International Journal of Pharmaceutical Research and Applications
Volume 9, Issue 2 Mar-Apr 2024, pp: 2338-2342 www.ijprajournal.com ISSN: 2456-4494

A Review on Oral Dispersible Film

Akshay Parmar*, Dr.Chainesh Shah, Dr. Umesh Upadhyay
Sigma Institute Of Pharmacy, Bakrol, Vadodara-390019

Date of Submission: 28-04-2024 Date of Acceptance: 08-05-2024

ABSTRACT
Orodispersible Films, or ODFs for short, are drug delivery systems that can be produced in a variety of ways on a large scale or for individualized medications and small-scale pharmacies. There are some restrictions on ODFs and how they are made. Numerous drug organizations and scholarly exploration habitats across the world collaborate to adapt to these issues and furthermore to find new details for a wide cluster of APIs what could make their turn out productive for themselves and helpful for patients too.Current patient-centric strategies include personalizing ODF formulations to meet the specific requirements of each patient and developing ODFs with patient-friendly characteristics like improved taste masking, simplified administration, and increased patient compliance. For rapid advancement in the rapidly developing field of orodispersible drug delivery, it is essential to investigate novel functional excipients that have the potential to improve the permeation of fragile proteins, high-molecular-weight polar drugs, and oligonucleotides.
KEYWORDS:Orodispersible films, drug delivery, pharmaceutical manufacturing, polymers

I. INTRODUCTION[1-5]

Tablets and cases are usually utilized strong oral medication details. However, for some patients, using these dosage forms on a daily basis is difficult, if not impossible. There are a few gatherings with gulping hardships, a feeling of dread toward stifling or dysphagia. These issues may be capable by geriatric, pediatric, or insane patients, individuals after sedation, with Parkinson's sickness, or Alzheimer illness. For some patients, nausea or a reduced water intake plan are additional reasons to avoid taking tablets or capsules. Additionally, because tablets and capsules require water for the proper disintegration and release of active pharmaceutical ingredients (APIs) over the gastrointestinal tract (GIT), travelers' limited access to water may be a problem.

To conquer these issues, orodispersible movies (ODFs) are viewed as an elective medication structure for tablets or cases. ODFs break up or deteriorate in the mouth after contact with spit (no water is required for this reason) and structure an answer or suspension that might be effortlessly gulped. Separating into delicate particles in the mouth forestalls distress for patients. Besides, the expansion of flavor enhancers or the utilization of Programming interface flavor-covering advancements can enormously build the inclination for this type of the medication, particularly in youngsters. The conveyance of medications by means of quick dissolving films is additionally a powerful option for drugs with low bioavailability when managed by different courses.

Fig1: oral film[26]

The European Pharmacopeia, published by Eur.), ODFs are characterized as sheets, either single or complex, made out of suitable materials and are expected for quick scattering in the mouth. They quickly crumble/break up in spit to shape an answer or suspension, subsequently empowering fast retention and conveyance of the medication into the circulatory system or a fast neighborhood impact. Additionally, ODFs provide consistent and rapid drug release, which may increase the bioavailability of certain medications.

The oral depression is lavishly vascularized and has low enzymatic movement, which might possibly support the bioavailability of medications with low watery solvency. This course is profitable for those medications characterized under the biopharmaceutical characterization

International Journal of Pharmaceutical Research and Applications
Volume 9, Issue 2 Mar-Apr 2024, pp: 2338-2342 www.ijprajournal.com ISSN: 2456-4494

framework (BCS) as Class II and Class IV. Fast pervasion across the mucosal covering of the oral hole can evade corrosive hydrolysis in the stomach and starting hepatic digestion. This pathway is especially appropriate for intense drugs, particularly those intended for intense circumstances, where they make a quick remedial difference, essentially due to oromucosal and pregastric retention, as well as immediate admittance to the jugular vein. However, certain substances are only absorbed through the gastrointestinal system after ingestion.

1.1.1 SUBLINGUAL ROUTE[6-8]

A Sublingual course is a fast beginning of activity and preferable patient consistence over orally ingested tablets. Sublingual in a real sense importance is "under the tongue", administrating substance by means of mouth so that the substance is quickly retained through veins under tongue. The piece of medication consumed through the sublingual veins sidesteps the hepatic first- pass metabolic cycles giving adequate bioavailability. Dosing geriatric, pediatric, and psychiatric dysphagic patients with sublingual technology is simple. With fewer side effects, sublingual drug delivery exhibits faster therapeutic action than oral ingestion. This survey features benefits, inconveniences, different sublingual Organ, sublingual detailing, for example, tablets, films drop, showers and so on, assessment boundaries.

Fig2Sublingualroute[27]

1.2 ADVANTAGES[9-11]

1. Advantageous dosing.
2. No water required.
3. No gamble of chocking.
4. masked taste.
5. Upgraded soundness.
6. Worked on persistent consistence.
7. The medication enters the fundamental flow with diminished hepatic first pass impact.
8. Site explicit and neighbourhood activity.
9. Accessibility of enormous surface region that prompts quick crumbling and disintegration inside oral cavity.
10. precision of the dose in comparison to syrup.

1.3 DISADVANTAGES[12-14]

1. The polymer should be dissolvable in an unpredictable dissolvable or water.
2. A steady arrangement with a sensible least strong substance and thickness ought to be formed.
3. Development of a homogeneous film and delivery from the projecting help must be possible.
4. There stay various specialized restrictions with utilization of film strips; the thickness whileprojecting the film. Glass Petri plates can't utilized for cast.
5. Dose uniformity is another technical issue with these dosage forms.
6. Films are difficult to pack and require special equipment for packaging.

1.4 METHOD OF PREPARATION[15-20]

Different methods for achieving fast dissolving film formulation by the following

a. Solvent casting method
b. Semisolid casting method
c. Hot melt extrusion
d. Solid dispersion extrusion
e. Rolling method.

a. Solvent casting method:

This cycle includes dissolving the medication alongside different excipients in a reasonable dissolvable while likewise dissolving water-solvent polymers in the dissolvable. The two arrangements are then consolidated and agitated. The air rises in this arrangement are consequently settled by vaporizing it to remove the gas. The last step is to projected the air pocket free arrangement into a Petri dish and let it dry. The foundation of the ongoing film arrangement is effectively disintegrated in spit without framing insoluble materials, and it has been utilized in oral consideration items to treat foul breath.

b. Semisolid casting method:

This method makes a water-dissolvable film-shaping polymer arrangement. Then the resultant arrangement is blended in with a corrosive insoluble polymer solution (for instance, butyrate and phthalate of cellulose acetate). The gel mass is then created by adding the appropriate amount of plasticizer. The movies or strips are then projected

International Journal of Pharmaceutical Research and Applications
Volume 9, Issue 2 Mar-Apr 2024, pp: 2338-2342 www.ijprajournal.com ISSN: 2456-4494

utilizing heat-controlled drums from the gel bulk. The movies ought to be somewhere in the range of 0.015 and 0.05 inches thick. The number of the film-framing polymer to the corrosive insoluble polymer ought to be 1:4.

c. Hot melt extrusion:

A hot melt extruder is used in this procedure. In this strategy, a polymer is warmed and afterward formed into a film. A combination of dry drug materials, including Programming interface, is added to the container, before being heated, mixed, and extruded as molten structure by the extruder. The film is projected utilizing the liquid mass that has presently set. The projecting and drying process is a significant stage. This technique has a great deal of advantages, for example, the chance of ceaseless activity, negligible item squander, great control of working boundaries, more limited home times and lower temperatures for the mix of drugs, no organic solvents, and scalability

d. Solid dispersion extrusion:

When an inert carrier is used to disperse one or more active chemicals in a strong structure while nebulous hydrophilic polymers are available, Solid dispersion is the name for this phenomenon. In this cycle, meds are before being added to the polyethylene, they are dissolved in appropriate solvents. glycol liquefy at a temperature underneath 70°C. At last, utilizing kicks the bucket, strong scatterings are shaped into the movies

e. Rolling method:

In the moving technique, a medication containing arrangement or suspension is moved on a transporter. Water and a liquor water combination make up the greater part of the dissolvable. The film is cut into the ideal shapes and sizes following its drying on the rollers. Using a processor with a high shear, additional materials, including the dynamic substance, are broken down in a little sum of fluid dissolvable. Hydrocolloids that are water solvent are broken down in water to make a homogeneous thick arrangeme.

1.5 EVALUATIONS[21-25]

- **Weight Uniformity:**

Movies can be burdened insightful equilibrium and average weight not entirely set in stone for each film. It is valuable to guarantee that a film containslegitimate measure of excipients and drug.

- **Thickness:**

The thickness of film can be estimated by micrometer screw check at various vital areas (something like 5 areas). This is fundamental to decide consistency in the thickness of the movie as this is straightforwardly connected with the precision of portion in the film.

- **Tack test:**

It is the diligence with which the strip sticks to an frill or a piece of paper that has been passed into contact with the strip. There are eight phases of the film drying process; instruments are additionally accessible for this study.

- **Tensile strength:**

It is greatest pressure applied to a place where the strip example break.
Tensile strength=F/a x b (1+L/l)

- **Disintegration time:**

The breaking down time cutoff of 30 s or less for orally crumbling tablets portrayed in CDER direction can be applied to quick dissolving oral strips. Albeit, no authority direction is accessible for oral quick deteriorating films strips, this might be utilized as a subjective rule for quality control test or at advancement stage. Pharmacopeia deteriorating test mechanical assembly might be utilized for this study. Commonplace crumbling time for strips is 5-30 s.

- **Drug content and content uniformity**

Content not entirely set in stone by assessing the Programming interface content in the singular strip. The restriction of content consistency is 85-115 %.

- **Folding endurance:**

Collapsing not set in stone by continued collapsing of the strip at a similar spot till the strip breaks. The times the film is collapsed without breaking is figured as the collapsing perseverance esteem.

- **Young's modulus:**

The strip's stiffness is measured by Young's modulus. addressing the proportion of applied worry about the strain in the versatile deformity area.

II. CONCLUSION

Quick dissolving films enjoy upper hands over traditional dose structures. Quick dissolving

International Journal of Pharmaceutical Research and Applications
Volume 9, Issue 2 Mar-Apr 2024, pp: 2338-2342 www.ijprajournal.com ISSN: 2456-4494

films are thought of as the fundamental medication conveyance framework because of fast breaking down furthermore, further developed disintegration.The fast-dissolving thin film has not been extensively studied in the literature, but it appears to be an ideal dosage. structure for use in small kids, particularly in geriatric and pediatric patients.This dose structure is appropriate in different crisis conditions like hypersensitive responses, asthmatic assaults, and hypertension, where the quick beginning of activity is required. So this innovation is developing quick, testing generally drug organizations to foster oral movies for an extensive variety of dynamic drug fixings.

REFRENCES:

[1]. Borges AF, Silva C, Coelho JF, Simoes S. Oral films: Current status and future perspectives: I-galenical development and quality attributes. J Control Release. 2015;206:1-19.

[2]. De Robertis S, Bonferoni MC, Elviri L, Sandri G, Caramella C, Bettini R. Advances in oral controlled drug delivery: The role of drug-polymer and interpolymer non-covalent interactions. Expert Opin Drug Deliv. 2015;12(3):441-53.

[3]. Thabet Y, Breitkreutz J. Orodispersible films: Product transfer from lab-scale to continuous manufacturing. Int J Pharm. 2018;535(1-2):285-92.

[4]. Cilurzo F, Musazzi UM, Franze S, Selmin F, Minghetti P. Orodispersible dosage forms: Biopharmaceutical improvements and regulatory requirements. Drug Discov Today. 2018;23(2):251-9.

[5]. Karki S, Kim H, Na S-J, Shin D, Jo K, Lee J. Thin films as an emerging platform for drug delivery. Asian J Pharm Sci. 2016;11(5):559-74.

[6]. Borges AF, Silva C, Coelho JF, Simoes S. Outlining critical quality attributes (CQAs) as guidance for the development of orodispersible films. Pharm Dev Technol. 2017;22(2):237-45.

[7]. Walsh J, Cram A, Woertz K, Breitkreutz J, Winzenburg G, Turner R, Tuleu C. Playing hide and seek with poorly tasting paediatric medicines: Do not forget the excipients. Adv Drug Deliv Rev. 2014;73:14-33.

[8]. Krampe R, Visser JC, Frijlink HW, Breitkreutz J, Woerdenbag HJ, Preis M. Oromucosal film preparations: Points to consider for patient centricity and manufacturing processes. Expert Opin Drug Deliv. 2016;13(4):493-506.

[9]. Scarpa M, Paudel A, Kloprogge F, Hsiao WK, Bresciani M, Gaisford S, Gaisford S, Orlu M. Key acceptability attributes of orodispersible films. Eur J Pharm Biopharm. 2018;125:131-40.

[10]. Kushwaha V, Akhtar J, Usmani S, Singh SP. A review on fast dissolving formulation technologies. World J Pharm Pharma Sci. 2015;11(14):574-85.

[11]. Tomar P, Gupta SK, Gautam N. Formulation and evaluation of orodispersible film of antihistaminic drug diphenhydramine hcl. World J Pharm Pharma Sci. 2017;6(8):1632-40.

[12]. Murthy AV, Ayalasomayajula LU, Earle RR, Jyotsna P. Formulation and Evaluation of Tramadol Hydrochloride Oral Thin Films. Int. J. Pharm. Sci. 2018;9:1692–1698.

[13]. Pragathi P, Vishnu P, Abbulu K. Formulation and evaluation of lovastatin oral disintegration thin films. GSC Biological and Pharmaceutical Sciences. 2018;3:35–42.

[14]. Bhowmik SC, Alam M, Pathan SI. Preparation and evaluation of palonosetron hydrochloride oral thin film. Bangladesh Pharmaceutical Journal. 2019;22:228–234.

[15]. Rani TN. Formulation development and optimization of oral thin films of zolpidem tartarate. Medical Science & Healthcare Practice. 2017;1:26- 41.

[16]. Venkateswarlu K. Preparation and evaluation of fast dissolving buccal thin films of bufotenin. Journal of In Silico & In Vitro Pharmacology. 2016;2:1–5.

[17]. Mushtaque M, Muhammad IN, Fareed Hassan SM, Ali A, Masood R. Development and pharmaceutical evaluation of oral fast dissolving thin film of escitalopram: A patient friendly dosage form. Pak J Pharm Sci. 2020;33:183–189.

[18]. 36. Bonde M, Sapkal N, Daud A. Full factorial design, physicochemical characterization of phenylephrine HCl loaded oral thin film. Asian Journal of Pharmaceutics. 2015;9:137–145.

[19]. 37. Adrover A, Pedacchia A, Petralito S, Spera R. In vitro dissolution testing of oral

thin films: A comparison between USP 1, USP 2 apparatuses and a new millifluidic flow-through device. Chemical Engineering Research Design. 2015;95:173–178.

[20]. amróz, W.; Szafraniec, J.; Kurek, M.; Jachowicz, R. 3D printing in pharmaceutical and medical applications–recent achievements and challenges. Pharm. Res. 2018, 35, 176.

[21]. Annaji, M.; Ramesh, S.; Poudel, I.; Govindarajulu, M.; Arnold, R.D.; Dhanasekaran, M.; Babu, R.J. Application of extrusion-based 3D printed dosage forms in the treatment of chronic diseases. J. Pharm. Sci. 2020, 109, 3551–3568.

[22]. Łyszczarz, E.; Brniak, W.; Szafraniec-Szczęsny, J.; Majka, T.M.; Majda, D.; Zych, M.; Pielichowski, K.; Jachowicz, R. The impact of the preparation method on the properties of orodispersible films with aripiprazole: Electrospinning vs. casting and 3D printing methods. Pharmaceutics 2021, 13, 1122.

[23]. Chaudhary, H.; Gauri, S.; Rathee, P.; Kumar, V. Development and optimization of fast dissolving oro-dispersible films of granisetron HCl using Box–Behnken statistical design. Bull. Fac. Pharm. Cairo Univ. 2013, 51, 193–201.

[24]. Zaman, M.; Hanif, M.; Amjad, M.W.; Mahmood, A.; Shah, S.; Raja, M.A.G.; Rasool, S.; Sarfraz, R.M. Development of thiomer based buccal films for the enhancement of bioavailability: An in-vivo analysis. Pak. J. Pharm. Sci. 2019, 32 (Suppl. S2), 759–764.

[25]. Zaman, M. Formulation and Evaluation of Tizanidine-Meloxicam Mucoadhesive Buccal Films by Central Composite Rotatable Design and Their Pharmacokinetic Studies; Bahauddin Zakariya University Multan: Multan, Pakistan, 2018.

[26]. https://images.app.goo.gl/KNT1KBHcc3NxronG9

[27]. https://images.app.goo.gl/w6MBr3AJUvCLKHKx5