INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

OPEN ACCESS

Review Article

Review on Oral Fast Dissolving Film Technology: Materials, Methods

Radhika D. Holkar*[1], P.G. Patil[2], S. J. Dighade[3]

[1]*Pharmaceutical Quality Assurance, Institute of Pharmacy and Research, Badnera-Amravati*
[2] *Pharmaceutical Chemistry, Institute of Pharmacy and Research, Badnera-Amravati*
[3]*Pharmaceutical Chemistry, Institute of Pharmacy and Research, Badnera- Amravati*

ARTICLE INFO

Published: 15 June. 2026
Keywords:
Oral dissolving films, Methods, Oral drug delivery system, film forming polymers, manufacturing techniques
DOI:
10.5281/zenodo.20705329

ABSTRACT

Oral films represent a novel and patient-friendly drug delivery system designed to overcome limitations associated with conventional oral dosage forms, particularly in paediatric, geriatric, and dysphagic patients. These thin polymeric films rapidly hydrate upon contact with saliva, leading to quick disintegration and drug release without the need for water, thereby enhancing patient compliance and providing a faster onset of action. ODFs are formulated using hydrophilic film-forming polymers combined with plasticizers, sweetening agents, saliva-stimulating agents, surfactants, flavors, and colouring agents to achieve optimal mechanical strength, palatability, and performance. Ideal APIs for ODFs are potent, low-dose drugs with stability in aqueous environments. Various manufacturing techniques, such as solvent casting, semi-solid casting, hot-melt extrusion, and solid dispersion extrusion, are employed to produce uniform films. Evaluation of ODFs involves assessment of physical properties, disintegration and dissolution behaviour, mechanical strength, surface pH, drug content uniformity, and weight variation. Due to their ease of administration, rapid disintegration, and improved patient acceptability, ODFs have significant potential in modern pharmaceutical therapy.

INTRODUCTION

Oral route of medicine administration is a most favored route due to its ease of administration, non-invasiveness, rigidity, patient compliance and adequacy. Regarding oral route of medicine administration, numerous backups have continuously been presented by using recent new technologies for pediatrics, elders, squeamish andnon-compliance cases. Bioadhesive mucosal lozenge forms including tenacious tablets,

***Corresponding Author:** Radhika D. Holkar
Address: *Institute of Pharmacy and Research, Badnera-Amravati*
Email ✉: radhikaholkar11@gmail.com

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

gels and patches are issues of technological development. Among colorful lozenge forms, the use of polymeric flicks for delivering drug into buccal depression has developed great eventuality in recent area. Orally disintegrating flicks(ODFs), when placed on lingo, incontinently hydrates by soaking slaver following decomposition and/ or dissolution releasing active pharmaceutical agent from the lozenge form. ODFs are kind of phrasings which are generally prepared using hydrophilic polymers enabling rapid-fire dissolution upon contact with slaver. Oral disintegrating tablets (ODTs) and oral disintegrating flicks(ODFs) are the typical exemplifications of orally disintegrating medicine delivery systems. These systems were developed in late 1970 to serve as an volition to conventional lozenge forms, for case, fast disintegrating tablets and capsules for elders and pediatric cases having difficulty in swallowing conventional lozenge forms. A typical ODF is generally equal to the size of a postage stamp [1] In request place, the preface of ODT was explosively associated with comforting of cases about the applicable administration by giving instruction like ‘‘ do not chew/ do not swallow’’ still, in malignancy of these instructions, incidents regarding biting and swallowing were frequently reported.[2]

1.1 Special features of Dissolving film [3]

- Thin elegant film
- Rapid drug release
- Fast disintegration and dissolution

Advantages of oral film [4]

- No need of water for administration
- Convenient for pediatric, geriatric and dysphasic patients having difficulty in swallowing.
- Rapid disintegrating and dissolution in the oral cavity due to larger surface area of films.
- Rapid onset of action
- Reduce dose, enhances the efficacy and safety profile of the drug with reduced side effects
- Ease of administration to mentally ill, disabled , uncooperative patients and the patients who are on reduced liquid intake plans

Ideal properties of film forming polymers [5]

- The polymers should be inert, nontoxic and non-irritant.
- The polymer should have a better mouth feel property and good shelf-life.
- The polymer should exhibit good spread ability and wetting property.
- The polymers need to possess sufficient tensile, shear and peel strengths.
- The polymer should be economical and readily available.

2. Formulation of dissolving film

- Active pharmaceutical ingredient
- Film forming polymers
- Plasticizers
- Sweetening agent
- Saliva stimulating agent
- Surfactants
- Flavouring agent
- Colouring agent

Active pharmaceutical agents: The active substance is may be from any class of pharmaceutically active substances that can be administered orally or through the buccal mucosa respectively. According to literature, API can be added from 5%-25% w/w of total weight of polymer. For the effective formulation, dose of drug should be in mgs (less than 20 mg/day). The drugs which are potent, show high first pass metabolism and patient non- compliant are best candidates for fast dissolving buccal films. Researchers have shown interest in development of fast dissolving films for drugs like: Pediatrics (antitussive, expectorants, antiasthamatics), Geriatrics (antiepileptic, expectorants), Gastrointestinal diseases, Nausea (e.g. due to cytostatic therapy), Pain (e.g. migraine), CNS (e.g. antiparkinsonism therapy).

Among which favored active agents include chlorpheniramine maleate, brompheniramine maleate, dexchloropheniramine, triprolidine hydrochloride, acrivastine, azatadine maleate, loratidine, phenylephrine hydrochloride, dextromethorphan hydrochloride, ketoprofen, sumatriptan succinate, zolmitriptan, loperamide, famotidine, nicotine, caffeine, diphenhydramine hydrochloride, and pseudophedrine hydrochloride, and their amounts per strip can be well known in the art.

Polymers A variety of polymers are available for medication of fast dissolving buccal flicks. The polymers can be used alone or in combination to gain the asked film parcels. The film attained should be tough enough so that there will not be any damage while handling or during transportation. The robustness of the strip depends on the type of polymer and the quantum in the expression. The colourful polymers to make fast dissolving flicks include cellulose or cellulosederivatives, pullulan, Gelatin, hydroxypropyl methyl cellulose,hydroxyethylcellolose,hydroxypropyl cellulose, polyvinylpyrrolidone, carboxymethylcellulose, polyvinylalchohal, sodium alginate, xanthine goo, tragacanth goo, guar goo, acacia goo, methylmethacrylate copolymer and hypromellose are most generally used for medication of fast dissolving flicks. Modified beans are also used for medication. Due to low cost of this excipient it's used in combination of pullulan to drop the overall cost of the product. Pullulan is a natural polymer attained from nonanimal origin and does n't bear chemical revision. About 50 to 80 percent w of pullulan can be replaced by bounce in the product of fast dissolving flicks without loss of needed parcels of Pullulan. Combination of microcrystalline cellulose and maltodextrin has also been used to formulate fast dissolving flicks. Kulkarni et al., 2010 explored different polymers for use in expression of oral fast dissolving strips. Different polymers viz., HPMC E15, HPMC K4M, HPMC E5, PVP, PVA, gelatin, eudragit RL100 and pullalan were used to formulate presto dissolving buccal flicks; by solvent casting system. Results verified that pullalan is stylish polymer for oral fast dissolving strips [6]

Plasticizers: Plasticizer 7- 8 is a vital component of the fast dissolving buccal flicks expression. The mechanical parcels similar as tensile strength and extension to

the flicks can be bettered by the addition of the plasticizer. Variations in their attention affect these parcels. The selection of the plasticizer will depend upon its comity with the polymer and also the type of solvent employed in its casting. Plasticizers include glycerine, sorbitol, propylene glycol, polyethylene glycol, triacetin, di-butylpthalate, triethyl citrate, acetyl triethyl citrate and other citrate esters. generally the plasticizers are used in the attention of 0- 20 w/ w of the dry polymer weight [7]. unhappy use of the plasticizer may lead to film cracking, unyoking, shelling of the strip and it may also affect the immersion rate of the medicine.

Surfactants: Surfactants are used as solubilizing or wetting or dispersing agents so that the film gets dissolved within seconds and release active agent incontinently. Surfactants also ameliorate the solubility of inadequately answerable medicines in fast dissolving buccal flicks. Some of the generally used are polaxamer 407, sodium lauryl sulfate, benzalkonium chloride, benzthonium chloride, tweens and spans etc [8]

Sweetening agents: Sweeteners have come the important part of pharmaceutical products intended to be disintegrated or dissolved in the oral depression. The classical source of sweetener is sucrose, dextrose, fructose, glucose, liquid glucose. The agreeableness of fructose is perceived fleetly in the mouth as compared to sucrose and dextrose. Fructose is sweeter than sorbitol and mannitol and therefore used extensively as a sweetener. Polyhydric alcohols similar as sorbitol, mannitol can be used in combination as they also give good mouth - sense and cooling sensation. Polyhydric alcohols are less carcinogenic and don't have bitter after taste which is a vital aspect in formulating oral medications. The artificial sweeteners have gained generation of the artificial sweeteners followed by acesulfame - K, sucralose, alitame and neotame which fall under the alternate generation artificial sweeteners. Acesulfame - K and sucralose have further than 200 and 600 time agreeableness. Neotame and alitame have further than 2000 and 8000 time enhancing power as compared to sucrose. Rebiana which is a herbal sweetener, deduced from factory Stevia rebaudiana(South American factory) has further than 200 - 300 time agreeableness [9]

Saliva Stimulating Agents: The purpose of using slaver stimulating agents is to increase the rate of product of slaver that would prop in the briskly decomposition of the rapid-fire dissolving strip phrasings. Generally acids which are used in the medication of food can be employed as salivary instigations. Citric acid, malic acid, lactic acid, ascorbic acid and tartaric acid [10] are the many exemplifications of salivary instigations, citric acid being the most favored amongst them.

Flavoring agents: seasoning agents can be named from the synthetic flavor canvases, oleo resins, excerpt deduced from colorful corridor of the shops like leaves, fruits and flowers. Flavors can be used alone or in the combination. Any flavor can be added similar as essential canvases or water answerable excerpts of menthol, violent mints similar as peppermint, sweetmint,

spearmint, wintergreen, cinnamon, clove, sour fruit flavor similar as bomb, orange or sweet confectionery flavors [11] similar as vanillin, chocolate, or fruit substance like apple, jeer, cherry, pineapple. The quantum of flavor demanded to mask the taste depends on the flavor type and its strength.

Coloring agents: A full range of colours is available including FD & C colors, EU colours, natural colouring more fashionability in pharmaceutical medications. Saccharin, cyclamate and aspartame are the firstColoring agents A full range of colours is available including FD & C colors, EU colours, natural colouring agents, and natral juice concentrates, colors similar as titanium oxide, silicon dioxide and zinc dioxide and custom pantone- matched colours. These all coloring agents should n't exceed attention situations of 1 w/ w. these agents are incorporated when some of the expression constituents or medicines are present in undoable or suspense form.

2.1 The ideal chracteristics of drug to be selected

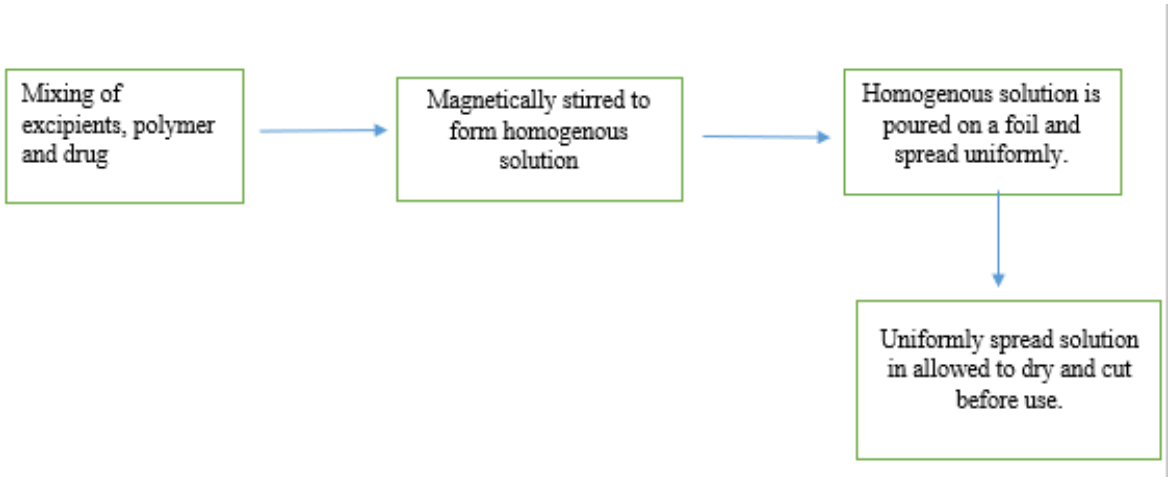
- The drug should have pleasant taste.
- The therapeutic dose of the drug should not be greater than 40 mg.
- The drug should have small molecular size and stability in water as well as in saliva.

Methods of preparation of Films

There are some methods in which oral dissolving films can be prepared, each of the methods are described below

1. Preparation of film using, solvent casting method
2. Semisolid casting
3. Hot melt extrusion
4. Solid dispersion extrusion
5. Rolling method

1. **Solvent Casting Method** It's one of the generally used styles for the expression of film. It's prepared using water-answerable polymers, excipients and medicine. Due to the operation of high shear, force a homogenous admixture is formed(Figure 1). The result attained is poured into antipode spread with coating cutter to gain invariant consistence [12]



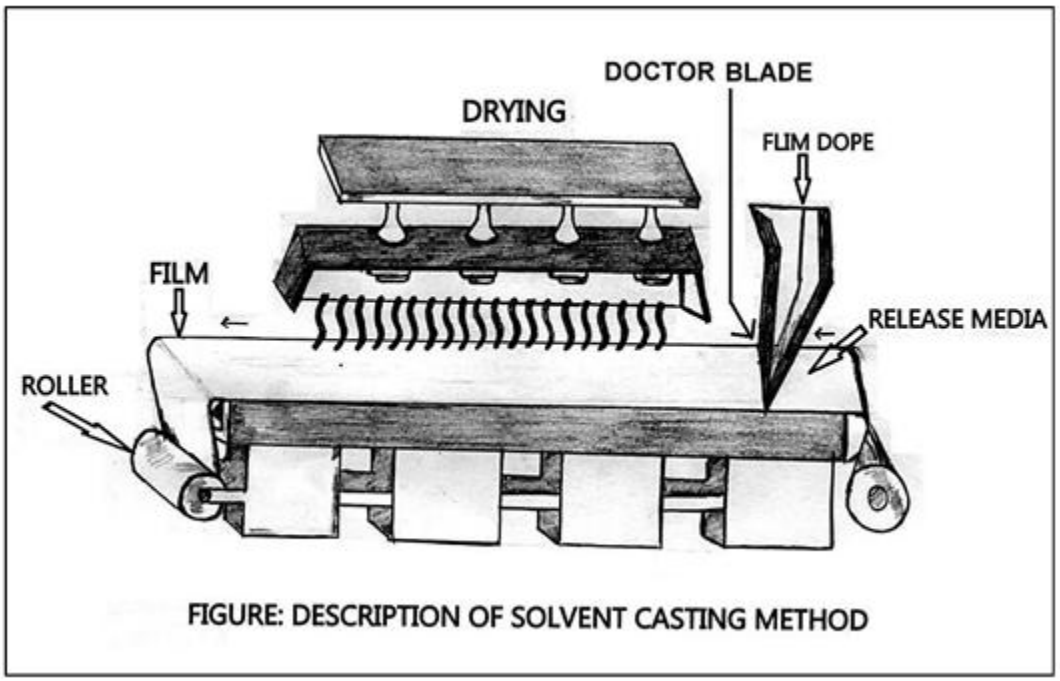
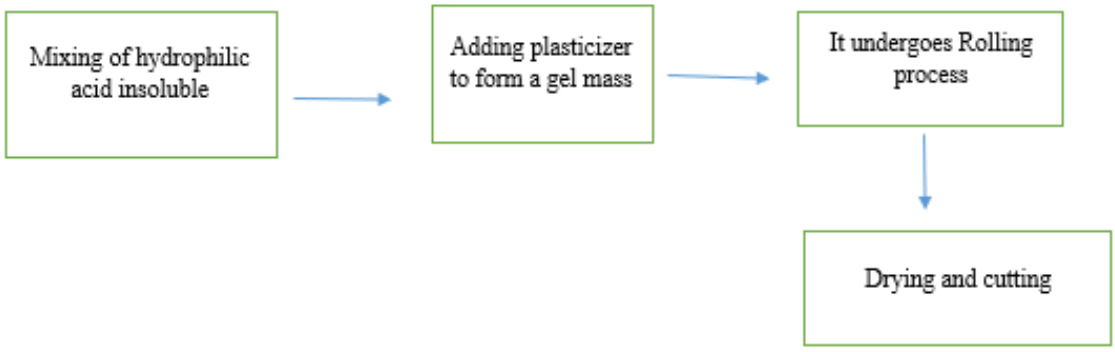


Figure 1: Solvent casting method

2. **Semi Solid Casting Method** In this method, water-soluble polymeric film is prepared then the polymeric solution is added to acid insoluble polymeric solution .The sufficient quantity of plasticizers is added to obtain gel, the gel is casted into plate by required thickness. The acid insoluble polymer and water soluble polymeric solution should be in the ratio1:4 [13-16]



3. **Hot Melt Extrusion:** Hot melt extrusion is a technique in which a admixture containing medicine, polymer and excipients is extruded under high temperature to form a homogenous mass, which is then glided to form smooth films. This is a solvent free process; still, the processing of thermolabile substances is a major debit of this process due to the use of high temperature during extrusion

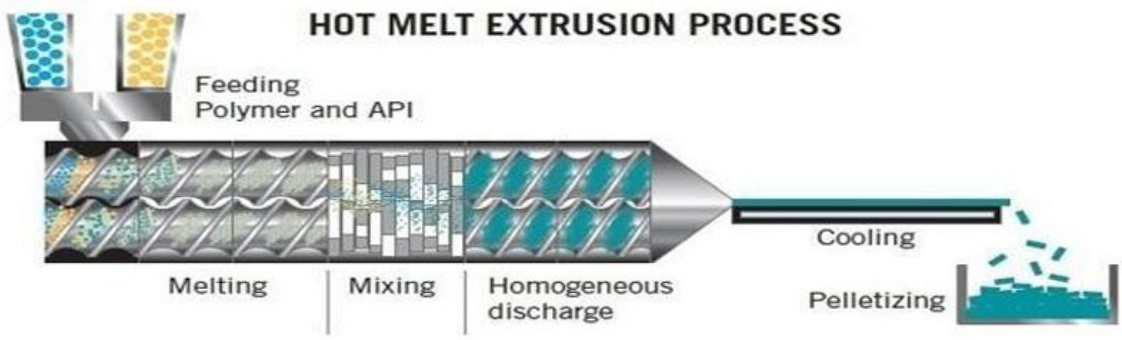


Fig No. 2 Hot melt extrusion

4. **Semi Solid Casting Method:** This system is rather espoused when acid undoable polymers are to be used in the medication of the flicks. Acid undoable polymers used to prepare flicks include cellulose acetate phthalate, cellulose acetate butyrate. Acid undoable polymer and film forming polymer should be used in the rate of 1:4.

Solution of water-soluble film forming polymer is prepared

↓

Resulting solution is added to a solution of acid insoluble polymer

↓

Appropriate amount of plasticizer is added so that gels mass is obtained

↓

Finally, the gel mass is casted in to the film or ribbons using heat-controlled drums

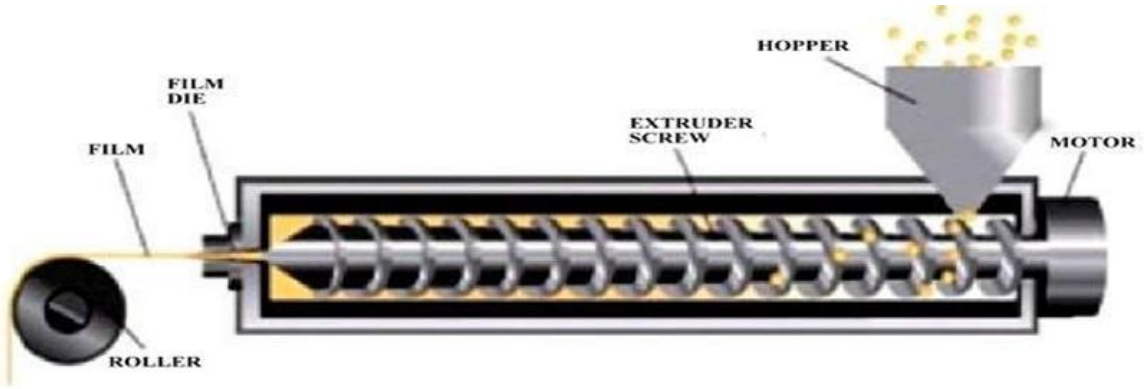


Fig No. 3 Semi solid casting method

5. **Solid Dispersion Extrusion Method:** Solid dispersion of domperidone using beta-cyclodextrin, PEG400 and HPMC E15 was successfully prepared and films were casted using solid dispersion extrusion method. [17-18]

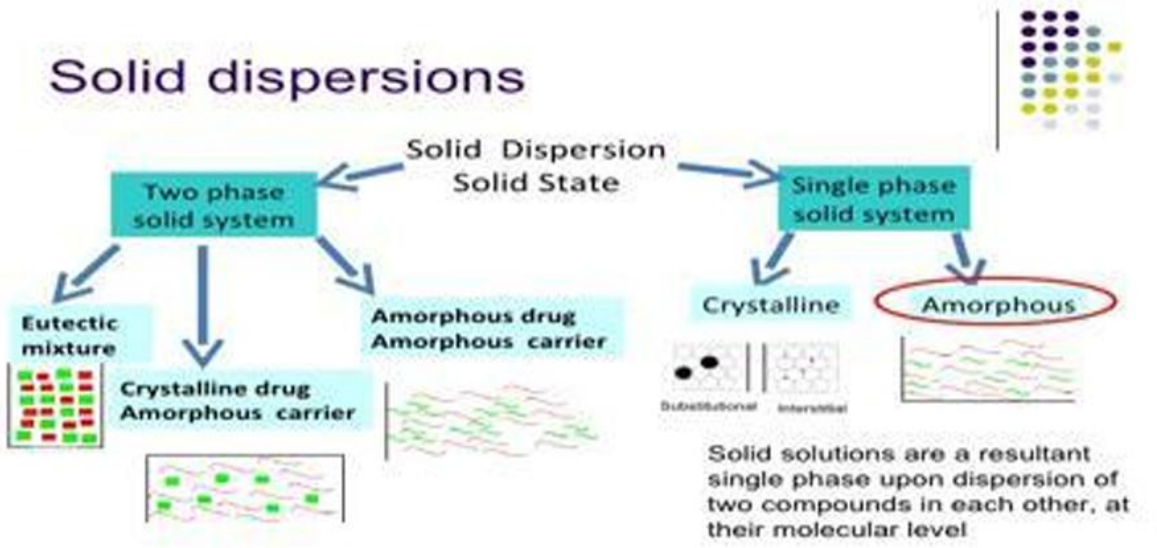


Fig No. 4.Solid Dispersion Extrusion Method

- **Evaluation of formulation**

1. **Physical characteristics observation** [19-20] Characteristics similar as homogecity, colour, translucency, inflexibility, fineness and face of the oral flicks were estimated by visual examination.
2. **Thickness** [21,22] The thickness of film is measured by micrometer screw gauge at different strategic locales. This is essential to ascertain uniformity in the thickness of the film as this is directly related to the delicacy of cure in the film.
3. **Folding endurance** [23] Folding endurance is determined by repeated

folding of the film at the same place until the film breaks. The number of times the film is folded without breaking is reckoned as the folding abidance value.

4. **In vitro disintegration studies** [24] The disintegration time limit of 30 seconds or lower for orally disintegrating tablets described in CDER guidance can be applied to orodispersible films. Although, no sanictioned guidance is available for oral fast disintegrating films/strips, this may be used as a qualitative guideline for quality control test or at development stage. Typical decomposition time for flicks is 5–30 seconds. Decomposition time gives an suggestion about the decomposition characteristics and dissolution characteristics of the film. The film as per the confines (2 x 2 cm) required for cure delivery was placed in a petridish containing 10 ml phosphate buffer (pH 6.8). Time needed for the film to break was noted as in vitro decomposition time. Petri dish was shaken with hands giving pulls. This test was performed on three flicks of each formulation and mean±S.D calculated.
5. **Dissolution test** [25]Dissolution testing can be performed using the standard handbasket or paddle apparatus described in any of the pharmacopoeia. The dissolution medium will basically be named as per the sink conditions and loftiest cure of the API. Numerous times the dissolution test can be delicate due to tendency of the film to float onto the dissolution medium when the paddle apparatus is employed. still, formerly film gets wet it goes into the result. Both apparatus are suitable to use and have substantiation to be use. The in vitro dissolution test was carried out in a paddle dissolution apparatus. Samples of Ondansetron Hydrochloride films were exactly counted. In this case, the film of 2×2 cm (4 cm2) was dissolved in 500 ml phosphate buffer (pH 6.8) at 50 rpm. The temperature of the dissolution media was maintained at 37±0.5 °C. During the study, 5 ml of aliquots were withdrawn at 1, 2, 3, 4, 5, 6, 7 and 8 min and were replaced by fresh buffer. The aliquots were filtered using wattman sludge paper and used for UV determination at 249 nm.
6. **Surface pH** A film with too important acidic or introductory pH affects the area of operation and causes damages to oral mucosal membrane leading to patient discomfort. It is likely that the chemical nature of the medicine and the excipients influences the pH of the set flicks. In this, the face pH of the set flicks was measured after allowing it to wet by keeping it in contact with distilled water for a short period at room temperature. It was measured by touching to bulb of pH cadence.
7. **Drug content and content uniformity** [26] Content uniformity is determined by estimating the API content in individual film. Limit of content uniformity is 85–115%. The film was cut in 2×2 cm in size dissolved in 50 ml of phosphate buffer pH 6.8, sonicated for 15 minutes ,also sludge using wattman sludge paper. This result was used for UV analysis and also attention of medicine is determined for checking medicine uniformity.

8. **Weight variations** [27-28] For weight variation, individual films are counted and the average weights are calculated. also the average weight of the flicks is abated from the individual weight of the flicks. A large variation in weight indicates the inefficiency of the system employed and is likely to have non-uniform medicine content. This test was carried out for three films of size 2×2 cm in size cut from single film.
9. **Tensile strength** [29] Oral film should retain moderate tensile strength, high chance extension (E), low Young's Modulus, and high percent of medicine release. Tensile strength is the outside stress applied to a point at which the film instance breaks. For the tensile strength, Brookfield's TexturePro CT V1.4 CT3 Texture Analyzer was used.
   Formula given below is used for determination of Tensile strength
   Tensile strength= Load at failure × 100
   Strip thickness × Strip width Type equation here.
10. **Percent Elongation** [30-31] When stress is applied, a film sample stretches and this is appertained to as strain. Strain is the distortion of film divided by original dimension of the sample. Generally, elongation of strip increases as the plasticizer content increases.
    % Elongation = Increase in length of strip × 100 Initial length of Strip

CONCLUSION

In conclusion, oral films represent an innovative and patient-centric drug delivery system that addresses many limitations of conventional oral dosage forms. These films rapidly disintegrate in the oral cavity without the need for water**,** offering enhanced patient compliance, comfort, and convenience**,** especially for paediatric, geriatric, dysphagia, and non-cooperative patients. ODFs improve therapeutic performance by enabling rapid onset of action, bypassing first-pass metabolism, and enhancing bioavailability**,** while also providing precise dosing and ease of administration. Although challenges such as limited drug loading, moisture sensitivity, and special packaging requirement**s** persist, ongoing research and formulation advancements continue to expand the practical utility of ODFs in pharmaceutical therapy. Overall, orally disintegrating films are a promising and adaptable platform that can potentially replace or supplement traditional dosage forms and improve the quality of drug delivery across diverse patient populations.

REFERENCES

1. Arya A, Chandra A, Sharma V, Pathak K. Fast dissolving oral films: an innovative drug delivery system and dosage form. Int J ChemTech Res. 2010;2:576–583.
2. Bhyan B, Jangra S, Kaur M, Singh H. Orally fast dissolving films: innovations in formulation and technology. Int J Pharm Sci Rev Res. 2011;9(2):9–15.
3. Bala R, Pawar P, Khanna S, Arora S. Orally dissolving strips: a new approach to oral drug delivery system. Int J Pharm Investig. 2013;3(2):67.

4. Jangra PK, Sharma S, Bala R. Fast dissolving oral films: novel way for oral drug delivery. Int J Uni Pharma Bio Sci. 2014;3(1):6–27.
5. Nagar P, Singh K, Chauhan I, Verma M, Yasir M, Khan A, et al. Orally disintegrating tablets: formulation, preparation techniques and evaluation. J Appl Pharm Sci. 2011;1:35–45.
6. Kulkarni AS, Deokule HA, Mane MS, Ghadge DM. Exploration of different polymers for use in the formulation of oral fast dissolving strips. J Curr Pharm Res. 2010;2(1):33–35.
7. Sakellariou P, Rowe RC. Interactions in cellulose derivative films for oral drug delivery. Prog Polym Sci. 1995;20(5):889–942.
8. Mahajan A, Chhabra N, Aggarwal G. Formulation and characterization of fast dissolving buccal films: a review. Der Pharm Lett. 2011;3(1):152–165.
9. Raymond CR, Sheskey PJ, Owen SC. Handbook of Pharmaceutical Excipients. 5th ed. London: Pharmaceutical Press; 2006.
10. Rowe RC, Sheskey PJ, Weller PJ, editors. Handbook of Pharmaceutical Excipients. 6th ed. London: Pharmaceutical Press; 2006. p. 94–96.
11. Prakash I, DuBois GE, Clos JF, Wilkens KL, Fosdick LE. Development of rebiana, a natural, non-caloric sweetener. Food Chem Toxicol. 2008;46(7 Suppl 1):S75–S82.
12. Siddiqui MN, Garg G, Sharma PK. A short review on a novel approach in oral fast dissolving drug delivery system and their patents. Adv Biol Res. 2011;5(6):291–303.
13. Barnhart SD. Thin film oral dosage forms in modified release. Drug Dev Technol. 2007;1:34–35.
14. Nishimura M, Matsuura K, Tsukioka T, Yamashita H, Inagaki N, Sugiyama T, et al. In vitro and in vivo characteristics of prochlorperazine oral disintegrating film. Int J Pharm. 2009;368(1–2):98–102.
15. Mahajan A, Chhabra N, Aggarwal G. Formulation and characterization of fast dissolving buccal films: a review. Der Pharm Lett. 2011;3(1):152–165.
16. Zayed GM, Abd-El Rasoul S, Ibrahim MA, Saddik MS, Alshora DH. In vitro and in vivo characterization of domperidone-loaded fast dissolving buccal films. Saudi Pharm J. 2020;28(3):266–273.
17. Patil H, Tiwari RV, Repka MA. Hot-melt extrusion: from theory to application in pharmaceutical formulation. AAPS PharmSciTech. 2016;17(1):20–42.
18. Thakur RR, Rathore DS, Narwal S. Orally disintegrating preparations: recent advancement in formulation and technology. J Drug Deliv Ther. 2012;2(3):87–96.
19. Goel H, Rai P, Rana V, Tiwary AK. Orally disintegrating systems: innovations in formulation and technology. Recent Pat Drug Deliv Formul. 2008;2(3):258–274.
20. Prabhu SC, Parsekar SD, Shetty A, Monteiro SS, Azharuddin M, Shabaraya AR. A review on fast dissolving sublingual films for systemic drug delivery. Int J Pharm Chem Sci. 2014;3(2):501–511.
21. Daud AS, Sapkal NP, Bonde MN. Development of Zingiber officinale in oral dissolving films: effect of polymers on in vitro, in vivo parameters and clinical efficacy. Asian J Pharm. 2011;5(3).
22. Nair AB, Kumria R, Harsha S, Attimarad M, Al-Dhubiab BE, Alhaider IA. In vitro techniques to evaluate buccal films. J Control Release. 2013;166(1):10–21.
23. Sievens-Figueroa L, Bhakay A, Jerez-Rozo JI, Pandya N, Romañach RJ, Michniak-Kohn B, et al. Preparation and characterization of hydroxypropyl methyl cellulose films containing stable BCS class II drug nanoparticles for pharmaceutical applications. Int J Pharm. 2012;423(2):496–508.

24. Liew KB, Tan YTF, Peh KK. Characterization of oral disintegrating film containing donepezil for Alzheimer disease. AAPS PharmSciTech. 2012;13(1):134–142.
25. Ahmed MG, Charyulu RN, Harish NM, Prabhu P. Formulation and in vitro evaluation of chitosan films containing tetracycline for the treatment of periodontitis. Asian J Pharm. 2009;3(2).
26. Saini S, Nanda A, Dhari J. Formulation, development and evaluation of oral fast dissolving anti-allergic film of levocetirizine dihydrochloride. J Pharm Sci Res. 2011;3(7):1322.
27. El-Setouhy DA, El-Malak NSA. Formulation of a novel tianeptine sodium orodispersible film. AAPS PharmSciTech. 2010;11(3):1018–1025.
28. Lakshmi PK, Sreekanth J, Sridharan A. Formulation development of fast releasing oral thin films of levocetirizine dihydrochloride with Eudragit® EPO and optimization through Taguchi orthogonal experimental design. Asian J Pharm. 2011;5(2).
29. Arya A, Chandra A, Sharma V, Pathak K. Fast dissolving oral films: an innovative drug delivery system and dosage form. Int J ChemTech Res. 2010;2(1):576–583.
30. Dixit RP, Puthli SP. Oral strip technology: overview and future potential. J Control Release. 2009;139(2):94–107.
31. Gauri S, Kumar G. Fast dissolving drug delivery and its technologies. Pharma Innov. 2012;1(2 Part A):34.

HOW TO CITE: Radhika D. Holkar*, P.G. Patil, S. J. Dighade, Establishment of Animal Research Facilities in Review on Oral Fast Dissolving Film Technology: Materials, Methods, Int. J. of Pharm. Sci., 2026, Vol 4, Issue 6, 3740-3751. https://doi.org/10.5281/zenodo.20705329