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TO FORMULATE AND EVALUATE ORAL STRIPS FOR QUICK RELIEF FROM ORAL ULCER

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ABSTRACT
Fast dissolving strips (FDS) have emerged as a novel oral drug delivery system offering rapid disintegration upon contact with the buccal mucosa, typically within seconds, without the need for water. This improves patient compliance, particularly among pediatric, geriatric, and dysphagic populations. By facilitating direct absorption into systemic circulation, FDS bypass first-pass metabolism and gastrointestinal degradation. Given the limitations of conventional tablets and capsules, which pose swallowing difficulties for 26–50% of patients, FDS present a patient-friendly alternative. Which contain API (lidocaine 4.5gm & Choline Salicylate 1.5gm), Polymer (HPMC 5gm), Plasticizer (Glycerin 4.5gm), Saliva stimulating agent (Citric Acid 0.5gm), Sweetening agent (Saccharine 0.5gm), Surfactant (Sodium Lauryl Sulphate 0.06gm), Propylene glycol(1), Peppermint oil(0.4gm), and water (QS) Recent developments have focused on formulation techniques, evaluation parameters, and industrial adoption of transdermal technologies to produce thin oral films.

KEYWORDS: Fast dissolving strips, Oral mucosa, Solvent casting, Disintegration, Permeability, Patient compliance.

INTRODUCTION

Mouth ulcers, also known as aphthous stomatitis or canker sores, are painful, recurrent lesions that appear on the mucous membranes inside the mouth. They are a common oral health problem, affecting nearly 20% of the general population. The condition causes severe discomfort, hindering normal oral functions such as eating, speaking, and swallowing. The exact etiology of mouth ulcers is not fully understood, but they are often associated with factors like:

- Trauma (accidental biting, dental work)
- Stress and hormonal fluctuations
- Nutritional deficiencies (e.g., vitamin B12, iron, and folic acid)
- Immune system dysfunction (autoimmune diseases)
- Infections (viral or bacterial)
- Genetics

Although most ulcers are self-limiting, their painful nature and recurrence can significantly reduce quality of life. Current treatments focus on providing symptomatic relief, such as pain relief and reducing inflammation, but these treatments often fall short in providing long-lasting relief and may have other limitations, such as the need for frequent reapplication.

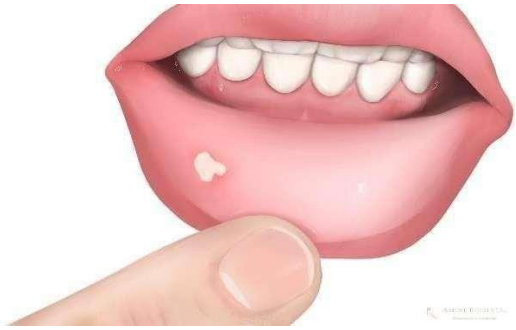

Fig. 1: Mouth ulcer.

One such alternative is Fast-Dissolving Oral Strips (FDOS), a novel dosage form designed to dissolve quickly in the mouth, allowing for rapid delivery of active ingredients directly at the site of the ulcer. These strips offer several advantages over conventional therapies, including enhanced patient compliance, faster onset of action, and convenience of use without the need for water. The active ingredients for mouth ulcer

treatment typically include local anesthetics, which provide immediate pain relief, and anti-inflammatory agents, which help reduce swelling and promote healing. By incorporating these ingredients into a fast-dissolving oral strip, it is possible to deliver the drug directly to the ulcer, ensuring targeted relief.

Mechanism of Action for Fast-Dissolving Oral Strips

FDOS work by using a combination of polymeric film-forming agents, plasticizers, and active pharmaceutical ingredients (APIs), which allow the strip to dissolve upon contact with the moisture in the mouth. Once placed on the affected area, the strip dissolves rapidly, releasing the active ingredients directly where they are needed. The oral mucosa (lining of the mouth) is highly vascularized, which enables the quick absorption of the active ingredients, ensuring rapid onset of relief.

Fig. 2: Oral strip.

Importance of Fast-Dissolving Oral Strips

Fast-Dissolving Oral Strips (FDOS) are a novel drug delivery system designed to dissolve quickly in the mouth, eliminating the need for water and offering a discreet and convenient solution for managing conditions like mouth ulcers. The key benefits of FDOS include:

- Rapid Drug Release: The strips are designed to dissolve within a few seconds to a minute, releasing the active ingredients directly to the affected area, leading to fast-acting relief.
- Localized Action: Since the strip dissolves at the site of application, it ensures that the drug is delivered directly to the ulcer, maximizing therapeutic efficacy.
- No Need for Water: Unlike conventional tablets or lozenges, FDOS do not require water for administration, making them convenient for on-the-go use.
- Improved Patient Compliance: The ease of administration and faster relief increase patient compliance, particularly in populations like children or elderly individuals who may have difficulty using other dosage forms.
- Non-invasive and Convenient: The strip can be easily placed inside the mouth, where it will dissolve without causing any discomfort.

Drug Rationale

Local anesthetic

- Mechanism of Action: API works by inhibiting sodium channels, preventing the transmission of nerve impulses and thus providing localized pain relief. It is commonly used in oral treatments for pain relief, and its quick onset of action makes it ideal for mouth ulcer management.
- Formulation Benefits: The incorporation of API in FDOS provides immediate analgesia, offering prompt relief to the patient upon application.

Non-steroidal anti-inflammatory drug (NSAID)

- Mechanism of Action: API inhibits the enzyme cyclooxygenase (COX), reducing the production of prostaglandins that mediate inflammation and pain. This results in a reduction in the swelling and irritation of the ulcer site.
- Formulation Benefits: API contributes to the anti-inflammatory action of the formulation, ensuring a more holistic treatment approach by addressing both the pain and underlying inflammation associated with mouth ulcers.

Together, The combination of two drug provide a synergistic effect, with API offering immediate pain relief and promoting long-term healing by reducing inflammation.

Benefits of the Formulation

- Rapid Onset of Action: Immediate relief from pain and discomfort due to the rapid dissolution and localized drug delivery.
- Long-Lasting Effect: Continuous release of API provides sustained relief from both pain and inflammation.
- Improved Bioavailability: Direct mucosal absorption enhances the bioavailability of the drugs, resulting in faster therapeutic effects.
- Convenience: The oral strip does not require water for use, making it portable and easy to administer anytime and anywhere.
- Enhanced Compliance: FDOS is more likely to be used regularly by patients due to its ease of use, compact form, and fast action.
- Safe and Non-Invasive: FDOS avoids the risks associated with injectable drugs and provides a safe, non- invasive, and effective alternative.

MATERIALS AND METHODS

Table 1: Material.

Sr. NO	Name of ingredients	Category	Manufacturing
1.	Lidocaine	Active Ingredient	purchase
2.	Choline salicylate	Active Ingredient	purchase
3.	HPMC	Polymer	P.W.C.O.P. Moha Phata
4.	Glycerin	Humectant and plasticizer	P.W.C.O.P. Girija Nagar
5.	Citric acid	PH adjuster	P.W.C.O.P. Girija Nagar
6.	Saccharin	Sweeting agent	P.W.C.O.P. Girija Nagar
7.	Sodium lauryl sulphate	Surfactant	P.W.C.O.P. Girija Nagar
8.	Propylene glycol	Solvent	P.W.C.O.P. Girija Nagar
9.	Peppermint oil	Flavoring agent	P.W.C.O.P. Girija Nagar
10.	Water	Solvent	P.W.C.O.P. Girija Nagar

Table 2: Equipments.

Sr.No.	Name Of Instrument	Manufacturing
1.	Magnetic stirrer	P.W.C.O.P. Girija Nagar
2.	Weighing balance	P.W.C.O.P. Girija Nagar
3.	Beaker and Measuring cylinder	P.W.C.O.P. Girija Nagar
4.	Petri dish	P.W.C.O.P. Girija Nagar
5.	PH meter	P.W.C.O.P. Girija Nagar
6.	Hot air oven	P.W.C.O.P. Girija Nagar

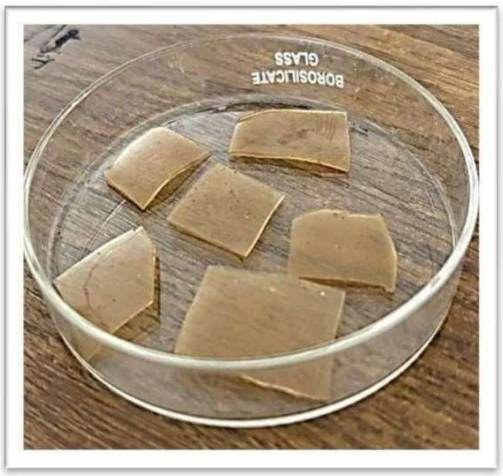

Fig. 3: [Batch A]

Fig. 4: [Batch B]

Fig 5 [Batch C]

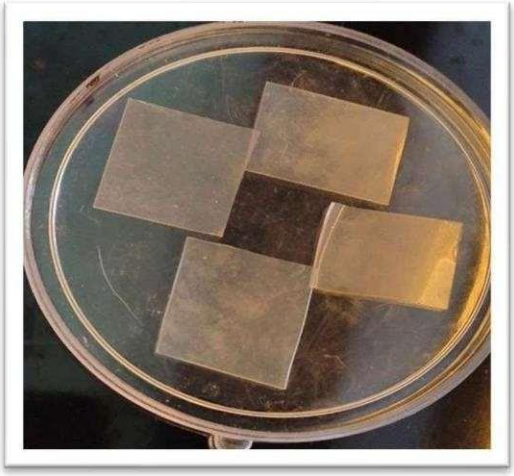

Fig 6 [Batch D]

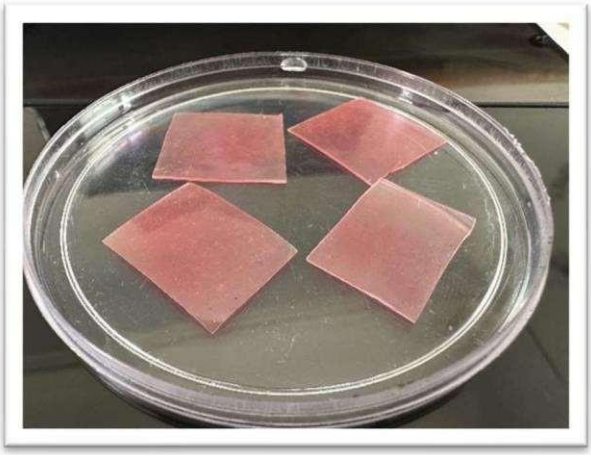

Fig 7[Batch E]

- **METHOD**
- **Preparation of oral strips**
- **Solvent Casting Method**

➢ Strip forming agent, plasticizers and saliva stimulating agent are dissolved in distilled water, the solution is then stir up to 4 hours continuously in a magnetic stirrer at 60^0c and 1000 rpm.

➢ After that the solution is kept stand for 1hr to remove all the air bubbles entrapped.

➢ At the same time in a separate container remaining excipients like sweetening agent disintegrating agent, flavoring agent and drug are dissolve in distilled water with continuous stirring for 45 minutes

➢ Both the solution are mixed together in a magnetic stirrer at room temperature and 1000 rpm

➢ Stand by the solution for 1 hour to let the foams settle down.

➢ Finally the solution is cast and dried at 60^0 c and cut the strip into the desires size.

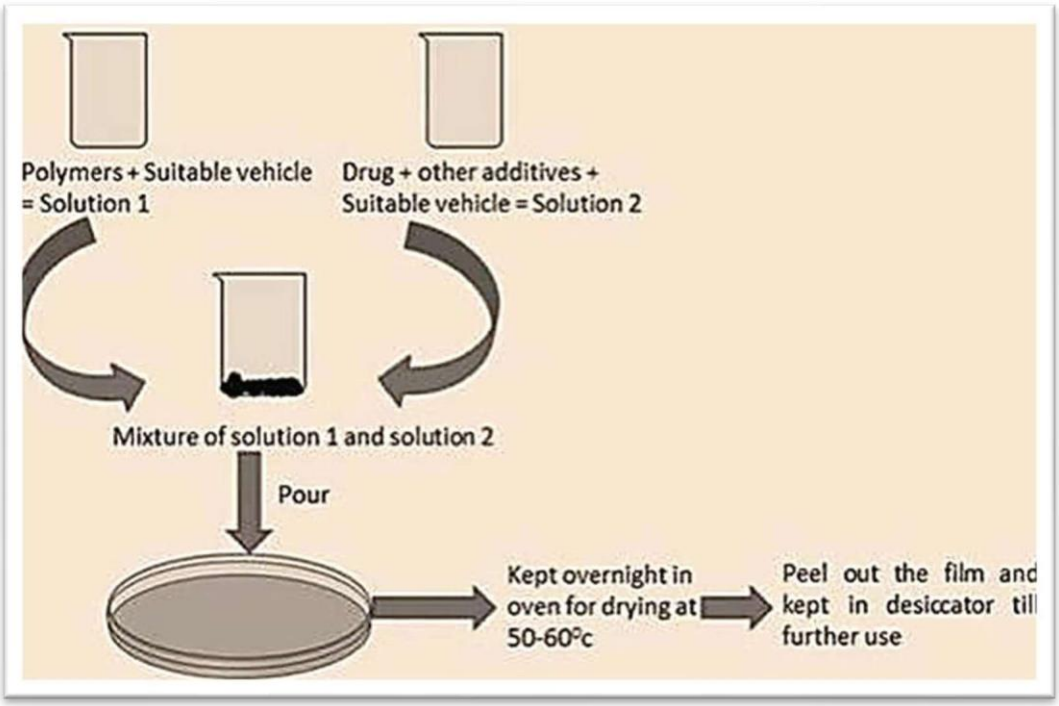

Fig. 8: Hot Melt Extraction.

- **EVALUATION TEST**

Determination of PH

The films were kept in contact with 1ml of distilled water for 5 min at room temperature and PH was observed 6.9 which indicates the PH is neutral and safe for use.

Disintegration

Disintegration time is defined as the time it takes for an oral film to start breaking when exposed to water or saliva for fast-dissolving films, the ideal disintegration time typically ranges from 5to30seconds. Disintegration time can be also determined by simply immersing the film in

25ml of water in a beaker, gently agitating the film begins to break apart or disintegrate. Observed and record the time taken for the film to disintegrate completely. The disintegration time of the strip ranges from 20-30 sec.

DISSOLUTION

The dissolution test is performed using a basket or paddle-type apparatus as per pharmacopeial standards. A suitable medium like phosphate buffer is selected to maintain sink conditions. The oral strip is placed in the medium at 37°C, and the drug is allowed to dissolve over time. Samples are taken at set intervals and analyzed using UV or HPLC to measure drug release. A dissolution profile is then created to show how quickly and efficiently the drug is released from the strip. The dissolution time taken by strip is 45 sec.

Preparation of standard Calibration curve

Table 3: Standard Calibration Curve.

Sr. No	Volume	Concentration	Absorbance
1	0.2ml	2 µg/ml	0.098
2	0.4ml	4 µg/ml	0.182
3	0.6ml	6 µg/ml	0.272
4	0.8ml	8 µg/ml	0.360
5	1.0ml	10 µg/ml	0.448

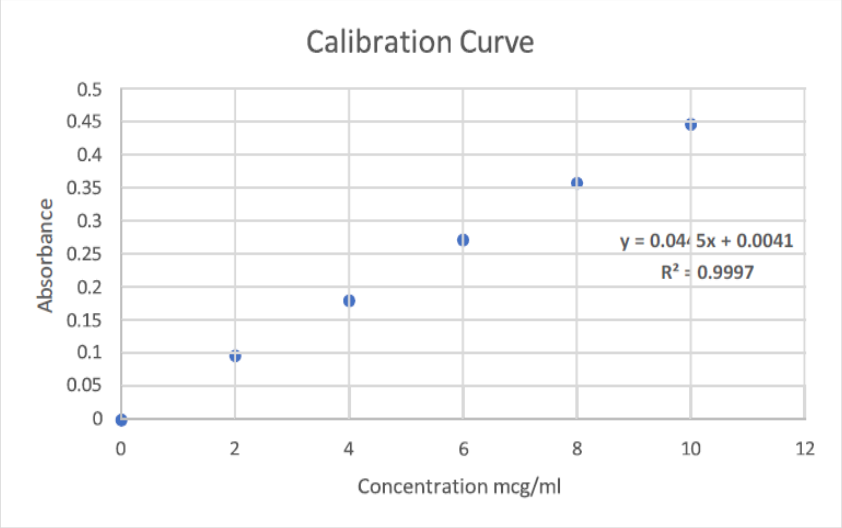

Fig. 9: Calibration curve.

Thickness

Micrometer screw gauge is use to measure the thickness of the strip. strip thickness should range from 5-200micrometers. The thickness measurements were taken at six distinct locations on each film and the average thickness was calculated. The thickness of fast dissolving oral strip ranges from 0.33 ± 0.01 mm.

Weight variation

To determine the film weight, three films from each formulation were individually weighed, and the average weight was calculated.

Folding endurance

Folding endurance was evaluated by repeatedly folding a small portion of the film at the same location until it broke. The average number of folds required to cause breakage was recorded as the folding endurance for each formulation.

Drug content

Drug content was assessed by analyzing three individual film segments, each sized 1.5 × 1.5 cm. Each segment was dissolved in 100 mL of phosphate buffer (pH 6.8). The resulting solutions were filtered and appropriately diluted using the same buffer. Drug concentration was then determined using UV spectrophotometry. The average drug content of the three samples was calculated, and the films were deemed acceptable if the drug content fell within 85% to 115% of the labeled amount.

Moisture content

Three film samples, each measuring 1.5 cm × 1.5 cm, were accurately weighed and placed in a desiccator for a duration of three days. After the specified time, the films were removed and reweighed. The percentage of m moisture loss was then calculated using the following

Moisture content (%)= ×100

❖ RESULTS AND DISCUSSION

The batch F5 was passed in the preparation of patient-friendly oral strips for quick relief from oral ulcer due to all evaluation test are passes including Thickness, Determination of PH, Dissolution test, Disintegration test etc.

- **Physical Characteristics of the Strips**

Evaluation Parameter	F1	F2	F3	F4	F5
Appearance	Transparent, smooth	Transparent, smooth, uniform	Transparent, smooth, uniform	Transparent, smooth, uniform	Transparent, smooth, uniform
Colour	Colourless	Colourless	Colourles s	Colourless	Colourless
Odour	Odourless	Odourless	Odourless	Odourless	Odourless
Flexibility (Folding endurance)	150	176	200	240	260

All batches exhibited a smooth, transparent, and uniform surface with no air bubbles or cracks, which is essential for patient acceptability and easy for use.

- **Physicochemical Properties**

Evaluation Parameter	F1	F2	F3	F4	F5
Thickness (mm)	0.20±0.04	0.24±0.03	0.26±0.02	0.28±0.02	0.33±0.01mm
Weight Variation	60±5	101±7	94.21±0.50	93±0.60	94.43±0.70
Surface PH	5.9	6	6.2	6.5	6.9
Moisture Content %	3%	2.5%	2.2%	2%	1.5%

Among all batches, Batch F5 shows uniform thickness and weight within the acceptable limits, ensuring, consistency in drug delivery and easy to use. The thickness of F5 shows 0.33±0.01mm.

The weight of the all strip across all batches (F1-F5) ranges from 47.1±1.3gm. Formulation F5 exhibited the lowest weight variation.

The surface PH of all batches ranges from 6 to 7. The batch F5 shows 6.9 PH which is close to neutral. After performing the test, batch F5 shows the minimum moisture content i.e 1.5%.

- **Drug Content Uniformity**

Evaluation Parameter	F1	F2	F3	F4	F5
Drug	95.6±2.	97.5%±2	97.8%±1	98.5%±0	98.9±0
Content	4%	%	.8%	.7%	.9%
Uniformity					
(%)					

The drug content for all batches was uniformly distributed, with values ranging from 95.8%-98.8%, batch F5 shows 98.9±0.9% drug contain indicating that the strip deliver consistent dose which is crucial for therapeutic efficacy.

- **Disintegration and Dissolution**

Evaluation Parameter	F1	F2	F3	F4	F5
Disintegration Time (sec)	2 min	1min 15 sec	60 sec	45 sec	30 sec
Dissolution Efficiency (%)	2min 5 sec	1 min 30 sec	1min 5 sec	55 sec	45 sec

The disintegration time of batch F5 shows 30 seconds which ensure that the strip dissolve quickly.

- **Calibration Curve Graph**

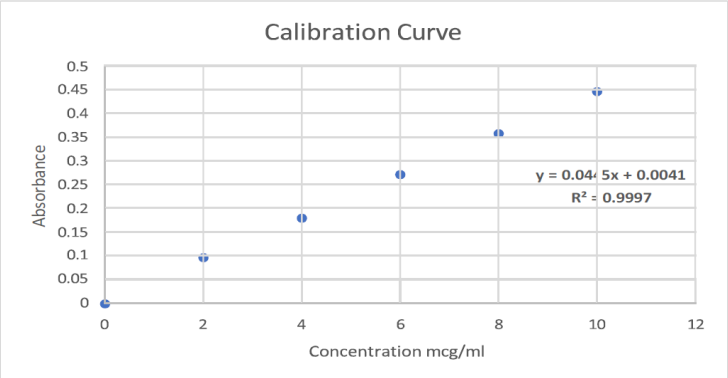

Fig. 10: Calibration curve.

The absorbance of a solution was determined using UV spectrophotometer between the range of 200-400 nm. The absorbance of a solution was found to be 261nm. As shown in a fig.10. After measuring the absorbance of solution at 261nm. The bear's range of API was found be 1 to 10mcg at shown in table 3. And the regression coefficient was found to be R^2 = 0.9997 as shown in fig.10.

➢ **Percent (%) CDR**

Sr.No	Time	F1 % CDR	F2 % CDR	F3 % CDR	F4 % CDR	F5 % CDR
1	60 sec	0.065	0.068	0.070	0.072	0.079
2	120 sec	0.069	0.072	0.075	0.078	0.085
3	180 sec	0.088	0.091	0.093	0.095	0.097
4	240 sec	0.090	0.093	0.094	0.096	0.098

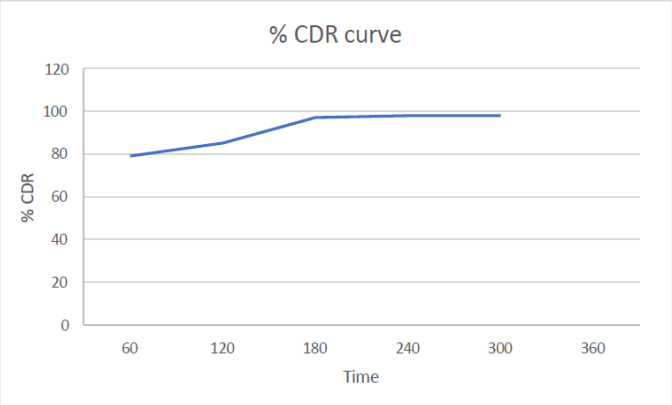

Fig.11: % CDR Curve.

❖ CONCLUSION

The Fast-Dissolving Oral Strips (FDOS) containing two API proved to be a promising delivery system for mouth ulcer management. The strips were designed to provide quick, efficient relief by dissolving rapidly upon oral administration. The formulation process was successful, and not all batches only one batch is necessary quality control criteria, including drug content uniformity, rapid disintegration, and dissolution rates.

- The strips showed excellent physicochemical properties and mechanical stability, ensuring that they are easy to handle and will dissolve quickly when placed on the oral mucosa.
- The drug content and dissolution profiles of all batches were within the acceptable range, ensuring that the therapeutic efficacy of the active ingredients is consistent across batches.
- Stability studies showed that the strips maintained their integrity and efficacy over a 3- month period, suggesting that they are stable for longer storage periods, making them suitable for commercialization.

This study demonstrates the feasibility of FDOS as a viable dosage form for mouth ulcer treatment, offering a patient- friendly solution with fast-acting relief. Further research and optimization of the formulation may be conducted to enhance the product's bioavailability and patient acceptability.

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❖ REFERENCES

1. Gorsky, M., & Noll, J. "Aphthous Stomatitis: A Clinical Review." American Family Physician, 2017; 96(4): 223–230.
2. Bensinger, W. I., & Heald, P. W. "Oral ulceration: diagnosis and management." The

Lancet, 2005; 365(9473): 1437–1445.
3. Purohit, S., & Thakkar, P. "Fast-dissolving oral films: A comprehensive review of the formulation, types, and applications." Asian Journal of Pharmaceutics, 2018; 12(3): 200-211.
4. Seager, H. "Drug-delivery products and the patenting of novel drug delivery systems." Journal of Controlled Release, 1998; 51(1-2): 5–24.
5. Kassem, A. A., & El-Din, S. S. "Evaluation of fast-dissolving oral strips as a dosage form for the treatment of oral mucosal diseases." International Journal of Pharmaceutics, 2013; 452(1-2): 93-102.
6. Gupta, M., & Kaur, M. "Formulation and evaluation of fast- dissolving oral films." Asian Journal of Pharmaceutical and Clinical Research, 2019; 12(5): 1- 6.
7. Cummings, T. M., & Brannon, J.R. "Pharmacokinetics of mucosal drug delivery via fast- dissolving oral films." Journal of Controlled Release, 2006; 112(1): 18– 22.
8. Dey, A., & Banerjee, S. "Fast-dissolving films: A review on their formulation and drug delivery system." Journal of Advanced Pharmaceutical Technology & Research, 2017; 8(2): 48-56.
9. Solomon, S., & Kumar, S. "Challenges in the formulation of mouth ulcer drugs and their management." Therapeutic Advances in Drug Delivery, 2018; 10(4): 173- 185.
10. Lee, K. D., & Dhanraj, S. "Barriers in the effective treatment of oral mucosal diseases." European Journal of Pharmaceutical Sciences, 2014; 61: 1-12.
11. Rajput, R., & Bhargava, K. "Formulation and characterization of fast-dissolving oral strips." Journal of Pharmaceutical Sciences, 2016; 106(3): 654-663.
12. Patil, A., & Deshpande, N. "Optimization and characterization of fast-dissolving oral films for mucosal drug delivery." Indian Journal of Pharmaceutical Sciences, 2017; 79(2): 187-197.
13. Mishra, R., & Agarwal, R. "Clinical efficacy of fast-dissolving oral films for mouth ulcer management." Journal of Clinical Pharmaceutics, 2019; 50(2): 212-219.
14. Patel, M., & Shah, P. "Evaluation of patient satisfaction and compliance in mouth ulcer treatment using FDOS." International Journal of Drug Delivery Technology, 2020; 14(1): 28-34.
15. Iyer, S., & Kumar, P. "Innovative approaches in fast-dissolving drug delivery systems: A focus on oral films and strips." Journal of Advanced Drug Delivery, 2021; 12(5): 300-310.
16. Narayan, S., & Verma, D. "In vitro and in vivo evaluation of fast- dissolving oral strips for mouth ulcer treatment." European Journal of Pharmaceutical Sciences, 2018; 122: 97-105.
17. Peshori, S. D., & Desai, A. M. "In vivo pharmacokinetic evaluation of fast- dissolving oral films for the treatment of mouth ulcers." Journal of Controlled Release, 2019; 318: 256-264.
18. Trivedi, S., & Rathi, S. "Development and characterization of bioactive oral films using novel polymer blends." International Journal of Pharmaceutics, 2017; 525(1-2): 73-85.
19. Jain, A., & Bhargava, S. "Polymer selection for fast-dissolving films in oral drug delivery." Journal of Drug Delivery Science and Technology, 2017; 40: 95-102.
20. Srivastava, S., & Chawla, R. "Toxicological safety evaluation of fast- dissolving oral films." International Journal of Toxicology and Pharmacology Research, 2018; 7(2): 140-147.
21. Borse, V. A., & Shinde, R. "Safety and biocompatibility of oral mucosal delivery systems: Focus on fast-dissolving films." Journal of Pharmaceutics, 2020; 16(5): 42-48.