

Oral Thin Films: A Novel Immediate Release Dosage Form and Drug Delivery System

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Abstract: Oral thin films are the recently emerging novel drug delivery systems which are believed to be enormously expanding their horizons and potentials in the pharmaceutical sector across the world. The dosage form was first developed in 1970's with the viewpoint of geriatrics, pediatrics and patients experiencing difficulty in swallowing the conventional dosage forms. The OTFs are designed in a manner such that on contact with the wet surface i.e., the tongue, the medication can be consumed owing to its instantaneous dissolution in the oral mucosa without need of water. The advantage of the Oral thin film is the drug enters directly into the systemic circulation bypassing the first pass metabolism. The dosage form can be regarded as highly versatile due to ease of self-administration and high patient compliance. This review is an attempt to comprehensively put together the formulation aspects, manufacturing processes as well as the evaluation parameters of this promising dosage form that can revolutionize the world of medicine and pharmacy.

Keywords: Oral Thin Films (OTFs), Solid Dispersion, Hot-Melt Extrusion

1. Introduction

Pharmaceutical dosage forms include an active pharmaceutical ingredient responsible for exhibiting therapeutic action on administration as well as excipients intended for providing bulk to the formulation and aid in its pharmacodynamic activity. The most patient compliant and cost-effective drug delivery systems are considered to be the oral dosage forms. However, there can arise a difficulty in swallowing and chewing by geriatrics and paediatrics [1]. The difficulties of patient compliance mainly related to dysphagia, parkinsonism and mucositis, thus in an approach to overcome this difficulty a novel invention of Fast dissolving drug delivery systems (FDDDS), the oral thin films(also regarded as OTF) had been introduced. Around 85.4 % of the population preferred the OTFs of vitamin D over the oral drop. The oral thin films first came into existence in the 1970's. The first oral dissolving film was introduced by Pfizer called as Listerine intended for the purpose of mouth refreshing. In simpler terms, these are the polymeric matrices along with another components in order to achieve an efficient drug delivery system. OTF also serves as an alternative to overcome limitations like unagreeable taste, instability and tendency of a formulation to microbial contamination. The oral thin films on placing in the oral cavity rapidly disintegrate bypassing the first pass metabolism thereby having an increased bioavailability. Water administration is not required. Super disintegrants have been said to have a promising role in the formulation of OTF. Hydrophilic polymers have been employed in the manufacture of OTF. The transdermal patch technology serves as a basis for the development of this novel FDDDS [2]. OTF have achieved reduction in dose frequency, improved efficacy of a pharmaceutical and also improve the onset of action. The oral thin films could be classified into oromucosal films and orodispersable films. The oromucosal films as name suggests are mucoadhesives meaning are intended to be adhered to sublingual, buccal or palate

mucosa. Thus, according to the site of application oromucosal films could be categorized as buccal, sublingual and palatal.

Whereas the orodispersables are intended to disintegrate instantly in the oral cavity on coming in contact with saliva. The further classification of orodispersable is based on dissolving in oral cavity (orally dissolving films) and disintegration into oral cavity (orally disintegrating films)[3]. Some pharmaceutical formulations manufactured on the basis OTF are anti-tussives, expectorants, anti-asthmatics and antiepileptic. The cost of manufacture of the oral thin films is competitive with that of the conventional tablet dosage forms even with its rapid disintegration ability.

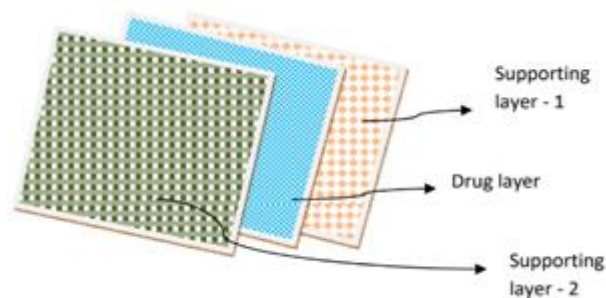


Figure 1: Oral Thin Films [4]

Structure of Oral Mucosa:

Oral mucosa mainly contains three layers of cells –

- 1) **Stratified squamous epithelium**– It is the outermost layer of the oral mucosa. Basement membrane is the interface between connective tissue and epithelial tissue.
- 2) **Lamina propria**– It is basically, a connective tissue which is below the basement membrane.
- 3) **Sub mucous membrane**–The innermost layer of the oral mucosal cavity.

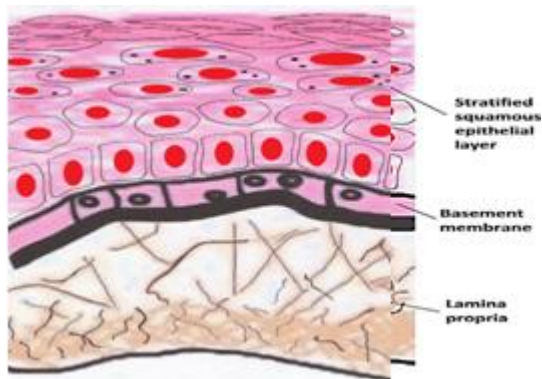


Figure 2: Oral Mucosal Cavity

Advantages of the oral thin films –

- Enhanced bioavailability.
- Greater stability as compared to the liquid dosage forms.
- Less friability as compared to the conventional tablet dosage form.
- Higher disintegration and dissolution due to greater permeation of the oral mucosa.
- Easy transportation.
- Patient compliance is better due to the wide acceptability of the oral route of administration.
- In case of geriatric and paediatric patients the risk of choking is overcome.

Disadvantages of the oral thin films –

- Loss of stability on exposure to high humidity conditions due to the high hygroscopic nature.
- Drugs irritating to the buccal mucosa incompatible Ph cannot be formulated into OTFs.
- High dose drugs cannot be incorporated. The dose of the drug to be formulated as oral thin film should be in the range of 1-30 mg.
- Achieving dose uniformity in the oral thin films can be challenging.

Composition of Oral Thin Films:

OTFs contains following key components –

1) Drug or (API):

API is the core component of polymeric films which are generally comprises of 5-30% (w/w) of the films.

Ex. antiallergic, antiemetic, antimigrant, etc.

The ideal characteristics of an API [5] –

- Pleasant Taste.
- Up to 40 mg of API Dose. (Permeability through mucosal tissue must be good.)
- The molecular weight of API must be smaller. API should be stable in the fluid present in oral cavity.

2) Plasticizer [6,7]:

It prevents breaking of films. It should have compatibility with other ingredients.

Ex. polyethylene glycol, phthalate, citrate derivatives, and castor oil.

3) Surfactants[8]:

They are solubility enhancers which also improves act as wetting, dispersing, or solubilizing agents.

Ex. Sodium Lauryl Sulphate (SLS), Tween, Benzalkonium Chloride.

4) Sweetening and Flavouring Agents[6,8]:

Sweetening and flavouring agents are important for odour and taste masking of the drug. This is mainly for paediatric patients. Natural or artificial sweeteners and flavours can be used.

Ex. Sucrose, fructose, aspartame, sorbitol, acesulfame-K, and sucralose, etc.

5) Saliva stimulating agent[7,8]:

These are useful to produce the saliva in mouth which gives fast disintegration.

Ex. Acids like tartaric, lactic, malic, ascorbic.

6) Superdisintegrants[9]:

They are used for quick disintegration of OTFs.

Ex. Croscarmellose, Sodium starch glycolate, PVP, calcium silicate.

7) Colouring Agents [7,9]:

They are used to enhance the appeal of the film. Mostly, pigments are used as colouring agents.

Ex. Titanium dioxide.

8) Film Forming Polymers [6,8,9]:

Biocompatible and hydrophilic polymers play significant role in formation of OTFs. The polymers must be non-irritant, non-toxic, and have no impurities in it.

To achieve the desired matrix of thin film, polymers can be used alone or in combination with other polymers. In general, hydrophilic polymers are used as film formers because they undergo rapid disintegration of OTFs, gives pleasant feel in mouth and gives mechanical properties to the films. The strength of the film mainly depends on two factors i.e., amount in the formulation and the type of polymer used. If molecular weight of polymer film increases, disintegration rate of that polymer decreases. Recently, as per some patents even the use of starch as modified starch and pea starch is also reported and used nowadays. Polymers generally takes 40% to 50% of the film matrix.

Ex. water soluble grades of cellulose ethers, polyvinyl alcohol (PVA), polyvinyl pyrrolidone (PVP) K-90, carboxymethyl cellulose (CMC) cekol 30, polyethylene glycols, hydroxy propyl methyl cellulose (HPMC) E-3 and K-3, methyl cellulose (MC) A-3, A-6 and A-15, polysaccharides, sodium alginate, hydroxypropyl cellulose (HPC) of grades E-5, E-15 and LV grades, maltodextrins and eudragit RD10, Pullulan, pectin, gelatine, Chitosan, starch.

The following table contains general composition of Oral Thin Films (OTFs):

Table 1: Percent composition of OTFs

Components	Composition (% w/w)
Active pharmaceutical ingredient	5-30
Film forming polymers	Upto45
Plasticizers	0-20
Surfactants	q. s.
Sweetening agents	3-6
Saliva stimulating agents	2-6
Superdisintegrants	Up to 8
Coloring agents	Up to 1
Flavouring agents	Up to 10

Methods of manufacture of the oral thin films:

Oral thin films could be manufactured as follows-

a) Casting and drying:

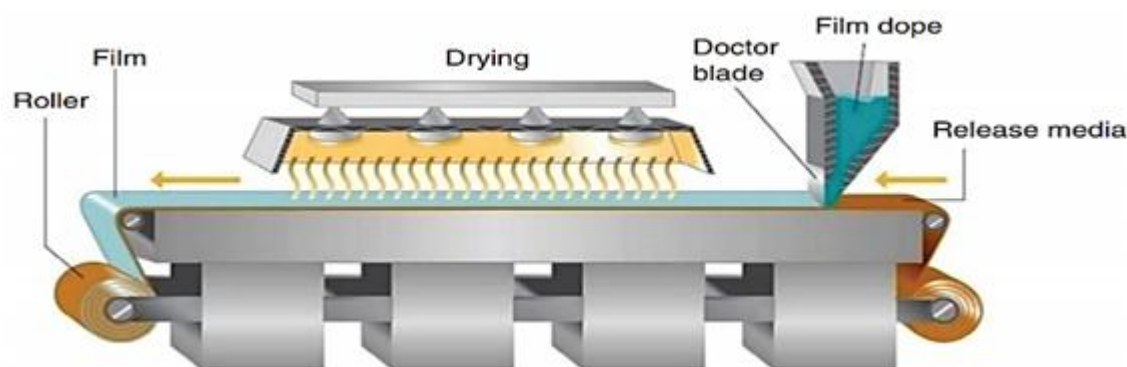
- Solvent Casting.
- Semi-solid Casting.

b) Extrusion:

- Hot Melt Extrusion.
- Solid Dispersion Extrusion.

c) Rolling method:**1) Casting and drying****Solvent Casting – [9,10]**

In this particular methodology, solvent extraction is the approach to formulate the OTFs. A clear viscous solution of water-soluble ingredients is prepared. The active pharmaceutical ingredient and the excipients are mixed with the small portion of the solution and then combined with the bulk, rather say the API is suspended or dissolved in the selected plasticizer. The material so formed is called as Film Dope. The solution so formed is casted in the form of films. The viscosity of the film depends on the temperature conditions.

**Figure 3:** Solvent casting Method [11]

Film coating techniques include- [11]

- Knife over roll.
- Reverse roll.
- Slot-die.
- Gravure cylinder.
- Mayer rod coating.

Consequently, drying is done in an oven or a convection chamber. Finally, the entrapped air is removed that is de-aeration is done to ensure proper strength of the product. Packaging of the dried material in atmospherically resistant pouches is the next step. The proffered film thickness is 12 - 100 um. heat labile nature of constituents (if any) could be protected since the temperature needed for this method is low.

a) Semi solid Casting – [11,12]

The presence of an acid insoluble polymer in the film ingredient requires formulation by the semi solid casting method. The soluble polymers of the product are initially solubilized in water. A solution of acid insoluble polymer is formed separately. Both the solutions so formed are mixed. Subsequently plasticizer is added to the mixture to obtain gel

mass. Using heat-controlled drums, the gel is casted on the films or ribbons. Ratio of the acid insoluble polymer to film forming polymer should be 1:4. Semi solid casting method can be regarded as the most widely used method for preparation of the oral thin films.

2) Extrusion –**a) Hot melt extrusion –[11,13]**

The principle involving HME is such that ingredients of the film are exposed to high temperature which results in thermal degradation. In this technique, mixing of the drug with solid carriers takes place. In order to manufacture Oral thin films by hot metal extrusion technique all the components of the formulation must be in the solid form. mixture is heated in order to make a molten mass with extruders. The molten mass is casted into films with help of dies. Consequently cooling, cutting and packaging of the films is to be done. For employing HME, the components of the formulation must be free from impurities and volatile solvents otherwise heat provided for film formation will cause boiling of the contaminants and affect the quality of the film.

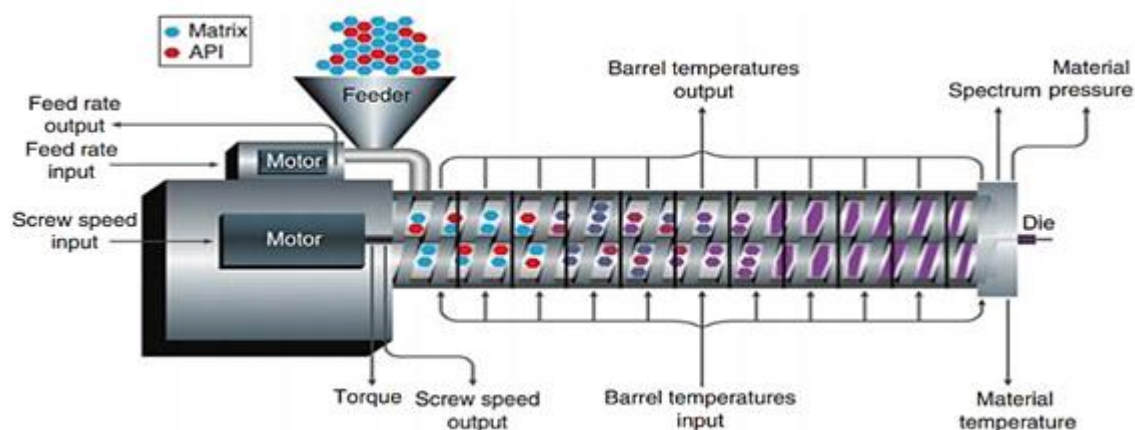


Figure 4: Hot Melt Extrusion Technique [13]

The major pharmaceutical drug products manufactured by hot melt extrusion process are sustained release tablets, granules, transdermal and transmucosal drug delivery systems. Hot metal extrusion has found to have an edge over the other techniques owing to ability of preparing OTFs with a better content uniformity as well as minimum product wastage.

b) Solid dispersion method – [14]

Solid dispersion method involves dispersion of solids which may be one or more active pharmaceutical ingredient in the formulations by using hot metal extraction. The drug is extruded with other immiscible constituents and the dispersion is shaped with help of dies. The solid dispersion is so obtained that the drug to be incorporated into the formulation is dissolved in a solvent and the solution so obtained is added to a suitable amorphous, hydrophilic polymer such as polyethylene glycol below 70 degrees Celsius without removal of the liquid solvent in order to obtain a dispersion.

c) Rolling method – [12-14]

In the system containing solvent usually water or mixture of water and alcohol, the drug is rolled and the film formed on the surface of the roller is allowed to dry. After the drying the films are cut and packed. Alternatively, the solution of the solvent and the drug is mixed thoroughly and consequently applied on the rollers, dried and cut as per

desired shapes. More specifically, a premix batch is prepared using all the constituents of the formulation except the API which is added to a batch feed tank. Following a predetermined amount of active ingredient is added which is mixed with the polymeric solution to form a homogenized matrix.

The film is formed on the substrate or the career and thus dried to be cut. Water soluble colloids are employed in order to obtain a homogenous viscous solution. It must be taken into consideration that rheologic behaviour of the suspension or the solution will have great significance in the formulated oral thin films.

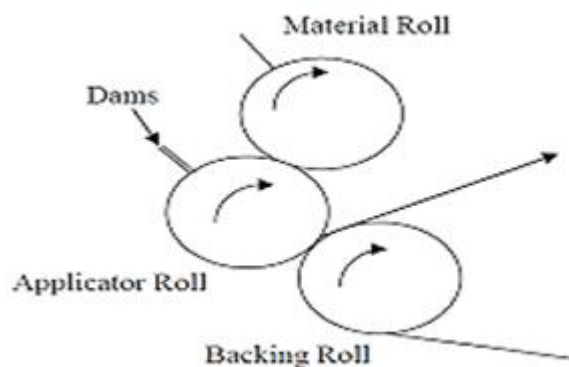


Figure 5: Rolling Method

Properties of Polymers in OTFS

Polymer	Organoleptic Properties	Solubility	pH	Moisture Content (%LOD)	References
Hydroxypropyl methylcellulose (HPMC)	White, creamy, odourless, and tasteless powder.	Soluble – cold water, but Insoluble – chloroform & ethanol,	3-11	1.6	[13,14,15]
Carboxymethyl cellulose (CMC)	White, odourless powder	Easily dispersed in water to form a clear or colloidal solution	6-8	10	[12,14,15]
Hydroxypropyl cellulose (HPC)	White to slightly yellow coloured, odourless, inert and tasteless powder	Soluble – water	5-8	1.6	[12-15]
Polyvinyl alcohol (PVA)	White to cream-colored granular powder	Wide range of solubility	5-8	5	[16]
Polyethylene oxide (PEO)	Non-ionic polymer	Readily soluble – water	8-10	<1	[16,17]
Chitosan	White or creamy powder or flakes, and odourless	Sparingly soluble – water; practically insoluble – ethanol (95%)	6.5-7.5	4.1	[17]
Pullulan	White, odourless, and tasteless powder	Soluble – hot as well as cold water	3-5	13	[13,15,18]
Sodium alginate	Occurs as a white or buff powder, which is odourless and	Insoluble – organic solvents and acids	3-3.5	6.5	[14,18,19]

	tasteless				
Gelatin	A light amber to faintly yellow coloured powder	Soluble – glycerine, acid, alkali and hot water	5-9	9-11	[20]
Kollicoat	Film forming polymer	>50% in water	6-7	1	[21]

Evaluation of Oral Thin Films – [22-37]

Mechanical properties –

1) Tensile strength

The maximum stress applied to the oral film until it eventually breaks is regarded as the tensile strength. The tensile strength of the oral thin film could be calculated using a formula stated as follows-

Tensile strength = force at break/ initial cross-sectional area of film in mm^2

Alternatively tensile strength could also be evaluated as-

Tensile strength = Load at failure \times 100/Strip thickness \times Strip width.

2) Elastic modulus

The elastic modulus generally referred to as the Young's modulus is the measure of the stiffness of film. Also, the elastic modulus of an oral thin film is calculated by the formula stated as follows-

Elastic modulus/Young's modulus = force at corresponding strain / Cross sectional area (mm^2) \times 1/ Corresponding strain

3) Elongation

On application of stress, the films stretch. This stretching is the strain that deforms the film before the point in breaks. The percent elongation proportionally increases with increase in the plasticizer content. Hounsfield universal testing machine is utilized for measuring the percent elongation. The elongation of the oral thin films could be evaluated using the following formula-

$$\text{Increase in length} / \text{Original length} \times 100$$

4) Folding endurance

The brittleness of the oral thin films is evaluated using folding endurance evaluation parameter. The oral thin films of uniform cross section and thickness are taken and folded repetitively until they break.

5) Thickness

The thickness of the oral thin films is measured using micrometres screw gauge or calibrated digital Vernier Callipers. The thickness of oral films should be in the range 5-200 μm .

6) Morphological study –

Scanning electron microscopy (SEM) is employed in studying the morphology of the OTF.

7) Swelling property

A simulation condition of the saliva is depicted herewith. The film to be evaluated is weighed and mounted upon a stainless-steel wire mesh, weight of which is priorly noted. The mesh is lowered into simulated saliva contained plastic

container and the increase in weight is noted. Increase in the weight of the oral thin film is an indicator of its swelling property. The degree of swelling was calculated using parameters = $w_t - w_0$

Where,

w_t = weight of film at time t.

w_0 = weight of film at time zero.

8) Contact angle

The contact angle of the oral thin film is evaluated using an equipment called as the Goniometer (AB Lorentzen and Wetree Germany). As per the instrumentation, a drop of water is placed on the dry film and within the time span of 10 seconds images are captured by means of a digital camera. Digitally, using a software- image J 1.28v software (NIH, USA) the images are analysed and the contact angle is evaluated.

9) In vitro disintegration time

For evaluating the in vitro disintegration time, 25 ml of distilled water is taken into a glass dish and the oral thin film is swirled into it every 10 seconds. Thus, the disintegration time is evaluated visually once the film starts to disintegrate. A fast-dissolving oral thin film generally has the disintegration time of 5 to 30 seconds.

10) In vitro dissolution studies

The USP paddle dissolution apparatus is employed for evaluation of the oral thin films. It is carried out at $37 \pm 0.5^\circ\text{C}$ in a simulated saliva medium using phosphate buffer 6.4. Results are obtained by withdrawing specific amount of sample at regular intervals and analysing it by the UV-Visible Spectrophotometer.

11) Drug content uniformity

In this evaluation parameter, the amount of drug in an individual oral thin film is estimated. The content uniformity limit is 85% -115%.

12) Organoleptic properties

The organoleptic properties such as taste, colour and odour are evaluated. These parameters are necessary from the perspective of patient compliance. Uniformity in the colour as well as attractiveness are important factors considered during the evaluation. Colour is evaluated visually. Along with that, the formulation must have an agreeable odour. Flavouring agent could be incorporated for the purpose of taste masking. Taste of the oral thin films are evaluated by human panel as well as the electronic tongue technique based on the principle of potentiometric titration.

13) Surface Ph test

Ph is an important evaluating parameter since the formulation should not be irritating to the oral mucosa. The Ph of the oral thin films should be 7 or close to neutral. The Ph is estimated by Ph paper and Ph electrode.

14) Transparency

Transparency of the OTF is evaluated by UV Spectrophotometer.

The formula is given as follows –

$$\text{Transparency} = (\log T600)/b = -\epsilon c$$

Where,

T600 i= the transmittance at 600 nm

b = film thickness (mm)

c i= concentration.

15) Permeation

The permeation of the formulation through the oral mucosa is evaluated. It should be noted that the permeation of oral mucosa is 4 to 1000 times greater than that of the skin. The equipment utilized is the Franz diffusion cell.

2. Conclusion

The fast-dissolving drug delivery systems will play a pivotal role in future development and advancements in the pharmaceuticals domains. The pharmaceutical companies across the globe have filed patents for specific drugs, thus increase industrial demand for OTFs has been rising over the years and will continue to blossom with the new research taking place. Thus, the oral thin films have a vivid and promising future in the present era. OTFs are a novel drug delivery system that offers many advantages over more traditional delivery methods like tablets, capsules, syrups, elixirs, etc. Market Research Future predicts that the global market for oral thin films (OTF's) will expand significantly from 2018-2023 at a compound annual growth rate (CAGR) of 10.50%. while, another source predicts that the global market value of all novel drug delivery systems, including OTFs, will grow at a more modest CAGR of 2.9% over the same time. There are some limitations associated with this OTF's method in drug development. As more drugs are developed or reconverted into OTF form, the solutions addressing these limitations will naturally arise. Although some factors will remain static - such as the amount of drug a film can accommodate, generally we do not think of these as limitations, but rather as attributes that cater preferentially to specific populations of patients. Children and the elderly are prime targets for OTF use as because it is very convenient for them to have orodispersible thin films rather than having a big dose of tablet which may arise difficulty for them during swallowing. Further research will expand the potential applications for OTFs, enabling this novel drug delivery system to become a standard dosage form for all pharmaceuticals.

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