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A Brief Overview; 'Oral Thin Films'

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ABSTRACT

Using a dissolving film or oral drug strip, thin film drug delivery delivers medication through absorption in the mouth (buccal or sublingual) and/or the small intestine (enteric). Hydrophilic polymers are used to create a film that quickly dissolves on the tongue or in the buccal cavity, releasing the medication to the bloodstream when it comes into touch with fluids. Thin film drug administration has become a cutting-edge substitute for the conventional tablets, capsules, and liquids frequently used in prescription and over-the-counter medicines. Thin film strips are primarily intended for oral administration. The user places the strip on or under the tongue (sublingual) or along the inside of the cheek. They are similar in size, shape, and thickness to postage stamps (buccal).

These drug delivery methods enable the medicine to skip the first pass metabolism, increasing the bioavailability of the drug. The medicine can enter the bloodstream enterically, buccally, or sublingually when the strip dissolves. The buccal mucosa is favoured above the sublingual mucosa when it comes to systemic trans mucosal medication delivery.

For conditions such trigeminal neuralgia, Meniere's illness, diabetes, and addiction, many buccal administration solutions have been commercialised or are being suggested. Several commercial non-drug goods, such as Listerine PocketPaks breath freshening strips and MeltzUltra Thin Mints, can be used as thin films. Since then, the industry has seen the introduction of thin film products for various gastrointestinal drugs, cold and flu treatments, and other breath fresheners.

Although oral thin-film technology is still in its infancy, it is the most widely used since it meets all of the needs of patients. These formulations with APIs will eventually be released on the market under the oral film technology.

Keywords: Oral thin film, , Polymers, Plasticizers, Novel drug delivery system.

I. INTRODUCTION

The intraoral route is the most favoured because to its ease and quick beginning of effect. The oral route of drug administration has been one of the most practical and acceptable routes of medication delivery. As an alternative to traditional tablets, capsules, and liquid treatments, intraoral dosage forms have developed. Quick-dissolving dosage forms have drawn significant interest due to increased patient compliance and simplicity of administration. 1 Orally disintegrating tablets (ODTs), the only dosage form of this kind acknowledged by the FDA and mentioned in the Orange book, are a quick-dissolving dosage form. These are classified as "orodisperse" tablets by the European Pharmacopoeia, which are meant to be put in the mouth before being quickly dispersed and swallowed. . ODT is described as "a solid form containing pharmaceutical chemicals, which disintegrates fast, generally within seconds, when put on the tongue" by the Centre for Drug Evaluation and Research. Formulations designed for pregastric distribution can solve issues with conventional dose forms, such as drug molecule dissolution and bioavailability. 2\s. The majority of introral dosage forms are designed to release, dissolve, or disintegrate the medication in the mouth cavity, where it can be partially or completely absorbed locally. Alternatively, it can be ingested and absorbed later throughout the gastro-intestinal tract (GIT). Different intraoral dose forms that are utilised to provide medication locally or systemically include Liquids (solution sprays, syrups) (solution sprays, syrups) Semi-solids (ointments, pastes) (ointments, pastes)

Sublingual pills, lozenges, films, filaments, gums, patches, and lollipops are examples of solid dose forms.Recently, novel dosage forms incorporating cutting-edge manufacturing techniques (such lyophilized wafers, solvent cast films, or mucoadhesive patches) have been launched.

Advantages

1. Oral thin films have increased the drug's bioavailability, which causes it to work more quickly.

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2. Drugs in oral thin films avoid the first pass action, in contrast to conventional dose forms, which reduces the quantity of medication that needs to be loaded.
3. Oral thin films are more stable than liquid dose forms.
4. Oral thin films do not need special packaging because the medicine is placed into an abuse-resistant matrix.
5. Oral thin films are less brittle than tablets.
6. According to research, oral thin films have less adverse effects.
7. Thin film's quick dissolution without the need for water gives patients with swallowing difficulties and those experiencing nausea an option, such as those gettingchemotherapy.
8. The creation of sensitive pharmacological targets that would not otherwise be attainable in tablet or liquid formulations may be made possible by thin film drug delivery.
9. From a business standpoint, thin-film drug delivery technology presents a chance to prolong revenue lifecycles for pharmaceutical firms whose drugs' patents are about to expire and who will soon be exposed to generic competition.
10. Sublingual film quickly absorbed beneath the tongue to ensure compliance by delivering a convenient, quickly dissolving therapeutic dosage enclosed in an abuse-deterrent film matrix that patients cannot crush or inject.

Clinical Benefits

1. Since oral thin films are administered via the oral route, it is simple to administer them.
2. There is a decreased risk of choking or suffocating in paediatric and geriatric patients.
3. Those who experience nausea are better off with oral thin films.
4. It is not necessary to ingest oral thin films with water.

Market Benefits

1. This innovative medication delivery technology enables pharmaceutical firms with patents that are about to expire to lengthen their income cycles.
2. Since OTFs are loaded with a precise dosage of the medicine, they discourage the abuse, manipulation, and misuse of some prescription pharmaceuticals.
3. The oral thin films industry is still in its infancy and currently consists of of a few over-the-counter medications sold in the American, Japanese, and European Union markets. So, there is a lot of room for research and business to create new, less expensive technologies and synthesise medications that haven't yet been made into OTFs.

The following are some **drawbacks** to the formulation of oral or buccal films:

1. The structural integrity of the formulation may be compromised by the bio-adhesive polymer swelling and hydration, which might result in the production of a slippery surface.
2. Restrictions on what you can eat and drink may apply.
3. The patient has a chance of swallowing the pill.
4. The benefits of the buccal route are lost once the medicine contained in swallowed saliva takes the oral route.
5. Only medications requiring a minimal dosage can be given.
6. This method cannot be used to give medications that irritate mucous membranes, have an offensive odour, a bitter or unpleasant taste, or both.
7. This method cannot be used to give medications that are unstable at buccal pH.

Some medications that can be included in fast-dissolving films are as follows:

Sr.no	Drug	Dose	Therapeutics actoin
1	Azatidine Maleate	1 mg	Anti histaminic
2	Ondensetron	2.5mg	Anti emetic
3	Nicotine	2mg	Smoking cessation
4	Salbutamol	4mg	Anti histaminic
5	Cetrizine	5-10mg	Anti histaminic
6	Loratidine	10mg	Anti histaminic
7	Famotidine	10mg A	Antacid
8	Dicyclomine hydrochloride	25mg	Muscle relaxant
9	Sumatriptan succinate	35- 70mg	Anti migraine

Table 1 is a list of a few medications that can be used in fast-dissolving films.

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Oral films are made up of the following ingredients:

- Chemical agent
- Super disintegrants,
- sweetening agents,
- surfactants,
- film-forming polymers
- Saliva-stimulating,
- flavouring,
- colouring substances

ODFs are thin, rapidly dissolving films with an area of 5 to 20 cm2 that contain an active pharmaceutical ingredient (API) embedded in a hydrophilic polymer matrix.

Excipients such as plasticizers, colourants, sweeteners, flavour mufflers, and other ingredients may be added in amounts up to 15 mg of the active medicinal ingredient. Plasticizer lowers the glass transition temperature of polymers and increases the workability, spreadability, and flexibility of films. ODFs' typical composition is depicted in (Table1). ODFs can also include APIs (antihistamines, anti-diarrheal, anti-depressants, vasodilators, anti-asthmatics, anti-emetic drugs, etc.). ODFs frequently contain drugs like salbutamol sulphate, rizatriptan benzoate, verapamil, ondansetron, dexamethasone, rofecoxib, cetirizine, pilocarpine, tianeptine sodium, indomethacin, and others.

PLASTICIZER

Plasticizer improves the flexibility a mechanical property of the film like tensile strength and elongation of the oral films and it decreases the brittleness of the film. The key excipient in the oral film is plasticizer. By lowering the polymer's glass transition temperature, plasticizer greatly enhances the characteristics of the strip.

Generally speaking, the addition of plasticizer to formulations enhances mechanical properties like tensile strength and% elongation. On average, plasticizer concentrations range from 0% to 20%. PEG, glycerol, diethyl phthalate, triethyl citrate, tributyl citrate, and other plasticizers are a few examples.

Sweeteners:

Sweetening substances are designed to break down or dissolve in the tongue.

In order to make ODFs, both artificial and natural sweeteners are used. Neotame and alitame are 2000–8000 times less sweet than sugar. Fructose has a greater ability to sweeten food than sorbitol and mannitol. Sucralose demonstrated 600–1000 times more sweetness than sucrose when multiple commercial ODFs were evaluated for flavour, aftertaste, and tongue feel.Aspartame and saccharin sodium are thought to be 200–500 times sweeter than sucrose. The flexibility of the film is also claimed to be slightly influenced by sweeteners and flavours.

Surfactants:

Surfactants are crucial because they function as wetting, solubilizing, and dispersion agents. They enable a film to break down quickly and release the integrated medication quickly.Surfactants that are often utilised include sodium lauryl sulphate, tweens, and benzalkonium chloride.

Polymers for film forming

Polymers are crucial to the development of film.

In order for the film to breakdown quickly in the mouth cavity and transport the medication to the systemic circulation when it comes into contact with saliva in the buccal cavity, hydrophilic polymers are mostly employed in the preparation. To achieve the necessary film qualities, film forming polymers can be employed alone or in combination in a film.

The kind and quantity of polymer used in the formulation affects how robust the film is. In the oral cavity, polymers of both natural and synthetic origin are utilised. Natural polymers are favoured over synthetic polymers since they are more efficient, safe, and don't cause negative effects.

Saliva stimulants:

By increasing saliva production in the buccal cavity, saliva stimulants, which are frequently acidic, help ODFs dissolve. Citric acid, malic acid, tartaric acid, ascorbic acid, and lactic acid are some of the most popular saliva stimulants.

Fragrance agents:

The compounds that are added to a formulation to enhance flavour are called flavouring agents. The sort of medicine that will be included in the formulation mostly determines the flavour choice. The initial flavour quality, which is noticed in the first few seconds after the product has been eaten and after the taste of the formulation lasts for at least 10 minutes, is the major factor in determining whether a person would accept an oral dissolving/disintegrating formulation. The kind and strength of the flavour will largely determine how

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much flavour should be applied to cover the taste.10% weight-to-weight of flavouring ingredient is utilised in the recipe.To the formulation, a US-FDA-approved flavour can be added at the consumers' discretion and age.
Pigments have been used as colouring agents in ODFs as colourants. It is strongly advised to utilise titanium dioxide as a colourant. In addition to titanium dioxide, a wide range of colours are offered, including custom pantone-matched colours and natural colours that are FD&C certified.

The RDF may be created using any one of the following procedures, alone or in combination:

- Extrusion using hot melt
- Extruding solid dispersion
- In motion
- Substantial Casting
- Solution Coating
- Extrusion of hot melt

Granules, extended-release pills, transdermal, and transmucosal drug delivery systems are frequently made using this technique. Instead of using the standard solvent casting method, this methodology for processing films involves heating a polymer to shape it into a movie. The extruder, downstream support machinery, and monitoring tools make up the equipment needed for hot melt extrusion. A feeding hopper barrel, screw, die, screw-driving mechanism, and heating/cooling equipment make up an extruder. With the process of film casting with aqueous or organic solvents, thin films for transdermal/transmucosal medication administration and wound care may be created.

Technique for solid dispersions: The term "solid dispersions" refers to the dispersion of one or more active components in a solid state when hydrophilic amorphous polymers are present. Drug is dissolved in an appropriate liquid solvent. The solution is subsequently added to the polyethylene melt. Finally, dies are used to shape the solid dispersion of glycol, which is achieved below 70 degrees Celsius, into films.

Rolling Technique

This process involves rolling the medication with a carrier and solvents.

A film-forming polymer-containing solution or suspension is made and then sent through a roller. Certain rheological considerations should be made for the solution or suspension. 1 Water and alcohol-water mixtures are the principal solvents employed in this procedure. API and other excipients are dissolved in a tiny amount of aqueous solvent using a high-shear processor. Hydrocolloids that are water soluble are dissolved in the liquid to create a slick, viscous solution. With the use of rollers, the resultant suspension or solution is utilised to create the film. 2 Using a second metering pump, a particular amount of solution is pumped into the pan. The film's thickness was determined by the metering roller.

Semisolid casting:

When using acid insoluble polymers, this approach is mostly utilised when creating oral quick dissolving films. Solutions of water-soluble film-forming polymers are created. The acid-insoluble polymer solution receives the solution. To create a gel mass, the right quantity of plasticizer is applied. Using heat-controlled drums, the resulting gel mass is subsequently cast into ribbons or films. The polymers cellulose acetate butyrate and cellulose acetate phthalate are acid insoluble and are used to create films. The ratio of film-forming polymer to acid-insoluble polymer is 4:1. The film is between 0.015 and 0.05 inches thick.

Technique of solvent casting

Solvent casting is now the most used production method for creating oral thin films.

In this procedure, distilled water is used to dissolve both the plasticizer and the water-soluble polymer. Using a magnetic stirrer, the solution is agitated for two hours before being set aside to remove any trapped air bubbles. Excipients and API are simultaneously dissolved and thoroughly agitated for 30 minutes, following which the two solutions are combined. The solution is finally poured onto a flat surface appropriate for moulding a film. After drying, the film is gently removed. 1 A breakthrough abuse deterrent and microemulsion-based sublingual film of buprenorphine hydrochloride was created using the same solvent casting technology.

EVALUATION OF FILMS:

A. Weight variation
B. Tensile strength
C. Thickness
D. Transparency
E. Folding endurance
F. Dissolution test
G. Tear resistance
H. Content uniformity
I. Percent elongatio

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J. Swelling property
K. Disintegration time
L. Young's modulus

A. Weight variation

By weighing each of the 10 randomly chosen oral films individually and figuring out their average weight, weight variation is analysed.

B. Tensile strength

The greatest stress that may be applied to a spot before the film specimen breaks is known as the tensile strength. 22 It is computed by dividing the applied load at rupture by the film's cross-sectional area.

C. Thickness:

A micrometre screw gauge may be used to measure the thickness of a film at several crucial spots (at least 5 locations). It is crucial to establish the consistency of the film's thickness since it directly affects the precision of the dosage applied to the film.

D. Transparency:

A simple UV spectrophotometer may be used to determine the transparency of the film. Rectangular pieces of the film samples are cut off and put on the inside of the spectrophotometer cell. At 600 nm, you can measure a film's transmittance.

E. folding tenacity

A piece of film is repeatedly cut and folded in the same spot until it breaks as a folding endurance test. The number of times the film could be folded at the same spot without breaking is used to calculate folding endurance. Film typically has a folding endurance of between 100 and 150.

F. Test for Dissolution:

Any of the pharmacopoeia's standard basket or paddle devices can be used to conduct a dissolution test. The sink conditions and the maximal dosage of the API will mainly determine the dissolving medium's choice. Because to the film's propensity to float into the disintegration medium when the paddle device is used, the dissolutiontest can frequently be challenging. Thus, the basket equipment is mostly used for assessment.

G. Tear resistance:

A film's tear resistance serves as the intricate function of its ultimate resistance to rupture. The maximal force necessary to rip the film is indicated by the tear resistance value. This test is typically attributed to the plastics industry.

H. Homogeneous content

After being dissolved in a suitable solvent for content uniformity, each film is filtered, and the drug content in each film is identified using the proper quantification technique. The relative standard deviation is predicted to be no more than 6%.

I. Percent Elongation:

When stress is applied, a film sample stretches and this is referred to asstrain.In essence, strain is the film's distortion divided by the sample's initial dimension.Usually speaking, when the plasticizer concentration rises, film elongation rises as well.

J. Increasing index

In order to test the film's swelling index, salivary fluid is used as a dummy. A preweighed stainless steel wire sieve is used to hold the weighted film sample. The mesh holding the film is dipped into 50 cc of simulated salivary medium and placed in a mortar. The film's weight is gauged at regular intervals until it reaches a set weight. The following formula is used to determine the degree of swelling:

SI=wt - wo / wo

SI stands for swelling index.

Wt is the weight of the film at time "t."

K. Disintegration Time:

The rapid dissolving oral film is subject to the same disintegration time restriction of 30 seconds or less for orally disintegrating tablets as indicated in CDER advice. Although though there isn't any formal advice for oral fast-dissolving films or strips, it can be used as an aqualitative guideline for quality control tests or during the development stage. For this investigation, pharmacopoeial disintegrating test equipment may be employed. Film typically dissolves between 5 to 30 seconds.

L. Youngs Modules;

As the saying goes, 'youth is elastic, but rigidity is elastic. In the area of elastic deformation, the ratio of applied stress to strain is displayed.

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Administration methods for thin films:

- Oral
- Ocular
- Transdermal

Oral: The development of polymeric films has improved drug absorption and patient adherence to pharmacological therapy when administered orally, particularly buccal and sublingually. Buccal mucosa has favourable anatomical and physiological properties for drug administration, like presence of smooth muscles with high vascular perfusion, simple accessibility, and bypassing the first-pass metabolism effect.

Ocular: More than 90% of commercially available ocular formulations are in the form of solutions or suspensions; nevertheless, this conventional dose form has not been proven to be successful in delivering positive therapeutic outcomes. Eye drops need to be used often to produce a therapeutic effect. The most frequent results are pulsed administration and patient noncompliance. These days, the production of ophthalmic films is widely used to improve ocular bioavailability and get around problems with ocular medicine administration.

Transdermal: A potential substitute for the existing transdermal dosing approach is drug-loaded transdermal films. The medicine is either dissolved or dispersed in the films to create a wide variety of sustained or controlled delivery systems. Transdermal distribution of steroidal hormones, analgesics, local anaesthetics, and antiemetics has been accomplished for systemic effects using the film making approach.

Future outlooks: In recent years, it has been common to incorporate pharmacological formulations into various movies.

The development of new polymeric thin films as a drug delivery system was prompted by undesirable drawbacks associated with existing dosage forms, such as difficulties in administration, lower bioavailability, and patient rejection. Pharmaceutical firms on both a local and large scale are closely monitoring this method of medication administration. The businesses make an effort to create a wide range of thin films for transdermal, oral, buccal, sublingual, and ocular routes. Hence, these polymeric thin films are employed to replace the traditional dosage forms, surpassing the drawbacks brought on by the current dosage forms. The film dosage form encounters a variety of issues during the formulation and manufacturing processes

These issues should be resolved when switching to large-scale manufacturing in order to improve the formulation as a whole. The development of thin film preparation methods is progressing quickly, thus the future of film technology seems promising.

II. CONCLUSION ;

Fast dissolving oral films, which avoid the hepatic system and exhibit greater therapeutic response, are the most palatable and precise oral dose form, according to the results of the current review. In the pharmaceutical industry, oral dissolving films are becoming more significant. In addition to having various advantages over other dosage forms, they also provide a simple method for manufacture and evaluation. Due to their cheaper price and customer desire, oral films can take the place of over-the-counter (OTC) medications, both generic and name brand. This technique is useful for managing the product life cycle and extending the patent life of already existing items. This review aims to bring together the existing information on oral dissolving films.

Due to customer demand and reduced price, oral films might take the place of over-the-counter medications, brands, and generic names on the market.

The ideal instrument for managing the product life cycle to extend the patent life of already existing items is this technology. OFDFs have the ability to deliver the drug both locally and systemically, and they offer a number of benefits over both fast-dissolving tablets and other dosage forms.

This explains the enormous study that is now being done on this technology. As a result, the development of oral dissolving films employing a variety of active pharmaceutical components is becoming more difficult due to this technology's rapid growth.

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