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Fast Dissolving Films: A Updated Review with Future prospects

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ABSTRACT

Fast dissolving oral films are a relatively new drug delivery technology with the potential to improve patient adherence by increasing the safety and effectiveness of the therapeutic molecule. The film may be put on the tongue's roof or underside for an effective medicine delivery method. This film instantly dissolves when placed on the tongue, releasing the medication into the saliva. Saliva travels down the oesophagus and into the stomach, where certain medications are absorbed. The drug's bioavailability is improved, and there's no danger of choking, and the pill feels great in the mouth. The inability to swallow pills, capsules, etc., quickly dissolves this barrier to medicine administration. Fast dissolving oral films are discussed in this review article along with their oral mucosa, formulation components, a technique of fabrication, an assessment, and potential future applications.

INTRODUCTION

The oral route of medication administration is the most popular of the many drug delivery methods. Patients are more likely to take their medication as prescribed when it is given orally, which is also considered the safest, most convenient, and most cost-effective mode of drug administration [1-4]. Dissolved or ingested medicine enters the body's bloodstream, where it may do its work [5-6]. Self-

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medication, convenience of administration, and pain avoidance compared to parenteral route make oral route of drug administration the most essential mode of administration of a medicine for systemic impact [7-10].

Anatomy of oral cavity

The oral cavity's morphology and physiology are analysed in order to get insight into the optimal conditions for medication administration [Fig. 1].

Drugs used orally bypass first-pass metabolism because they are absorbed directly into the bloodstream from the oral mucosa. The oral cavity's epithelium is quite similar to the skin's, with the exception of the mucous layer that acts as a barrier and lubricant [11]. Oral mucosa is four to one thousand times more permeable than skin. The lips and cheeks form the exterior lining of the mouth, while the palates, the floor of the mouth, and the tonsils make up the inner lining [12]. Many different pharmaceutical medications come in a broad range of dosage forms, but it has been known for decades that oral drug delivery is the most popular mode of administration. [13].

Fast dissolving drug delivery system (FDDS)

As an alternative to tablets, capsules, syrups, and other formulations for paediatric and geriatric patients who experience difficulty swallowing traditional solid dosage forms, fast dissolving drug delivery systems, also known as fast-dissolving/disintegrating film for the oral delivery of the drugs, came into existence in the late 1970s [14]. The elderly, the young, the intellectually impaired, the nauseous, and the recalcitrant all benefit from the simplicity and effectiveness of FDDS [15]. The solid dose forms used in this method dissolve rapidly (within seconds) in the mouth without the need for additional liquid. The

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oral strip used in the delivery method is very thin and is meant to be put on the tongue or other oral mucosal tissue, where it will be wetted by the patient's saliva [16]. The area where the film is applied quickly becomes hydrated. After being swallowed, it quickly dissolves and disintegrates, releasing the medicine for absorption via the mouth and throat. Patients and carers alike like fast dissolving oral thin films for their convenience, mobility, and precision in dosage [17]. Dissolution period for orally dissolving film is typically 5-20 min. as per pharmacopoeia [18, 19], and film durability is determined by the kind and quantity of polymer utilised. Oro-mucosal absorption of the medication passes straight from the site of injection to the systemic circulation, bypassing the first-pass metabolism to provide the intended effect [20], allowing for a rapid commencement of action in a matter of seconds.

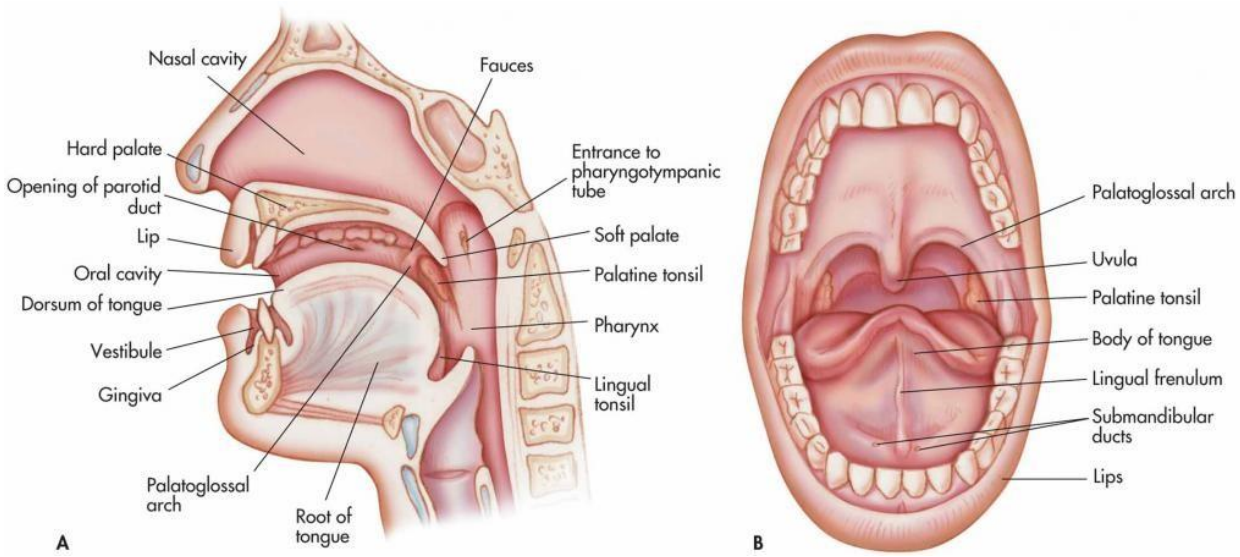

Figure 1: Anatomy of the oral cavity (http://baldaivirtuves.info/human-anatomy-mouth/human-anatomy-mouth-anatomy-mouth-oral-cavity-human-

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anatomy-library- physiology/)

Advantages of fast dissolving oral films **[21]**

The following are some of the benefits of FDOFs compared to other oral formulations:

- The drug's onset of action is sped up, its dose is reduced, and its effectiveness and safety profile are improved due to the rapid disintegration and dissolving in the oral cavity made possible by the increased surface area.
- Because of their fragility and brittleness, ODTs often need special packaging while being stored or transported. The films, however, are flexible, making them less brittle than ODTs and making them convenient to carry, handle, and store.
- Every strip guarantees accurate dosing every time.
- OTC medicines come in liquid, tablet, and capsule formats, but OTFs have been widely accepted by both the pharmaceutical industry and consumers. Without the need for water or measurement apparatus, OTFs provide rapid, precise dosage in a safe, effective, portable format [22].
- Technology based on oral strips offers an alternative delivery system for medications subject to first-pass metabolism [23].
- Patients with dysphagia, recurrent emesis, motion sickness, or mental impairments who are unable to swallow a substantial amount of water benefit greatly from this dose form.
- In order to rapidly release one or more APIs, OTFs are generally the size of a postage stamp and dissolve on the tongue. Aqueous polymer matrices with a

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broad molecular weight (MW) range are often used in the formulation of dissolvable films because of the versatility they provide in achieving desired physical qualities.

- New economic opportunities, such as product differentiation, product marketing, patent extensions, and lifecycle management, are made possible by advances in thin film drug delivery technology.

Disadvantages of fast dissolving oral film **[24]**

- It is not possible to provide drugs that are unstable at buccal pH.
- It is not possible to use this method of administration for drugs that cause mucosal irritation.
- Only drugs with very low dosage needs will be given.
- Most medications have an unpleasant aftertaste that must be covered up.
- OFDFs need specialised packaging since they are perishable and must be kept dry.

Comparison between Fast Dissolving Oral Films and Fast Dissolving Tablets **[25, 26]**

The difference between the two dosage forms is listed in table 1.

Table 1: Comparison between Fast Dissolving Oral Films and Fast Dissolving Tablets

S. No.	***Fast Dissolving Oral Film***	***Fast Dissolving Tablet***
1.	Large surface area gives greater dissolution.	Less surface area gives lesser dissolution than FDOF.

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2.	Fast dissolving oral films are flexible and durable.	Fast dissolving tablet is brittle and less durable than FDOF.
3.	Only low dose can be incorporated in the formulation.	High dose can also be incorporated in the formulation.
4.	Fast dissolving films are of thickness 0.015-.05 inches.	Fast dissolving tablet is of the same size of a conventional tablet.
5.	Patient compliance is more.	Patient compliance is less than FDOF.

Formulation Components of FDOF

Active Pharmaceutical Ingredient [27]

The film's active medicinal component makes up between 1% and 30% of the composition by weight. For this reason, fast-dissolving films should only ever contain modest doses of active pharmacological components. Antihistamines, antidiarrheals, antidepressants, vasodilators, anti-asthmatics, anti-emetics, and many more medications may all be utilised as fast-dissolving oral films [28]. ODFs may also include dimenhydrinate to cover up odours and flavours. Salbutamol sulphate, rizatriptan benzoate, verapamil, ondansetron, dexamethasone, rofecoxib, cetirizine, pilocarpine, tianeptine sodium, indomethacin, etc. are all examples of medicines that are often used in ODFs [29].

Film-Forming Polymers

The main component of the rapidly disintegrating oral film is polymers. The oral strip's polymer concentration determines the film's durability. The standard polymer content, expressed as a percentage of the dry film's total weight, is 45%

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w/w. Because the tensile strength of oral films relies on the kind and quantity of polymer employed, the choice of polymer is one of the most significant and vital elements for the effective production of oral films [30]. Because of how quickly they break down in the mouth when exposed to saliva, hydrophilic polymers are mostly employed in the oral strip [31]. To make quick dissolving film, scientists now utilise both natural and manmade polymers.

Table 2: List of polymers used in oral thin films [32, 33]

Group	Class	Example
Natural	*Carbohydrate*	Pullalan, pectin, sodium alginate, maltodextrin, Sodiumstarch glycolate (SSG)
	Proteins	Gelatin
	Resin	Polymerized rosin (novel film former)
Synthetic	*Cellulose derivatives*	Hydroxypropyl methylcellulose (E3, E5, E15, K3, K15, K50), Methylcellulose (A3, A6, A15), Carboxy methylcellulose secekol- 30, Sodium carboxymethyl cellulose, Microcrystalline cellulose, Croscarmellose sodium (CCS).
	Vinyl polymer	Poly vinyl pyrrolidone (K-90, K-30), Poly vinyl alcohol, poly ethylene oxide

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	Acrylic polymer	Eudragit (RD-100, 9, 10, 11, 12 and RL-100)

Plasticizer

The glass transition temperature of the polymer is lowered by the addition of plasticiser, which increases flexibility and decreases brittleness of the strip. Plasticisers are chosen based on their compatibility with the polymer and the formulation's solvent [34, 35]. Glycerol, propylene glycol, low molecular weight polythene glycols (PEGs), phthalate derivatives like dimethyl, diethyl, and dibutyl phthalate, citrate derivatives like tributyl, triethyl, acetyl citrate, triacetin, and castor oil, are all commonly used plasticisers. To prevent the film from cracking, splitting, or peeling, a plasticiser concentration of 0-20% w/w of dry polymer weight is recommended [36, 37]. Certain plasticisers may potentially have an impact on medication absorption [38]. To bring the glass transition temperature of the polymer down to below 75 oC for aqueous environments, the plasticizer's characteristics are crucial [39]. Plasticization of cellulosic hydrophilic polymers was achieved with relative ease by using plasticisers containing hydroxyl groups, such as polythene glycol, propylene glycol, glycerol, and polyols. Esters of citric acid and phthalic acid were used to plasticize less hydrophilic cellulosic polymers [40]. Diethylene glycol may be used for both Hypromellose and polyvinyl alcohol films, while glycerol is a superior plasticiser for polyvinyl alcohol [34].

Surfactants [41, 42]

To speed up the dissolution of the film and the subsequent release of the active ingredient, surfactants are utilised as a wetting, solubilizing, or dispersion agent. Poloxamer 407, benzalkonium chloride, sodium lauryl sulphate, tweens, and benzethonium chloride are all frequently used examples. Poloxamer 407 is one of

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the most widely used surfactants.

Sweetening agents [43, 44]

The majority of FDOFs utilise sucrose as their sweetener. Sucrose dissolves easily in water and does not change the formulation's appearance since it is colourless. Dextrose, sucrose, fructose, glucose, isomaltose, polyhydric alcohols (sorbitol, mannitol), etc. are all examples of regularly used sweeteners. Saccharin, cyclamate, aspartame (first generation), sucralose, alitame, and neotame (second generation) are all acceptable alternatives to sugar.

Saliva stimulating agents [45]

To accelerate the disintegration of quick dissolving strip formulations, saliva stimulating chemicals are employed to stimulate saliva production. Acids like citric, malic, lactic, ascorbic, and tartaric may stimulate saliva production.

Flavouring agents [43]

There can be no toxicity, insolubility, instability, or incompatibility between the excipients and the flavours employed in the formulation. Depending on the kind of flavouring agent and its intensity, different amounts will be needed to cover up the flavour.

Table 3: Preferred flavours as per the type and taste of the drug [46]

Drug	***Preferred Flavour***
Antibiotics	Cherry, maple, pineapple, orange, raspberry, banana-vanilla, butterscotch, coconut-custard, fruit-cinnamon, strawberry, vanilla

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Antihistamines	Apricot, cherry, cinnamon, grape, honey, lime, peach-orange, peach-rum, raspberry, wild cherry
Barbiturates	Banana-pineapple, banana-vanilla, cinnamon-peppermint, orange, peach-orange, grenadine-strawberry,
Decongestants &Expectorants	Anise, apricot, butterscotch, cherry, coconut-custard, custard-mint- strawberry, grenadine-peach, strawberry-lemon, gooseberry, orange-lemon, coriander, pineapple, raspberry.
Electrolyte-solutionsgeriatrics	Cherry, grape, lemon-lime, raspberry, wild cherry syrup, grenadine-strawberry, lime, port-wine, cherry-wine, wild-strawberry.
Salt taste drugs	Butterscotch, maple
Bitter taste drugs	Wild cherry, walnut, chocolate-mint, licorice
Sweet taste drugs	Fruit, berry, vanilla

Colouring agents [47]

Colourants like those on the FD&C authorised list, as well as natural hues and pigments like titanium dioxide, are often used. There should be no more than 1%w/w of colouring chemicals.

Manufacturing Methods [48-50]: Fast dissolving oral films may be made using one of five approaches, either alone or in conjunction with the procedure below.

i) Solvent casting

ii) Semisolid casting

iii) Hot melt extrusion

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iv) Solid dispersion extrusion

v) Rolling

Solvent-casting method

Solvent casting is the technique of choice for creating the OTF because it allows the water-soluble elements to be dissolved into a clear, viscous solution. The active pharmaceutical ingredient (API) and other agents are dissolved in the solution and then added to the bulk. The aqueous viscous solution receives this combination. The suction pulls out the trapped air. The finished solution is poured into a film mould, dried, and then sliced into the necessary sizes.

Advantages:

- Clearer and more consistent in thickness than extrusion.
- The film has a high sheen and is devoid of flaws like die lines.
- Film's physical characteristics and adaptability are superior.
- Depending on the API loading and dissolving requirements, the final film thickness may range from 12 to 100 m.

Disadvantages:

- Either a volatile solvent or water solubility is required of the polymer.
- The goal is to create a stable solution with a minimal solid content and viscosity that is acceptable.
- It is essential that a uniform film can be formed and separated from the casting support.

Hot Melt Extrusion

The current technique involves a first step of bulk preparation using temperature

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and steering speed control. After that, the film goes through a drying tunnel where it is coated and dried while the environment, airflow, and line speed are all managed. The films are then punched, pouched, and sealed, and slitting comes next.

Advantages:

- Without the requirement for a wet or dry solvent.
- A streamlined processing time.
- The API's compressibility features may be irrelevant.
- An improved replacement for medicines with low solubility.
- Because of the vigourous stirring and agitation, the dispersion is more even.
- Saves power compared to high shear techniques.

Disadvantages:

- Thermal degradation due to use of high temperature
- Flow properties of the polymer are essential to processing
- A limited number of available polymers
- All excipients must be devoid of water or any other volatile solvent

Semisolid Casting

This technique involves combining a solution of an acid-insoluble polymer (such as cellulose acetate phthalate or cellulose acetate butyrate) with a solution of a water-soluble film-forming polymer. Sonication is followed by coating on untreated casting film. The final film thickness ranges from 0.38 to 1.27 centimetres. An ideal mixture would include 1 part acid insoluble polymer to 4 parts film-forming polymer.

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Solid Dispersion Extrusion

The medication and its insoluble components are used to make a solid dispersion. At last, dies are used to cut the solid dispersions into film.

Care must be taken while creating a solid dispersion of a medicine since the liquid solvent employed may have an effect on the polymorphic form of the drug that has precipitated out of solution.

3.1 Rolling Method

The medicine is rolled onto a carrier in the form of a solution or suspension. The solvent consists mostly of water or a water-and-alcohol combination. The film is dried on rollers, which also helps to shape and size it before it is packaged.

Evaluation Parameters of FDOFs [52-59]

Thickness

Because film thickness has a direct bearing on the homogeneity of the drug's active ingredients, measuring it is essential. Several key points may be measured using a micrometre screw gauge or a set of calibrated digital Vernier Callipers. The ideal film thickness is between 5 and 200 μm.

Dryness test/tack tests

Currently, we know of eight distinct drying phases for film: 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. Most studies may be easily modified to assess pharmaceutical OFDF, even though they were originally designed for use with paint films. The scope of this assessment does not include the specifics of evaluating these criteria. Tack is the degree to which the strip stays attached to a surface (in this case, a sheet of paper) after being pushed against. For this

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investigation, there are various instruments available.

Tensile strength

Maximum stress at which a strip specimen fails under tension is known as its tensile strength. As shown in the following equation, it is determined by dividing the applied load at rupture by the strip's cross-sectional area.:

$$Tensile\ strength = load\ of \frac{breakage}{Strip\ thickness \times Strip\ Width}$$

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Percent elongation

Strain is the length changed in a strip sample under stress. A strain is defined as the amount of strip deformation expressed as a percentage of the original sample size. As the plasticiser concentration rises, so does the strip's elongation.

$$\%\ Elongation = \frac{Increase\ in\ length \times 100}{Original\ length}$$

Young's modulus

The stiffness of a strip is quantified by its Young's modulus, also known as its elastic modulus. As the ratio of stress to strain in the area of elastic deformation, it looks like this:

$$Young's\ modulus = \frac{Force\ at\ corresponding\ strain}{cross-sectional\ area} \times \frac{1}{corresponding\ strain}$$

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

Tear resistance

The ultimate strength of a plastic film or sheet determines how resistant it is to tearing. The force required to start tearing is measured by applying a very low rate of loading, namely 51 mm (2 in)/min. To measure tear resistance, scientists measure the amount of stress or force (in Newtons or pounds-force) needed to tear the specimen. This number is often determined just before the specimen tears.

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Folding endurance

The strip's folding durability is measured by repeatedly folding it at the same spot until it snaps. The folding endurance value is determined by counting the number of times the film can be folded without tearing.

Organoleptic evaluation

Controlled human taste panels are utilised to assess the product's psychophysical qualities. To achieve this goal, scientists are turning to in-vitro procedures that make use of taste sensors, specialised equipment, and drug release using modified pharmacopoeial approaches. High-throughput taste screening of oral pharmaceutical formulations is an ideal application for this in-vitro taste evaluation equipment and procedures.

Surface pH of the film

The films' surface pH was measured by putting them on 1.5% w/v agar gel and then touching them with pH paper (pH range 1-11). It is important to note the shift in hue on pH paper.

Swelling property

The swelling of films is tested using a saliva substitute. A stainless steel wire mesh is used to weigh and store each film sample. The film sample, which is contained in a mesh, is placed in a plastic container with 15 ml of media. The film's weight was measured periodically until a steady increase was seen.

Parameters were used to determine the level of enlargement.

$$\alpha = \frac{wt - wo}{wo}$$

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wt is a weight of film at time t and wo is a weight of film at time zero.

Transparency

The films' opacity may be measured using a cheap UV spectrophotometer. Rectangles of film were cut and put on the inside of the spectrophotometer cell. Films' transmittance at 600 nm is measured. The following formula was used to determine the films' transparency::

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

Where T600 is the transmittance at 600 nm and b is the film thickness (mm) and c is concentration.

Assay/ Content uniformity

This is done using any of the pharmacopeial test methods indicated for the specific API in question. The API content of a single strip is estimated to establish content homogeneity. 85–115 percent is the upper limit for content similarity.

Disintegration time

Orally rapid dissolving films need USP disintegration equipment in order to be broken down. Fast dissolving oral strips may adhere to the CDER's recommendation that disintegration time be 30 seconds or less. Disintegration times may range from 5 to 30 seconds, however this will depend on the formulation. However, there is no official advice for using fast-dissolving film strips in the mouth.

Dissolution test

Any of the pharmacopoeias will detail the conventional basket or paddle equipment needed to conduct a dissolution test. The sink conditions and maximum dosage of the API will be used to determine the optimal dissolving

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medium. When using the paddle apparatus, the dissolving test might be complicated since the strip has a propensity to float onto the dissolution medium.

Future Prospects

Oral medication delivery systems have seen significant development in the pharmaceutical sector. Modern fast-dissolving and fast-acting tablets/films have gone a long way from the traditional tablets/capsules on the market. Keystone that has shifted the emphasis of pharmaceutical firms to create innovative oral dosage forms to remove these constraints include reduced bioavailability of oral solid medications, the hassle of delivering injections, and imprecise dosing by liquid formulations. The majority of these difficulties may be overcome by using fast dissolving oral thin films. Several oral thin films may be purchased without a prescription, therefore the idea is not novel. Oral thin films containing prescription medications have been developed due to their widespread user approval and the rising demand for these items in the over-the-counter market. Both large pharmaceutical corporations and smaller biotech startups are showing interest in this new field. Oral dispersible, sublingual, and buccal films are only a few examples of the new kinds of oral thin films being developed by companies using their oral thin film technology. Oral thin films are being developed for numerous hormones and vaccinations with the same goal in mind as the medication formulations. MonoSol Rx, Applied Pharma Research/Labtec GmbH, BioDelivery Sciences, and NAL Pharma are some of the major participants in this industry. Oral thin films are being used by several corporations in conjunction with these technology providers as a means of managing the lifespan of their branded pharmaceuticals after they lose patent protection for other dosage forms.

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Oral thin films are not widely accessible with prescriptions at this time, although there is more potential in the pipeline. The market is expected to increase steadily over the next decade, despite the fact that its development, approval, and penetration rate are all subject to uncertainty. If the product is bioequivalent to an already approved oral drug product, the US Food and Drug Administration (US FDA) will approve it via the Abbreviated New Drug Application (ANDA) process. This generic approval procedure does not need clinical trials (section 505 (j) of the Food, Drug, and Cosmetic Act). A instance in point would be a study comparing the bioequivalence of two different dosage forms, such an ODT and an ODF. However, the pharmacokinetic profile of the developed oral film product may vary from that of the already marketed product. As a "new dosage form," the ODF requires clearance under Section 505(b)(2) of the FDA's regulations. In such a scenario, fresh clinical research is needed. A new clinical study's benefit is that it grants the product three years of commercial exclusivity. If the chemical is identical to the one already on the market, further preclinical toxicity testing is not necessary. These studies need to show that the treatment is safe, well tolerated, and effective. Animal models and human subjects both undergo testing for oral mucosa irritation. As new methods of preparing thin films are quickly developed, the future of film technology seems bright.

CONCLUSION

When compared to traditional oral dosage forms, FDOFs tend to have higher patient compliance rates, as well as potential improvements in biopharmaceutical characteristics, effectiveness, and safety. New products like FDOFs are a novel and promising dosage form, particularly for usage in geriatric patients, since they are designed for administration in the oral cavity. A broad variety of medications

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(including NSAIDS, antiulcer, antihistamine, Hypnotics & sedatives, antipsychotics, antiparkinsonism, antiemetic, antimigraine, and antidepressants) may benefit from the introduction of quick dissolving pharmacological items onto the market. Since it takes less than a minute for this system to start working, it will likely become the standard in the near future. Future research into these dose formulations will grow in response to rising patient demand.

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