IJPSR (2020), Volume 11, Issue 12 (Review Article)

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 26 February 2020; received in revised form, 25 May 2020; accepted, 24 November 2020; published 01 December 2020

ORAL STRIPS: A NOVEL DRUG DELIVERY TECHNOLOGY

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Keywords:

Oral strip, Oral dispersible films, Solvent casting, Semisolid casting, Hot melt extrusion, Solid dispersion extrusion, Rolling

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ABSTRACT: In the development of a new drug molecule, there are many problems with respect to the dissolution, absorption, and bioavailability. Thus, formulation scientists are majorly focusing on the development of the formulation, which will increase the efficacy of the existing drugs. Oral dispersible films are one of such a novel approach. In given review article, the advantages of oral dispersible films over other oral dosage form and especially over oral dispersible tablets and their applications are discussed. In further part the major advantages regarding first-pass metabolism, disable patients, fast onset, *etc*., are covered. Furthermore, the overview of all the ingredients used in the formulation of fast dissolving films with the evaluation of these films is discussed in the given review article. Solvent casting, semisolid casting, hot-melt extrusion, solid dispersion extrusion, rolling are the methods which are employed, along with the evaluation parameters like thickness, tear resistance, dryness test of the prepared films are also explored in the article. This review article gives a complete overview of oral dispersible films and their novel approach in the formulation.

INTRODUCTION: Among the delivery routes, the oral route is the most acceptable with respect to patient compliance. Many pharmaceutical firms have directed their research activity in reformulating existing drugs into new dosage forms. One such relatively new dosage form is the oral film, a thin film that is prepared using hydrophilic polymers that rapidly dissolves on the tongue or buccal cavity. Developing formulations for children has been a challenging task. Amongst other factors, the palatability of formulations of pediatric oral medications is one of the most significant factors influencing compliance with therapeutic regimens [1, 2].

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.11(12).6010-19

This article can be accessed online on www.ijpsr.com

DOI link: http://dx.doi.org/10.13040/IJPSR.0975-8232.11(12).6010-19

Although solid dosage forms are widely accepted by elders and adolescents, younger children tend to prefer liquid formulations that are easier to swallow [3]. Keeping the ease of administration and swallowing in mind, pharmaceutical research has led to the development of Oral Disintegrating Tablets (ODTs). ODTs have been defined as "A solid dosage form containing medicinal substances which disintegrate rapidly, usually within a matter of seconds, when placed upon the tongue".

United States Food and Drug Administration further defines ODTs as solid oral preparations that disintegrate rapidly in the oral cavity, with an *in-vitro* disintegration time of approximately 30s or less, when based on the United States Pharmacopeia (USP) disintegration test method or alternative [4]. Research and development in the oral drug delivery segment have led to the transition of dosage forms from simple conventional tablets/ capsules to modified-release tablets/capsules to an oral disintegrating tablet (ODT) to wafer to the

recent development of oral strip (OS). The concept of the oral film comes from confectionary industry [5-11]. Basically, the OS can be considered as an ultra-thin strip of postage stamp size with an active agent or active pharmaceutical ingredient and other excipients. The advantages of the convenience of dosing and portability of OS have led to a wider acceptability of this dosage form by the pediatric as well as geriatric population equally. Generally, the shelf life of the film is 2-3 years; it depends on the API added to the film, but films are very sensitive to environmental moisture [12]. The introduction of ODT in the market was accompanied by educating the mass about the proper way to administer the product like giving instructions "do not swallow" or "do not chew". The process of manipulating the ODT in the oral or buccal cavity was also important. However, since the OST derived products were readily popular in the market in the form of breath-freshening strips, no further efforts were needed to re-instruct the populace about the technique of administration of this dosage form.

This dosage form enjoys some distinct advantages over other oral formulations such as-

1. Availability of larger surface area that leads to rapid disintegrating and dissolution in the oral cavity.

2. The disadvantage of most ODT is that they are fragile and brittle, which warrants a special package for protection during storage and transportation. Since the films are flexible, they are not as fragile as most of the ODTs. Hence, there is the ease of transportation and during consumer handling and storage.

3. As compared to drops or syrup formulations, precision in the administered dose is ensured from each of the strips.

4. The advantage of the ease of swallowing and no need for water has led to better acceptability amongst dysphagic patients. The difficulty encountered in swallowing tablets or capsules is circumvented. The large surface area available in the strip dosage form allows rapid wetting in the moist buccal environment. The dosage form can be consumed at anyplace and anytime as per the convenience of the individual.

5. The oral or buccal mucosa is highly vascularized; drugs can be absorbed directly and can enter the systemic circulation without undergoing first-pass hepatic metabolism. This advantage can be exploited in preparing products with improved oral bioavailability of molecules that undergo first-pass effect [13].

6. Since the first pass effect can be avoided, there can be a reduction in the dose, which can lead to a reduction in side effects associated with the molecule.

Applications: [14-17]

- ✓ Oral films are preferred for local action and also to manage pain, allergies, sleeping difficulty, and CNS disorders.
- ✓ Dissolvable films are feasible for topical application for wound care as analgesics or antimicrobial agents.
- ✓ Oral films are applicable to enhance the bioavailability of poorly bioavailable drugs.
- ✓ Taste masking of bitter drugs.
- ✓ Dissolvable films are loaded with sensitive reagents to allow controlled release when exposed to biological fluids or to create isolation barriers for separating multiple reagents to enable a timed reaction with a diagnostic device.

Formulation Consideration: [18, 19] From the regulatory perspective, all the excipients used in the formulation and development of oral films and are regarded as safe (GRAS listed) and should be approved for use in oral pharmaceutical dosage forms. The area of oral thin films is 1-20cm^2 (depend on the dose and drug loading containing drug). An overview of different ingredients employed in the formulation of fast dissolving films is given in **Table 1.**

TABLE 1: COMPOSITION OF FAST DISSOLVING ORAL THIN FILMS

Components	% w/w
Active pharmaceutical ingredient	5- 30
Film-forming polymers	45
Plasticizers	0- 20
Surfactants	q. s.
Sweetening agents	3- 6
Saliva stimulating agents	2- 6
Colouring agents	1
Flavouring agents	10

1. Active Pharmaceutical Ingredients: Different type of API can be successfully incorporated in the oral strip technology. Micronized API can improve the texture of the film and also dissolution and uniformity of the oral fast-dissolving film.

Different molecules can be incorporated into the delivery system. Since the size of the thin films has to be small enough to be conveniently placed on the tongue, those active pharmaceutical ingredients with high doses are not suitable candidates for incorporation into fast dissolving oral thin films.

Ideal characteristics of active pharmaceutical ingredients to be incorporated into fast dissolving oral thin films

1. Low dose
2. Palatability
3. Small molecular weight
4. Stability in saliva
5. The drug has extensive high first-pass metabolism.
6. It should have a quick onset of action.
7. The dug should have high solubility and high permeability (BCS class I).

Some of the suitable candidates for incorporation into a thin film formulation is given in **Table 2**.

Active pharmaceutical ingredients can also be added as milled, micronized or in the form of nanocrystals or microcapsules.

TABLE 2: SUITABLE CANDIDATES ALONG WITH EXCIPIENTS USED FOR INCORPORATION INTO THIN FILM FORMULATION

API	Category	Polymer	Plasticizer	Super-disintegrant	Sweetener	Method of preparation	Property improved
Valdecoxib	NSAIDs	HPMC, Eudragit EPO	Glycerol	-	Aspartame	Solvent casting method	Improve drug release, mask bitter taste
Domperidone	Anti-emetic	PVA	Glycerine	-	Mannitol	Solvent casting method	Quick onset of action
Valsartan	Antihyper-tensive	HPMC (E5, K4M, 50cps), Propylene glycol, guar gum	PEG	-	Sorbitol	Solvent casting method	Taste masking of drug, improve drug solubility and bioavailability
Salbutamol sulphate	Antiasthematic	HPMC, HPC, Sodium Alginate	-	-	Aspartame	Solvent evaporation method	Taste masking of bitter Drug
Metaclopramide Hydrochloride	Anti-emetic	HPMC E6, SCMC	Glycerol	Sodium bicarbonate	Saccharine sodium	Solvent casting method	Patient compliance, physical property improve

1.1. Taste Masking of Bitter Active Pharmaceutical Ingredients: [20-26] Various taste-masking technologies for bitter active pharmaceutical ingredients are given in **Table 3**.

TABLE 3: TASTE MASKING TECHNOLOGIES FOR BITTER ACTIVE PHARMACEUTICAL INGREDIENTS

Active pharmaceutical ingredient	Taste masking technology	Material used
Famotidine Terfenadrine	Coating with polymers	Hydroxypropyl methylcellulose, hydroxyl propyl cellulose, Sodium alginate, carrageenan
Ibuprofen	Inclusion complexation with β-cyclodextrins	Hydroxylpropyl- β- cyclodextrin
Sulphathiazale	Solid dispersion systems	Povidone
Beclamide	Microencapsulation	Gelatin
Pseudoephedrine	Ion- exchange resins	Amberlite CG 50
Chloroquine phosphate	Liposomes	Egg phosphatidylcholine
Chloramphenicol, Clindamycin	Prodrugs	Palmitate ester, Diacetate ester

2. Film Forming Polymers: A variety of polymers are available for the preparation of Oral strips. The polymers can be used alone or in combination to obtain the required strip properties. The film obtained should be tough enough so that there won't be any damage while handling or during transportation. The robustness of the strip depends on the type of polymer and the amount in the formulation [27]. On the other hand, fast-dissolving strip dosage form should have the property to disintegrate in seconds when placed in mouth and deliver the drug to the oral cavity instantaneously. A list of polymers and their properties are given in **Table 4**. As the strip forming polymer (which forms the platform for the OS) is the most essential and major component of the OS, at least 45%w/w of polymer should generally be present based on the total weight of dry OS.

TABLE 4: CHARACTERISTICS OF SOME NATURAL AND SYNTHETIC POLYMERS EMPLOYED IN ORAL FILMS AND THEIR APPLICATIONS

Polymer	Film-forming ability	Viscosity	Melting point	Solubility	Application
Pullulan gum	It form flexible film in 5-25% solution	It is 100 180mm^2/s viscous at 10%w/w, and at 30°C	107°C	Soluble in hot and cold water	Used in the food industry to provide bulk and texture, as plasma expender in replacement of Dextran, for coating of immediate-release tablets, for preparation of capsule shell
Sodium Alginate	It have film-forming capacity	Typically, a 1% w/v aq. Soln, at 208C, will have a viscosity of 20 400 mPa s (20–400 cP)	>300°C (572°F)	Slowly soluble in water and form colloidal solution	Stabilizing agent; suspending agent; tablet and capsule disintegrant; tablet binder; viscosity increasing agent
Hydroxy-propyl cellulose	It has a good film forming property and 5%w/w solution is generally used for film coating	The viscosity of solutions ranges from 75 mPa s-6500 mPa s	It softens at 130 °C; chars at 260–275 °C	It is freely soluble in water, soluble in many cold and hot polar organic solvents	Used as a tablet binder, in preparation of modified release dosage form, microcapsules, As a thickening agent in the oral and topical formulations. Due to its nonionic nature, as emulsifier in the cosmetic formulations
Hydroxy-propyl methyl cellulose	It has a film-forming ability in 2–20%w/w concentrations	Viscosity of various grades ranges from 3 mPa s–100,000 mPa s	Browns at 190 200 °C glass transition temperature is 170–180 °C	Soluble in cold water, forming a viscous colloidal solution, insoluble in chloroform, ethanol	Used as a tablet binder, film coating agent, film-forming agent and as a matrix for use in extended-release formulations, suspending and thickening agent, emulsifier, suspending agent and stabilizing agent in gels and ointments, adhesive in plastic bandage and as a wetting agent in contact lenses
Polyvinyl alcohol	Good film-forming property	High viscosity 40.0–65.0, Medium viscosity 21.0– 33.0, Low viscosity 4.0–7.0	228°C for fully hydrolyzed grades; 180-1908°C for partially hydrolyzed grades	Soluble in water; slightly soluble in ethanol (95%); insoluble in organic solvents	Coating agent; lubricant; stabilizing agent; viscosity increasing
Carboxy-methyl cellulose	Good film-forming property	The 1% w/w aqueous solution has viscosity in the range of 5–13,000 mPa s	Browns at 227 °C and chars at 252 °C.	It is easily dispersed in water to form a clear or colloidal solution	Used as a viscosity increasing agent, stabilizer for preparation of suspensions and emulsions, utilized as a binder or disintegrant, cryoprotective agent. It is reported for use in combination with other film-forming polymers for preparation of oral films

2.1. Ideal Properties of Polymers:

1. Non- toxic
2. Non- irritant
3. Bland
4. Should be stable for a long period.
5. Should not alter properties of the drug or the excipients incorporated.
6. Inexpensive
7. Should have good wettability and spreadability.
8. Should not retard the disintegration time of the film.
9. Should have optimum peel strength and tensile strength.

3. Plasticizers: Plasticizer is a vital ingredient of the Oral strip formulation. It helps to increase the flexibility of the strip and reduces the fragility of the strip. The transitioning glass temperature of the polymer is decreased by plasticizers. Plasticizers are chosen on the basis of compatibility with polymer and type of solvent used in strip forming. Flow and strength of the polymer are enhanced by the use of plasticizers. Glycerol, propylene glycol, low molecular weight polyethylene glycols, phthalates such as dimethyl phthalate, diethyl phthalate, dibutyl phthalate, citrate derivatives such as tributyl citrate, triethyl citrate, acetyl citrate, triacetin, and castor oil are some of the commonly used plasticizers [28-36]. Typically, the plasticizers are used in a concentration of 0-20%w/w of the dry polymer weight. However, inappropriate use of plasticizer may lead to film cracking, splitting, and peeling of the strip [37-39]. Some of them also affect the absorption rate of the drug.

The plasticizer should impart permanent flexibility to the film. They are important for their property of decreasing glass transition temperature to 40-60°C for Non-aqueous system and below 75°C for the aqueous system.

Some drug molecules themselves act as plasticizers. An example of this phenomenon is Ibuprofen, which interacted with Eudragit RS 30 D and played the role of a plasticizer. The glass transition temperature of Eudragit RS 30 D decreased. The smooth film formation was observed due to the hydrogen bonding between the drug and the polymer. When the concentration of ibuprofen is increased, its dissolution rates were found to be decreased [40].

Plasticization takes place by two mechanisms-internal plasticization, which involves chemical interaction, and external plasticization. The external plasticization does not involve chemical interactions in the product. Hence, it is the preferred mechanism of polymerization.

Plasticizers used in different thin film formulations are shown in **Table 5.**

TABLE 5: PLASTICIZERS USED IN DIFFERENT THIN FILM FORMULATIONS

Plasticizer	Thin film formulation
Propylene glycol	Tianeptine sodium [41]
Polyethylene glycol 400	Rizatriptan benzoate [42]
Polyethylene glycol 4000	Ambroxol hydrochloride [43]
Glycerin	Nicotine [44]

4. Surfactants: They cause the film to dissolve within seconds and release API quickly. Here they act as wetting and dispersing agents. Sodium lauryl sulfate and polysorbates are commonly used surfactants. One of the most important surfactant is Poloxamer 407 that is used as wetting, solubilizing and dispersing agent [45].

5. Sweetening Agent: [46-50] This is an important component used in oral films. Generally, sweeteners are used for the taste masking of bitter drugs so that drugs are palatable. Sweeteners are used alone or in combination between the concentrations of 3-6% w/w. Natural as well as artificial sweeteners are used in the preparation of the oral film. Natural sweeteners used are glucose, sucrose, maltose, xylose, ribose, stevioside, dextrose, fructose, liq. glucose and isomaltose. Fructose is widely used as a sweetener. It is sweeter than mannitol and sorbitol. Artificial sweeteners used in oral films are sodium or calcium saccharin salts, cyclamates salts, Acesulfame K, etc. Acesulfame K and sucralose have more than 200 & 600 times sweetness. Neotame and Altitame are 2000-8000 times sweeter than sucrose. Dipeptide based sweeteners: Aspartame. Protein-based sweetener: Thaumatin I & II.

6. Saliva Stimulating Agents: [51-53] This causes increases in saliva production. This leads to an increase in the disintegration rates of the formulation. Generally, food-grade acids can be used as saliva stimulating agents. Citric acid, malic acid, lactic acid, ascorbic acid, and tartaric acid are some of the saliva stimulating agents. Among them, citric acid is the most preferred one and is most widely used. These agents can be used alone or in combination. The stimulation of salivation can be measured by comparing the amount of resting flow and stimulated flow at an equal time under the same conditions.

7. Coloring Agents: FD&C approved coloring agents, EU colors, natural coloring agents; pigments can be incorporated up to 1% w/w but not more than that. These are added into the formulation when some of the formulation ingredients are in solution or suspension form [54, 55].

8. Flavoring Agents: The selection of flavor depends on the type of drug to be incorporated. The acceptance of the oral disintegrating or dissolving formulation by an individual depends on the initial flavor which is perceived in the first few seconds after the dosage form has been consumed, and the after taste of the formulation, which lasts for at least about 10 min [56]. The use of flavors can be alone or in combination. Up to10 % w/w flavors are preferably added in the formulations.

Flavors used for taste masking of different tastes are given in **Table 6.**

TABLE 6: FLAVORS USED FOR TASTE MASKING OF DIFFERENT TASTES

Basic taste	Flavors used for taste masking
Bitter	Wild cherry, mint, anise, walnut, chocolate
Sweet	Vanilla, fruit, berry
Salty	Mint, butterscotch , peach, vanilla, wintergreen, maple, apricot
Sour	Raspberry, citrus, licorice root

Method of Preparation: [57-75] Different methods for preparation of oral films is shown in **Fig. 1**.

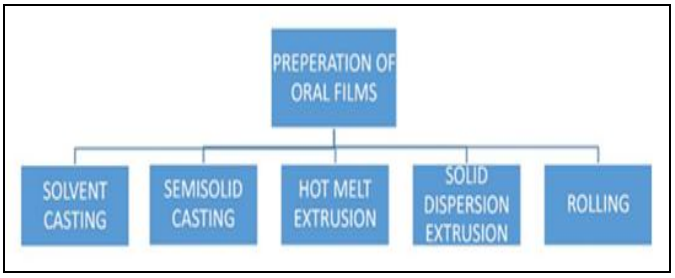

FIG. 1: METHODS OF PREPARATION OF ORAL FILMS

1. Solvent Casting Method: This is the most preferred method to manufacture fast dissolving film. In this method, firstly, water-soluble ingredients are mixed in water to form a viscous solution. Using a high shear processor, the initially mixed small amount of solution prepared by dissolving API and remaining ingredients is combined with the bulk. A vacuum is used to remove the air entrapped. The solution formed is then cast as a film and pour the solution into a glass mould and allow the solution to dry in an oven at 45-50°C which is then cut into pieces of the desired size as shown in **Fig. 2**.

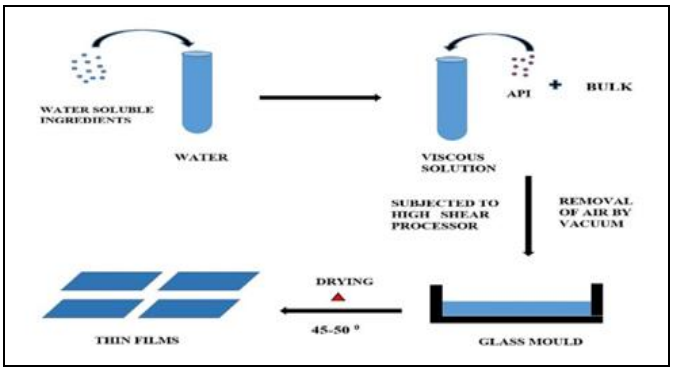

FIG. 2: SOLVENT CASTING METHOD

2. Semisolid Casting: This method is preferred when acid insoluble polymers are used in the preparation of oral fast dissolving film. Firstly solution of water soluble polymers is prepared. The solution is added to a solution of acid insoluble polymer. Plasticizer is added in the appropriate amount so that a gel mass is formed. The gel mass formed is then casted into the films or ribbons by using heat controlled drums. Acid insoluble polymers used to prepare films include: cellulose acetate phthalate, cellulose acetate butyrate. The thickness of the film is about 0.015-0.05 inches. Acid insoluble polymer and film forming polymer are used in the ratio of 1:4.

3. Hot Melt Extrusion: In this method, the polymers which have low molecular weight and low viscosity are preferred. The drug is mixed with the carrier in the solid form so that granular material is formed. These granules are then dried and then introduced into the extruder. For the granules to remain 3-4 min inside the extruder, the speed of the screw should be 15 rpm. The processing temperatures should be 80°C (zone 1), 115°C (zone 2), 100°C (zone 3), and 65°C (zone 4). The extrudate (T= 65°C) was then pressed into a cylindrical calendar to obtain a film.

4. Solid Dispersion Extrusion: This method is more used with immiscible components. These components are taken and extruded with drugs. Solid dispersion is then prepared, and by means of dies, the solid dispersion is shaped into films.

5. Rolling Method: In this method, firstly solution or suspension of a drug is prepared, which have certain rheological consideration. According to components, the solvent can be used as a water or a mixture of water and alcohol. The solution or suspension is rolled over the carrier. Films are dried on the rollers and cut into desired shapes and sizes.

Evaluation of the Oral Film:

1. Thickness: The thickness of the strip can be measured by a micrometer screw gauge at different strategic locations. This is essential to ascertain uniformity in the thickness of the film as this is directly related to the accuracy of the dose in the strip.

2. Dryness Test/Tack Tests: Around eight stages of the film drying process have been identified, and they are set-to-touch, dust-free, tack-free (surface dry), Dry-to-touch, dry-hard, dry-through (dry-to-handle), dry-to-recoat, and dry-print-free. Although these tests are primarily used for paint films, most of the studies can be adapted intricately to evaluate pharmaceutical OS as well [76]. The details of the evaluation of these parameters can be checked elsewhere and are beyond the scope of this review. Tack is the adhering ability of the strip to a paper which is in contact with it. There are instruments available for this study.

3. Tensile Strength: It is the maximum stress that breaks the strip if applied at the point. It can be

calculated as load at which strip breaks divided by cross-section of the strip and given in the equation below:

Tensile strength = Load at failure × 100 / Strip thickness × Strip width

4. Percent Elongation: Sample stretches when stress is applied, and that is referred to as a strain. It is the ratio of change in length by the initial length of the strip. Generally, elongation of strip increases as the plasticizer content increases [77].

% Elongation = Increase in length of strip × 100 / Initial length of strip

5. Tear Resistance: Tear resistance of a film or sheet is a complex function of its ability to resist the rupture. Basically, very low rate of loading 51 mm (2 in.) /min is employed and is designed to measure the load to initiate tearing. The maximum load (that just initiates the tearing) required to tear the strip is recorded as the tear resistance value in Newtons (or pounds-force).

6. Young's Modulus: Young's modulus or elastic modulus is the measure of the stiffness of strip. It is represented as the ratio of applied stress over strain in the region of elastic deformation as follows:

Young's modulus = Slope × 100 / Strip thickness × cross - head speed

Hard and brittle strips demonstrate high tensile strength and Young's modulus with small elongation.

7. Folding Endurance: It is calculated 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 [78].

8. Disintegration Time: [79] The disintegration time limit of 30 s or less for orally disintegrating tablets described in Center for Drug Evaluation and Research (CDER) guidance can be applied to fast dissolving oral strips. Although no official guidance is available for oral fast disintegrating films/strips, this may be used as a qualitative guideline for quality control test or at the development stage. Pharmacopoeial disintegrating test apparatus may be used for this study. The strip typically gets disintegrated in 5-30 sec.

9. Dissolution Test: Standard basket or paddle apparatus can be used as described in any pharmacopeia. The dissolution medium will essentially be selected as per the sink conditions and the highest dose of the API [80]. For floating strips, the paddle apparatus is used.

10. Assay/Drug Content and Content Uniformity: This can be checked according to any pharmacopeia for any particular active constitute. This is determined by estimating the API content in an individual strip. The limit of content uniformity is 85-115%.

11. Organoleptic Evaluation: It is very important that the strip should have acceptable organoleptic properties cause of its intended oral use with longer timing and faster disintegration rates. It should have flavor and sweetness, which should be acceptable over a larger population. For psycho-logical evaluation special controlled human test panels are used as test models. For this purpose *In-vitro* methods like specially designed apparatus, taste sensors, and different Pharmacopoeial methods are used. These *in-vitro* taste assessment apparatus and methodologies are well suited for high throughput taste screening of oral pharmaceutical formulations. The difference in between the sweetness levels of taste-masking agents can be detected with the help of electronic tongue measurement.

12. Clinical and Regulatory Aspects: [81] In the product approval process (other than the New Drug Application procedure) in the US Food and Drug Administration, if the product is intended to be bioequivalent to that of the existing oral product of the drug, an Abbreviated New Drug Application route is followed. In this, *in-vitro* dissolution studies and therapeutic equivalence (bioequivalence study in which the 90% confidence interval of the log-transformed ratio of Test and Reference product pharmacokinetic parameters AUC0-t, AUC0-inf and C_{max} should be within the acceptable limits of 80% to 125%). There are no clinical studies associated with this generic approval process (section 505(j) of the Food, Drug, and Cosmetics Act). An example of such a case would be comparative bioequivalence between an ODT formulation and OS product. However, developed oral strip products may also exhibit a different

target pharmacokinetic profile compared to the existing marketed product.

The OS product is categorized as 'new dosage form', and section 505(b) (2) approval process needs to be followed. In this case, a new clinical study would be required. A new clinical study awards three years of marketing exclusivity to the product , and this is an advantage. Pre-clinical toxicity studies are not required to be demonstrated if the molecule is the same as that of the approved product. Generally, a randomized, double-blinded, placebo-controlled clinical trial is recommended.

Safety, tolerability, and efficacy features are to be demonstrated in such trials. In Europe, Marketing Authorization approval (Abridged Application) is essential as per the European Medicines Evaluation Agency guidelines. Either of the two modes *i.e.*, the decentralized procedure or the mutual recognition route, can be adopted. The Ministry of Health, Labour, and Welfare is primarily responsible for product approvals in Japan. Many of the regulatory agencies lay special emphasis on the taste and palatability aspects especially if the product is intended to target the paediatric population.

CONCLUSION: Being a consumer-friendly alternative, many of the pharmaceutical companies are switching their product franchise from ODTs to OSTs. This technology option can also provide a good platform for patent non-infringing product development. OST allows a brand extension for products. The OST is a good tool for product life cycle management for increasing the patent life of existing molecules or products. Compared to some of the complicated and expensive process (like lyophilization) used to manufacture ODTs, the OST is relatively easy to fabricate; thus reducing the overall cost of the therapy.

The application of OTF has not only been limited to buccal fast-dissolving system but also expands its horizon to other applications like gastro retentive, topical, implant-able, sublingual delivery options. This delivery platform shows potential business promise for the future in pharmaceuticals, nutraceuticals as well as cosmeceuticals.

AUTHOR CONTRIBUTION: Atreya Karandikar and Vivek Kedar were responsible for the Literature review and writing of the manuscript. Chaitali Surve was responsible for writing, reviewing, and corresponding to the manuscript.

ACKNOWLEDGEMENT: Nil

CONFLICTS OF INTEREST: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

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How to cite this article:
Karandikar A, Kedar V and Surve C: Oral strips: a novel drug delivery technology. Int J Pharm Sci & Res 2020; 11(12): 6010-19. doi: 10.13040/IJPSR.0975-8232.11(12).6010-19.