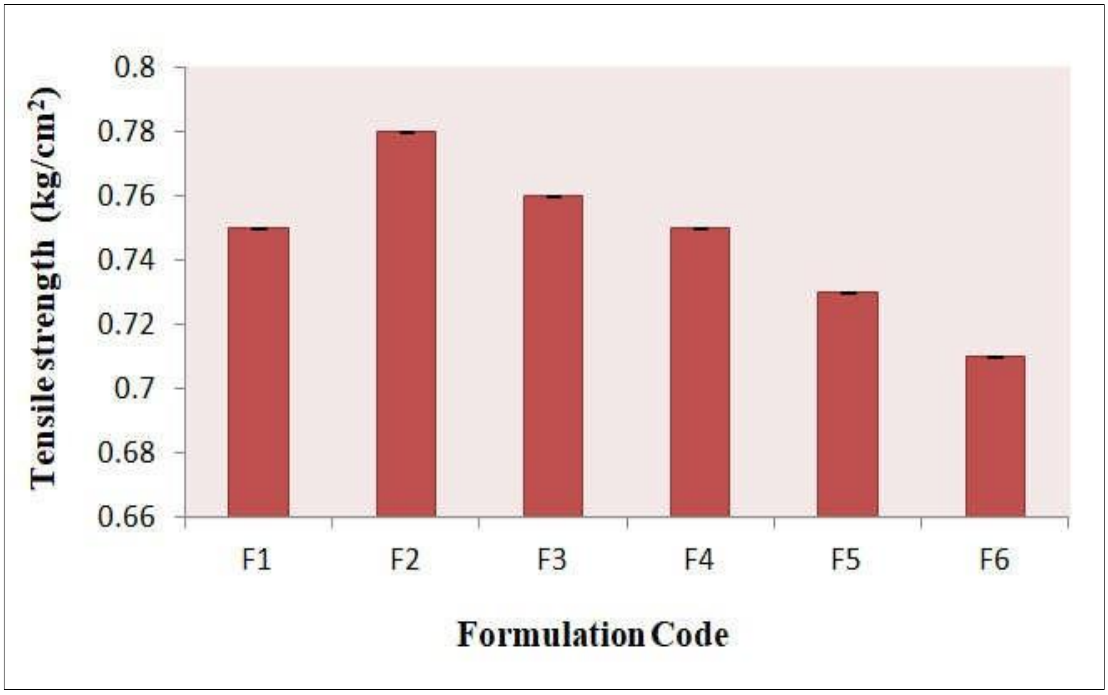

Figure 4: Graph of result of tensile strength.

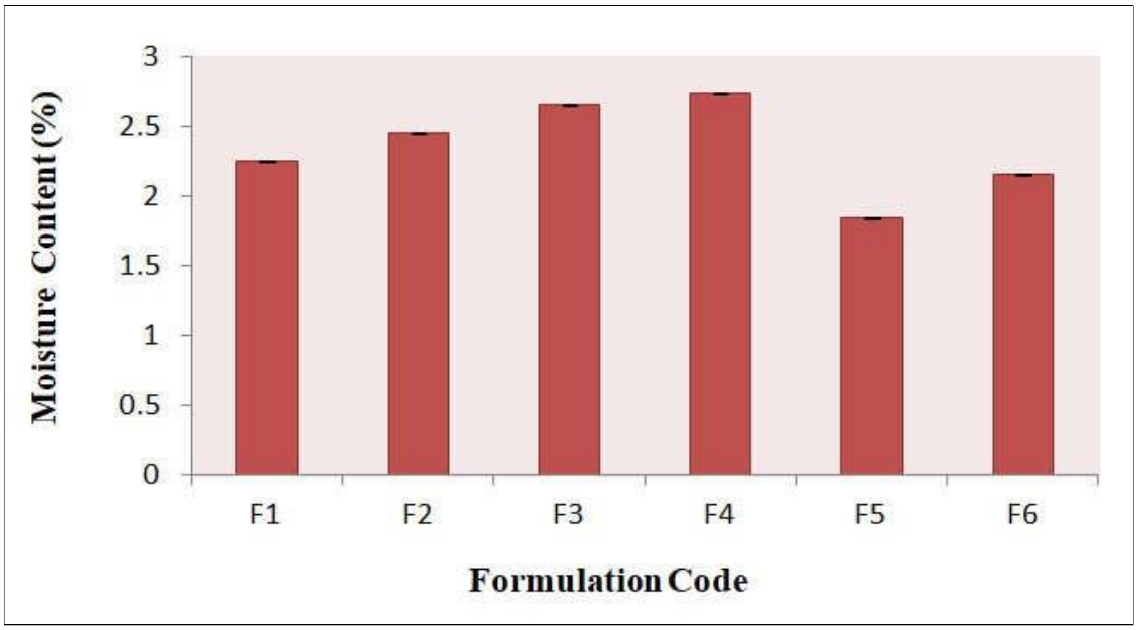

Figure 5: Graph of result of moisture content.

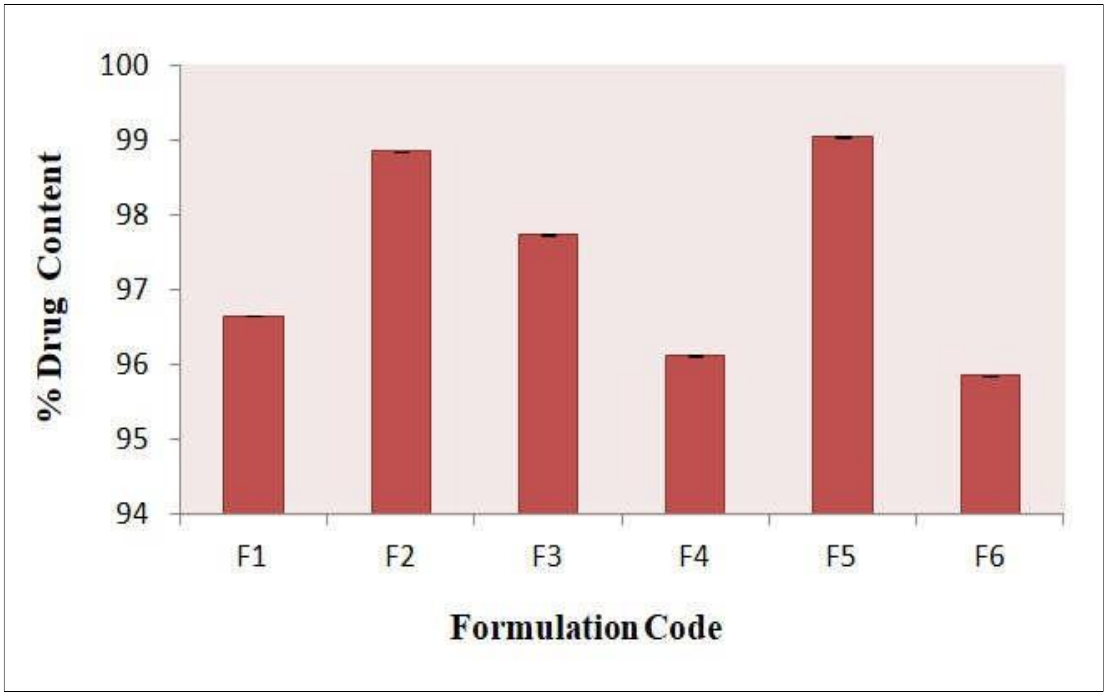

Figure 6: Graph of result of percentage drug content.

Table 4: Results of Optimized formulation F-5.

Name of Ingredients	Composition (mg) Per Strip
API	600
HPMC (mg)	600
PEG-400 (mg)	100
Sodium alginate (mg)	-
Guar Gum (mg)	150
Xanthan gum (mg)	200
Aspartame	25
Citric acid	50
DM water qs to (ml)	30

Results of *in-vitro* release study of optimized formulation F5

The optimized formulation (F5) of Lacosamide fast-dissolving oral film demonstrated a rapid and efficient drug release profile. The cumulative percentage drug release at 1 minute was found to be 46.65%, indicating the film's ability to quickly initiate disintegration and release the drug in the buccal cavity. This rapid initial release is crucial for fast onset of action, particularly desirable in managing conditions like epilepsy, where Lacosamide is commonly prescribed.

By 2 minutes, the drug release sharply increased to 74.45%, and by 5 minutes, it reached 89.98%, suggesting a high rate of drug diffusion through the film matrix. This can be attributed to the optimized polymer concentration and plasticizer content, which likely contributed to rapid film hydration, disintegration, and drug dissolution.

A near-complete release of 98.89% was achieved within 15 minutes, indicating that the formulation meets the required criteria for a fast-dissolving oral delivery system. The film's quick dissolution and high drug release efficiency not only ensure better patient compliance but also potentially improve the bioavailability of Lacosamide by bypassing first-pass metabolism.

These results affirm that formulation F5 is highly effective in releasing Lacosamide rapidly, making it a promising candidate for fast therapeutic action in clinical applications. Further in-vivo correlation studies can help establish the pharmacokinetic benefits of this optimized formulation.

Table 5: Results of *In-vitro* release study of optimized formulation of fast dissolving oral film F5.

S. No.	Time (Min.)	Cumulative % Drug release
1.	1	46.65±1.85
2.	2	74.45±1.45
3.	5	89.98±1.96
4.	10	92.28±1.85
5.	15	98.89±1.74

(n=3)

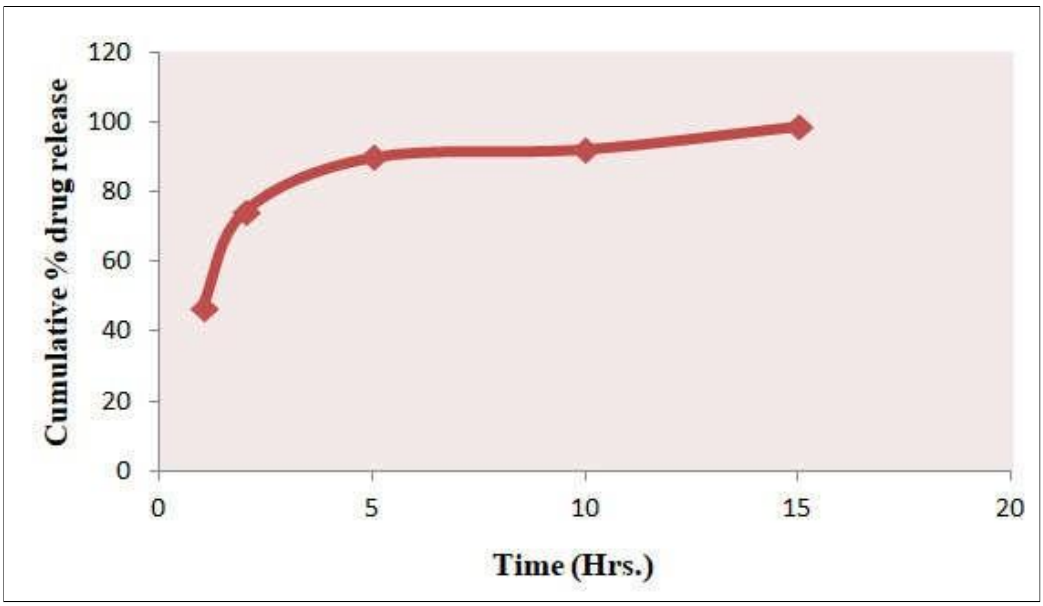

Figure 7: *In-vitro* release study of optimized formulation F5.

5. SUMMARY AND CONCLUSION

The formulation and evaluation of fast-dissolving oral films of Lacosamide offer a promising alternative to conventional dosage forms. The solvent casting method, coupled with careful selection of natural polymers and excipients, provides a viable technique for creating films with desirable properties. While the provided document outlines the methodology, it lacks specific data on the results of the evaluation tests. Further research would be required to analyze the final product's performance, including stability and bioavailability, to confirm the efficacy of this formulation.

REFERENCES

1. Mandeep K, Rana AC, Nimrata S. Fast Dissolving Films: An Innovative Drug Delivery System. International Journal of Pharmaceutical Research & Allied Sciences, 2013; 2(1): 14-24.
2. Prasanna P. Ghodake, Kailas M. Karande, Riyaz Ali Osmani, Rohit R. Bhosale, Bhargav R. Harkare, Birudev B. Kale., Mouth Dissolving Films: Innovative Vehicle for Oral Drug Delivery. International Journal of Pharma Research & Review, 2013; 2(10): 41-47.
3. Dixit RP, Puthli SP. Oral strip technology: Overview and future potential. Journal of controlled release, 2009; 139(2): 94-107.
4. Shinde SR, Jadhav RV, Devale TL and Vanshiv S., Formulation and evaluation of taste masked oral disintegrating tablet of lacosamide. Int J Pharm Sci & Res, 2024; 15(5): 1405-1420.
5. Ayushi. A. Kanhed, A. M. Mahale, Gourav Bothra, Rinku. S. Rathod., Formulation and evaluation of fast dissolving oral films. JETIR, 2024; 11(1): 602-609.
6. Dhote, V. K., & Dhote, K. (2020). Gastroretentive dosage form: Novel approach to drug delivery. *LAP LAMBERT Academic Publishing*. ISBN: 9786202523943ResearchGate+1
7. Dhote, V. K., & Dhote, K. (2020). Micro beads for targeted delivery of medicaments. *LAP LAMBERT Academic Publishing*. ISBN: 9786202523868
8. Dhote, V. K., & Dhote, K. (2019). Fundamentals of polymers science applied in pharmaceutical product development. In S. P. Pandey, T. Shukla, & R. K. Tekade (Eds.), *Basic Fundamentals of Drug Delivery* (pp. 85–112). Academic Press. https: //doi.org/10.1016/B978-0-12-817909-3.00003-0
9. Dhote, V. K., & Dhote, K. (2018). Coarse dispersion. In S. P. Pandey, T. Shukla, & R. K. Tekade (Eds.), *Basic Fundamentals of Drug Delivery* (pp. 113–132). Academic Press. https: //doi.org/10.1016/B978-0-12-817909-3.00004-2
10. Dhote, V. K., & Dhote, K. (2018). Colloidal drug delivery systems. In S. P. Pandey, T. Shukla, & R. K. Tekade (Eds.), *Basic Fundamentals of Drug Delivery* (pp. 133–152). Academic Press. https: //doi.org/10.1016/B978-0-12-817909-3.00005-4

11. Dhote, V. K., & Dhote, K. (2017). Development of novel fast melt granules for Balchaturbhadrika churna. *LAP LAMBERT Academic Publishing*. ISBN: 9786202075695ResearchGate
12. Shivani S, Poladi KK. Nanosponges-novel emerging drug delivery system: a review. Int J Pharm Sci Res, 2015; 6: 529.
13. Selvamuthukumar S, Anandam S, Krishnamoorthy K, Rajappan M. Nanosponges: A novel class of drug delivery system-review. Journal of Pharmacy & Pharmaceutical Sciences, 2012 Jan 17; 15(1): 103-11.
14. Dhote, V. K., & Dhote, K. (2015). Micropellets: A promising strategy for controlled release of lansoprazole. *Asian Journal of Pharmaceutical Education and Research, 4*(3): 1–7. https: //www.ajper.com/AbstractView.aspx?PID=2015-4-3-1ResearchGate
15. Ghurghure SM, Pathan MS, Surwase PR. Nanosponges: A novel approach for targeted drug delivery system. Int. J. Chem. Studies, 2018 Nov; 2(2).
16. Singh S, Monika K, Nanosponges as Emerging Carriers for Drug Delivery, Sys Rev Pharm, 2022; 13(1): 55-62.
17. Dhote, V. K., Mishra, D. K., & Dhote, K. (2015). Formulation and characterization of microbeads as a carrier for the controlled release of rioprostil. *Asian Journal of Pharmaceutical Education and Research, 4*(4): 1–6. https: //www.ajper.com/AbstractView.aspx?PID=2015-4-4-1ResearchGate+1
18. Suchita G. Waghmare, Rasika R. Nikhade, Dr. Satish and B. Kosalge. (2017). Nanosponges: a novel approach for controlled release drug delivery system. International Journal of Pharmacy and Pharmaceutical research, 9(3): 101-116.
19. Sharma R, Roderick B and Pathak K. (2011). Evaluation of kinetics and mechanism of drug release from econazole nitrate nanosponges loaded carbopol Hydrogel. Indian Journal of Pharmaceutical Education and Research, 45(1): 25-31.
20. Dhote, V. K., & Dhote, K. (2015). Dendrimer: Novel strategies for drug delivery system. *Asian Journal of Pharmaceutical Education and Research, 4*(4): 1–7. https: //www.ajper.com/AbstractView.aspx?PID=2015-4-4-2Google Scholar
21. Dhote, K., Dhote, V. K., & Khatri, K. (2015). Phytochemical screening and pharmacological activity in Punica granatum. *Asian Journal of Pharmaceutical Education and Research, 4*(4): 1–6. https: //www.ajper.com/AbstractView.aspx?PID=2015-4-4-3ResearchGate
22. Nilholm C, Larsson E, Roth B, Gustafsson R, Ohlsson B. Irregular dietary habits with a high intake of cereals and sweets are associated with more severe gastrointestinal symptoms in IBS patients. Nutrients, 2019; 11: 1279.
23. Dhote, K., Dhote, V. K., & Mishra, D. K. (2015). Management of diabetes mellitus: Herbal remedies. *Asian Journal of Biomaterial Research, 1*(1): 12–16. https: //www.ajbr.in/AbstractView.aspx?PID=2015-1-1-3Google Scholar+2ResearchGate+2
24. Dhote, K., Dhote, V. K., & Khatri, K. (2015). Formulation and evaluation of herbal cosmetic formulation containing Calendula officinalis. *Asian Journal of Pharmaceutical Education and Research, 4*(4): 1–6. https: //www.ajper.com/AbstractView.aspx?PID=2015-4-4-4ResearchGate
25. Shastrulagari S, Poladi KK. "Nanosponges: Novel Emerging Drug Delivery System." IJPSR, 2015; 6(2): 529–540.
26. Dhote, V. K., Dhote, K., & Mishra, D. K. (2015). Floating gastro retentive systems: A potential emergence to oral drug delivery system. *Asian Journal of Pharmaceutical Education and Research, 4*(4): 1–6. https: //www.ajper.com/AbstractView.aspx?PID=2015-4-4-5ResearchGate+2GGU+2
27. Shah A, Atneriya UK, Joshi U, Solanki D. Development and Evaluation of Pullulan Based Mouth Dissolving Film of Furosemide. Fabad Journal of Pharmaceutical Sciences, 2024; 49(1): 65-80.
28. Tulbah AS, Elkomy MH, Zaki RM, Eid HM, Eissa EM, Ali AA, Yassin HA, Aldosari BN, Naguib IA, Hassan AH. Novel nasal niosomes loaded with lacosamide and coated with chitosan: A possible pathway to target the brain to control partial- onset seizures. International journal of pharmaceutics: X, 2023; 6: 1-13.
29. Paul D, Ray P. Exploring the potential of fast dissolving oral films. Current Trends in Pharmaceutical Research, 2023; 10(2): 20-35.
30. Sandeep Kanna, Rama Rao Nadendla, Juluri Satyanarayana, Vajrala Karthikeya, Muthumula Venkata Sonu and Pusuluri Naga Bhargavi. Formulation and Evaluation of Fast-Dissolving Oral Film of Rivaroxaban. Journal of Young Pharmacists, 2023; 15(4): 687-695.
31. Pushkar S. Chavan, Avish D. Maru, Majid S. Khan.Formulation and Evaluation of Mouth Dissolving Films of Captopril by using Natural Polymers. Research.