Library Progress International
Vol.44 No.3, Jul-Dec 2024: P. 26447-26456

Print version ISSN 0970 1052
Online version ISSN 2320 317X

Original Article

Available online at www.bpasjournals.com

WHAT WE KNOW ABOUT FAST-DISSOLVING TABLETS (FDTs), UPCOMING OPPORTUNITIES IN THE MARKET, HOW WE MAKE THEM, AND WHAT THEY COULD BECOME

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How to cite this article: Rajendra Pal , Rajiv Kukkar (2024) WHAT WE KNOW ABOUT FAST-DISSOLVING TABLETS (FDTs), UPCOMING OPPORTUNITIES IN THE MARKET, HOW WE MAKE THEM, AND WHAT THEY COULD BECOME. Library Progress International, 44(3), 26447-26456

ABSTRACT— This study set out to find a way to make Mirtazapine & Clebopride tablets that dissolve quickly. The subliming substance was camphor, while the super disintegrants were sodium starch glycolate (SSG) and cross carmellose sodium (CCS). To improve the tablet's porosity, an optimum camphor concentration was applied. To examine the combined impact of two formulation factors, a 32-complete factorial design was utilized: The quantity of SSG and CCS. Older adults and children are more likely to have trouble swallowing tablets, and patients are less likely to take their medication as prescribed when they find the taste unpleasant. Because their muscles and neural systems are still developing, young people sometimes have trouble swallowing. A product of the pharmaceutical industry's never-ending quest for technical perfection is fast-dissolving tablets or FDTs. The patient's cooperation is greatly enhanced with FD pills. Because they provide the benefit of liquid medicine in a solid form, FD tablets are a convenient way to deliver several different medications. Patients of all ages, including those with dysphasia, have shown positive reactions to these new dose formulations. No water or chewing is required for the rapid dissolving or disintegration of FDTs in the mouth. Also known as fast-melts, rapid-melts, porous tablets, fast disintegrating tablets, or orally disintegrating tablets, it is designed for oral administration (FDTs). Children, the elderly, and those who are bedridden, as well as energetic people who are often on the go and do not always have access to water, can all benefit from fast-acting or orally dissolving pills. These pills usually melt or disintegrate in less than 60 seconds when placed in saliva.

KEYWORDS- Tablets that dissolve quickly, Tech that has been patented, Strategies for development, A method for hiding the flavor Decomposition process, Future possibilities, and research trends.

INTRODUCTION:

During the formulation process, it is important to choose appropriate excipients and use appropriate procedures to mask the medicine's unpleasant taste and ensure rapid oral dissolution [1]. Several methods exist for this purpose, including complexation, microencapsulation, and taste-masking agents [2]. To improve the taste and dissolve rate of tablets, excipients are used. These may include sweeteners, flavors, and disintegrants [3].

The development phase involves intensive testing of several formulation prototypes to assess their stability, disintegration duration, dissolve rate, and taste-hiding capabilities. Common techniques for evaluating the effectiveness of tablets in synthetic physiological settings include organoleptic testing, in vitro dissolving studies, and accelerated stability testing [4].

To guarantee production repeatability and to fine-tune its qualities, more optimization is carried out on a promising formulation [5]. Manufacturing parameters and composition need to be fine-tuned to obtain the perfect

combination of quick dissolving, durable tablets, and taste masking.

The penultimate stage is to test the efficacy and safety of the revised formulation in human clinical and preclinical studies. Pharmacokinetic studies may ascertain the fast-dissolving tablets' bioavailability in comparison to conventional dosage forms [6].

A multidisciplinary approach combining pharmaceutical science, sensory evaluation, and clinical research is needed to formulate, develop, and evaluate fast-dissolving tablets with improved taste and digestibility of severely bitter psychotropic drugs. This will help meet patients' complex needs while ensuring therapeutic efficacy.

Emerging Opportunities in the FDT Market

The market for Fast-Dissolving Tablets (FDTs) is experiencing a significant surge in interest and growth, driven by a confluence of factors that present exciting emerging opportunities [7]. Firstly, there's a noticeable shift in consumer preferences towards more convenient dosage forms. Patients increasingly seek easier-to-administer medications, particularly those with swallowing difficulties or aversions to traditional tablets and capsules [8]. This trend is fuelled by a growing aging population globally, where the ease of medication administration becomes paramount for compliance and therapeutic efficacy.

Technological advancements play a pivotal role in expanding the opportunities within the FDT market [9]. Innovative formulation techniques have enabled the development of FDTs with improved performance, including rapid disintegration, enhanced taste masking, and prolonged stability. Moreover, there's a notable expansion in the range of drugs suitable for FDT delivery, with advancements in drug delivery systems facilitating the administration of biologics, sensitive molecules, and complex drug formulations.

Ideal property of fast-dissolving tablets [10]

- Rapid disintegration within seconds when in contact with saliva.
- Smooth and pleasant taste for enhanced patient compliance.
- Sufficient mechanical strength for handling and transportation.
- High drug loading capacity to accommodate therapeutic doses.
- Stability under varied environmental conditions.
- Compatibility with a broad variety of medicinally active substances.
- Consistent and reproducible dissolution profile for reliable drug release.
- Non-toxic and biocompatible excipients for safety.
- Cost-effective manufacturing process for scalability.
- Eco-friendly packaging options for sustainability.

Making something new:

Pick the correct sweeteners, flavors, disintegrants, and agents to mask flavor as excipients. Determining the optimal ratio of excipients to API is crucial for rapid and efficient API dissolution and flavor masking.

You can determine the amount of sweetener needed to mask the bitterness by comparing its sweetness to sucrose.

Development:

Organoleptic testing is the way to go for a subjective assessment of taste masking effectiveness [11]. Use in vitro dissolution procedures that mimic physiological conditions to find out how the tablet dissolves. Calculating properties like dissolve efficiency and dissolving rate allows for an objective evaluation of the tablet's performance.

Conduct stability experiments to ascertain the chemical and physical stability of the formulation. Ascertain the degradation rates, if required.

Optimization:

Change the ingredients and processing settings of the formulation according to what you learn from the development studies.

To find the optimal formulation for taste masking, disintegration time, and solubility rate, statistical analysis may be required.

Evaluation:

Do preclinical studies, which could include animal testing, to find out how well and how safely the product works. Assess pharmacokinetic parameters such as area under the curve (AUC) and maximum plasma concentration (C_{max}) [12].

Conduct clinical trials to determine the efficacy, compliance, and patient acceptability of this alternative to conventional dosage forms. Ascertain statistical significance if applicable.
Find out how often any bad effects occur and how bad they are.
All of these processes could need a plethora of calculations, such as:
Using excipients' taste-masking
Capabilities to guide proportional formulations by dividing the entire quantity of medication by the amount that has dissolved, and then multiplying the result by 100, one may compute the dissolving efficiency (%DE) and other dissolution parameters.
Deterioration rates and other stability factors are calculated using kinetic models like first-order or zero-order kinetics.
Pharmacokinetic parameters such as AUC and C_{max} may be calculated using well-established equations and techniques of pharmacokinetic modeling [13].
Due to its self-administration simplicity, small size, and ease of production, the tablet is the most often used dosage form. Poor patient compliance is a result of the fact that traditional pills are difficult for children and elderly patients to swallow. Innovative medication delivery techniques, such as "melt in the mouth" or "mouth dissolve (MD)" tablets, have been created by scientists to circumvent this shortcoming. These new pill formulations melt and disseminate in saliva. Their particular benefits, like the ability to be delivered anywhere and at any time without the requirement for water, make them appropriate for both pediatric and elderly patients. Bedridden patients, who suffer from mental illness, or do not have simple access to water might also benefit from these. The advantages of these tablets as a dosage form of choice in the present market are patient compliance, quick start of action, enhanced bioavailability, and high stability.
This dose form is suitable for a wide variety of medications, including antibiotics, narcoleptics, analgesics, and cardiovascular medicines. When used for other types of vestibular complaints, it works as well as well. Due to its quick and effective absorption from the GI tract, MZP achieves its peak plasma concentration within two hours of an oral dose, whether given once or repeatedly.
The presence of meals modifies the rate of absorption slightly but not the amount. The approximately 50% absolute bioavailability is primarily explained by the gut wall and hepatic first-pass metabolism. MZP has an elimination half-life of 20–40 hours (26 hours in males and 37 hours in females), with shorter half-lives in young boys and infrequently longer half-lives of up to 65 hours. Because of the prolonged elimination half-life, a single daily dose is recommended. MZP attaches to 85% of plasma proteins nonspecifically and permanently. MZP exhibits linear pharmacokinetics between 15 and 80 mg [14]. The pharmacokinetics of clebopride have been studied in rats, dogs, and humans, among other mammals. Reports state that the drug's half-life is around 1.5 hours, and that it achieves its maximum plasma concentration in humans 15–45 minutes after oral administration [15].
Among the many critical components of pharmacy practice is ensuring patient compliance. To guarantee that patients get their medications effectively and with minimal adverse effects, pharmaceutical firms are now developing innovative drug delivery methods. Solid dosage forms are favored for several reasons, including simple administration, accurate dosing, self-medication, pain avoidance, and, most significantly, patient compliance.
Tablets and capsules are the most common solid dose forms, however, some patients have trouble swallowing them, which is a major downside [16]. For oral dose forms, water is an essential swallowing aid. For several reasons, including a lack of water, motion sickness (kinetosis), and sudden bouts of coughing due to the common cold, allergies, or bronchitis, swallowing traditional dose forms like tablets might be a challenge. Tablets with fast-dissolving or disintegrating properties in the mouth have so garnered a lot of interest. For this reason, the idea of Fast Dissolving Tablets came to be.
A fast-dissolving medicine delivery device is usually a tablet that dissolves or mixes in the mouth without the need for water or chewing. To the tune of 50-60% of all dose formulations, the oral mode of administration enjoys widespread approval. The recent adoption of the phrase "Orodispersible tablet" as a name for tablets meant to be put in the mouth and swiftly dispersed before swallowing by the European pharmacopeia highlighted their increasing significance [17].
People who have trouble swallowing are not the only ones who should use orodispersible pills; those who lead active lifestyles also benefit greatly from them. The medicine in fast-dissolving tablets dissolves or disperses in

saliva the moment they are placed on the tongue [18]. A drug's absorption and the start of its therapeutic impact are both affected by how quickly it is dissolved in water. Dysphagia, or trouble swallowing, is prevalent across all age groups but is more prevalent in the pediatric and elderly populations, as well as in institutionalized patients and those who suffer from motion sickness, nausea, or vomiting. FDTs that are flavorful and have a pleasant taste make bitter medications more acceptable to a wider range of people [19].

An interesting and novel aspect of technology is its potential impact on the development of medication delivery systems that increase patient compliance. There are several reasons why over half of all pharmaceutical goods are taken orally, including the fact that many of these medicines include medications with a disagreeable taste—sometimes quite bitter. Because of their very unpleasant flavor, these medications will not be developed further for use in oral formulations or clinical settings.

It is no longer acceptable for useful pharmaceuticals to have a bitter taste as the social quality of life continues to grow [20]. Effective medications that are pleasant to taste and easy to administer are designed to be taken by people. As a result, improving the product quality necessitates masking the unpleasant taste of a medicine. Particularly for the young, the old, and the frail, this will boost patient compliance and the final product's worth. As a result, the pharmaceutical industry spends a lot of time, energy, and money making sure its drugs taste good. To do this, they use a variety of flavor masking strategies.

In comparison to other dosage forms including effervescent tablets, dry syrups, and chewing gums/tablets, FDTs have several benefits that help patients take their medication as prescribed [20]. Water must be consumed in order to prepare the body to administer dry syrups and effervescent tablets or granules.

The taste masking layer can rupture during mastication, exposing the elderly patient to the bitter or unpleasant flavor of the medicine in its dose form, and they may also be unable to chew big tablets or gums. It has always been difficult to produce formulations for use in children and the elderly that have an oral medication delivery method that is both bitter and has an acceptable degree of palatability.

Hence, it is difficult for pharmacists to formulate taste-masked products.

The medication is released into the saliva by these components, which enable the tablets to dissolve rapidly when placed on the tongue. Increases in the bioavailability of certain drugs may result from the oral cavity absorption of medications and the pregastric absorption of pharmaceuticals distributed in saliva. Furthermore, in comparison to the quantity of medication that goes through first-pass metabolism in a regular pill, this amount is significantly reduced.

People in their later years make up a sizable chunk of the global population these days, thanks to rising life expectancy rates. Previous research found that the biggest reason why 26% of the 1576 patients who took the pills had trouble swallowing them was their size, followed by their surface, shape, and flavor. Even patients on the go, who may not always have access to water, have trouble taking their pills [21].

Our Technology: Zydis [22]

Among the first commercialized new technology tablets, Zydis was the most well-known because of its ability to dissolve and disintegrate in the mouth. A novel freeze-dried tablet formulation, Zydis contains the medicine either physically encased or dissolved inside a matrix of rapidly dissolving carrier material. Zydis units, if swallowed, dissolve instantly due to their freeze-dried nature; water is not necessary for this process.

The many components that make up the Zydis matrix work together to accomplish a multitude of goals. Incorporating polymers like gelatine, dextran, or alginates gives the material strength and resilience when handling. A glossy amorphous structure is formed by them, which gives it strength. Saccharides like as mannitol or sorbitol are used to enhance crystallinity, attractiveness, and toughness. The manufacturing method involves the use of water to guarantee the development of porous units, which facilitate quick disintegration, and a variety of gums to avoid the sedimentation of dispersed drug particles. Zydis units are shrinkage-resistant during freeze-drying and long-term storage, thanks to collapse protectants such as glycine. Blister packs are used to keep Zydis goods dry and safe from environmental moisture.

The active ingredient in Zydis is lyophilized, or freeze-dried, inside a matrix that often includes gelatine. The product is delicate and small, thus it comes in a specific blister pack for dispensing. Zydis is designed to disintegrate in 2 to 3 seconds when placed on the tongue. The improved bioavailability of the Zydis product in comparison to conventional tablets is one of its main selling points.

Significant pre-gastric absorption may occur from this formulation due to its oral dispersion and disintegration in saliva. Medications that are heavily processed by the liver may benefit from pre-gastric absorption as it prevents them from going through first-pass metabolism.

To be sure, Zydis technology isn't without its complaints. Zydis should not be stashed in the bottoms of handbags or backpacks due to their very light and delicate composition, as indicated before. Lastly, when exposed to greater temperatures and humidity, the Zydis formulation does not hold up well. At relative humidity levels over 65%, it starts to degrade rapidly due to its high water absorption rate.

Durasolv, a mouth-dissolving/disintegrating tablet developed by CIMA Lab, is a second-generation formulation that is protected by patent. When working with products that call for minimal active ingredients, Durasolv is the way to go. Drugs, filler, and lubrication make up the tablets produced by this method.

The tablets exhibit excellent stiffness (friability less than 2%), and they are made using traditional tableting equipment. Blisters, pouches, or vials are some examples of more traditional packaging systems that can accommodate them. Cima produces DuraSolv like OraSolv; however, the use of higher compaction pressures during tableting gives DuraSolv much more mechanical strength than OraSolv.

This allows for a more efficient and less expensive production of the DuraSolv product. Since the formulation is compressed to such a high degree by DuraSolv, one drawback of the technique is that it cannot accommodate active ingredient concentrations that are higher.

Orasolv Software: [23]

In contrast to Zydis, the OraSolv technology uses hardly detectable effervescence to spread in saliva. The OraSolv technology can be simply described as an orally disintegrating tablet since the tablet matrix dissolves in less than a minute, leaving coated drug powder.

At first glance, the OraSolv tablet seems like any other compressed tablet. On the other hand, compared to regular tablets, the OraSolv ones are weaker and more brittle since they are only slightly crushed. Because of this, Cima created a unique packaging and handling method for OraSolv.

The low degree of compaction of OraSolv has the added benefit of protecting the flavor-masking particle coating against processing-related fractures. Multiple or single active ingredients may be accommodated in these formulations, and tablets with a drug content of more than 1.0 g have been created. They break down within 30 seconds. Hygroscopicity is low for OraSolv formulations. The OraSolv formulations' mechanical strength is their biggest drawback.

Technology for Flash Doses:

Flash dosage technology is FUISZ's invention. Biovail Corporation presents Nurofen meltlet, a unique formulation of ibuprofen in the form of melt-in-mouth tablets produced using flash dose technology, as its first commercial offering. "Floss" is the name given to the self-binding shear form matrix that makes up flash dosage tablets. Flash heat processing is used to create shear form matrices.

A crystalline structure resembling floss—like cotton candy—is created by the Flash Dose technology's one-of-a-kind spinning mechanism. After adding the active medicine, this crystalline sugar may be crushed into a tablet. A large surface area for solubility characterizes the finished product. Once applied on the tongue, it dissolves and disperses rapidly.

Technology based on flash tabs: [24]

Prographarm Laboratories is the patent holder of the technology underlying the Flash tab. This method of preparing tablets involves the use of microcrystals as an active ingredient. Common ways for creating drug micro granules include coacervation, microencapsulation, extrusion spheronization, and simple pan-coating procedures. The conventional tableting technique was used for all processes. Compressed into tablets, the active component's microcrystals of micro granules are added to the granulated mixture of excipients created by wet or dry granulation. The produced tablets are said to possess exceptional mechanical strength and a disintegration time of under a minute.

Rapid Technology by Oraquick [24]

Using a proprietary taste masking technology, Oraquick is designed to dissolve and disintegrate quickly in the tongue. The flavor masking procedure results in more efficient manufacturing without the use of solvents. With a lower heat of manufacturing compared to other mouth-disintegrating technologies, Oraquick is suitable for heat-

sensitive medications. Oraquick asserts rapid dissolving in seconds with good taste-masking, Analgesics, scheduled medications, cough, and cold remedies, psychotropics, and anti-infectives are among the goods under research at KV Pharmaceutical, however, no Oraquick-based products are available to consumers at this time.

The Technology of Quick-Dis

Developed and patented by Lavipharm, the innovative intra-oral medication delivery method is a thin, flexible, and rapidly dissolving film known as Quick-DisTM.

Depending on whether the film is located on the tongue's floor or top. The active ingredient is quickly released from its retention at the application site, allowing for local and/or systemic absorption. For a 2 mm thick Quick-DisTM film, the usual disintegration period is merely 5 to 10 seconds.

The Field of Nanocrystals [25]

The unique NanoCrystal technology developed by Elan may enhance the activity of compounds and the end product's properties, allowing for the creation of mouth-dissolving tablets. The dissolving rate is enhanced when the surface area increases due to smaller particles. The use of NanoCrystal technology allows for the quick and predictable completion of this task. NanoCrystal particles are manufactured by grinding the medicinal component using a patented wet milling method. These particles are generally smaller than 1000 nm in diameter.

The drug material is mixed with water-soluble components to form nanocrystal colloidal dispersions, which are then put into blisters and lyophilized. Surprisingly strong, the resulting wafers disintegrate in seconds in very little amounts of water.

We use Shear form Technology TM [25] and the floss, or "shear form matrix," that forms the basis of the Shear form technology is made by flash heating a feedstock that contains a sugar carrier. In this process, the sugar is simultaneously exposed to a temperature gradient and centrifugal force. The former raises the mass's temperature, resulting in an internal flow state that permits some of the sugar to move in relation to the mass.

The mass is in motion because of the spinning head, which is responsible for flinging the floss. The resulting floss is amorphous, therefore it undergoes further processing to provide consistent flow characteristics and recrystallization, allowing for easier mixing. An active component and additional tablet excipients are then mixed with the recrystallized matrix. A tablet is made by compressing the resultant mixture. Before performing recrystallization, the active component and other excipients may be mixed with floss. Flashdose or EZ chew tablets are compacted from a mixture of shear form floss and coated or uncoated microspheres using conventional tableting machinery.

Technology by Ceform TM

Microspheres containing active medicinal ingredients are manufactured using Ceform technology. The core of the ceform microsphere production method is loading a dry powder that contains either extremely pure drug material or a special mix of drug material with extra pharmaceutical ingredients and excipients into a precisely designed, quick-spinning machine. The dry medication mixture is hurled through tiny, heated apertures at high speed by the centrifugal force of the reform machine's revolving head. The microburst of heat that forms melts the medication mixture into a spherical shape while keeping the drug's stability intact. The microspheres are then mixed and/or crushed into the dose form that was previously selected for oral delivery.

Incorporating elements into the microsphere at the same time as the drug and excipient creates a one-of-a-kind microenvironment that may change the medication's properties, such as making it more soluble and stable. Flashdose, EZ chew, Spoon Dose, and regular tablets are just a few examples of the fast-dissolving tablet types that may integrate the microspheres [26].

Among the technologies is Pharmaburst. SPI Pharma, located in New Castle, has a patent on this method. The co-processed excipients are used to generate ODT, and the medication dissolves in 30 to 40 seconds. Using this approach, the medication, flavoring, and lubricant are compressed into tablets following a dry mixing step. Blister packs and bottles may accommodate the obtained tablets because of their potency.

"Amorphous sugar" refers to sugars that may be granulated in an amorphous form using processes such as freeze-drying or spray-drying. These amorphous sugars include lactose, lactose, maltose, sorbitol, trehalose, and lactitol.

The relative humidity of a drug-amorphous sugar combination is found using its apparent critical relative humidity. The selected relative humidity for the given humidity state is one that is higher than or equal to the critical relative humidity of the aforementioned combination. Amorphous sugars are advantageous because they can absorb water at low moisture levels due to their low critical relative humidity. There can be issues with production due to tablet adhesion in a high-humidity environment.

What is sintering? [27]

A powder compact is densified and its average grain size rises when heat energy is added to it. Grain growth, sintering, or densification are the essential processes happening during this procedure. According to a method revealed by Lagoviyer et al., one way to make tablets stronger is to sinter them at high temperatures before resolidifying them at lower ones. Carbohydrates, calcium carbonate, and magnesium carbonate are all acceptable bulk agents that may be used in this formulation to add volume to the whole tablet. There are a variety of solvents available, including water, ethyl alcohol, isopropyl alcohol, or a combination of these. Molecular weights ranging from 1000 to 1,000,000 Dalton are typical for water-soluble polymers used as binders, such as polyethylene glycol (PEG). The next step is to compress the granules into tablet shape gently. To dissolve the binding component, these pills are heated to the right temperature for an extended period. To melt the binding agent and form intra-tablet bonds, the product is heated.

This process also aids in welding the product into shape. Most laboratory ovens are calibrated to operate between 50 and 100ºC. You may cook it for anything from three to forty-five minutes. As the temperature drops to room temperature, the binding agents resolve. On average, the disintegration time ranges from three to sixty seconds.

Procedures used in the creation of FDTs:

The rapid disintegration of FDTs is caused by the rapid entry of water into the tablet matrix, which speeds up the dissolving process. Optimizing the tablet matrix's porosity structure is, hence, one of the fundamental ways to create FDTs.

Using the right dissolving agent or agents Including excipients in the formulation that are extremely soluble in water Various methods based on various ideas have been developed so far.

1. Dyeing using cold air or lyophilization
2. Forming Tablets
3. Using a spray dryer
4. The process of sublimation
5. Straight compression
6. Extrusion machinery
7. Making cotton candy
8. Using nanoparticles

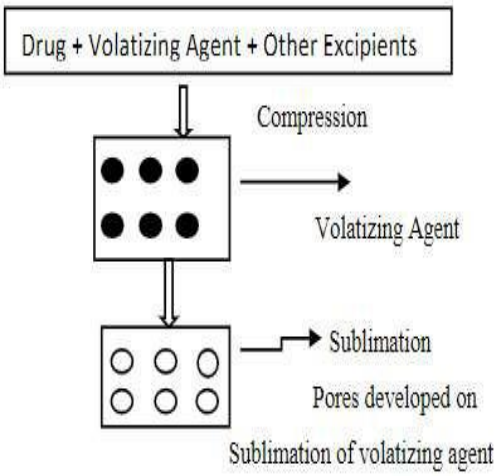

Fig. 1: Schematic Diagram of Sublimation Technique for Preparation of FDT

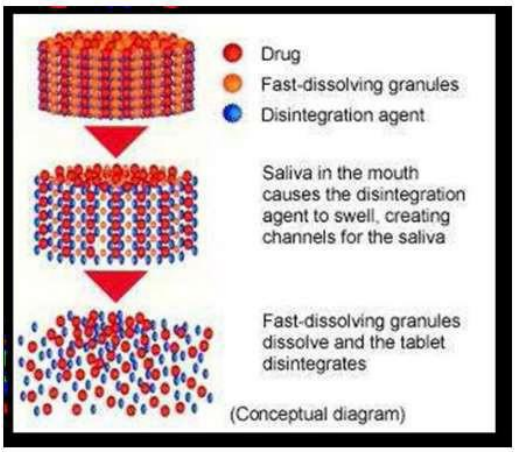

Fig. 2: Theoretical framework for FDT Degradation

Advantages of Fast Dissolving Tablets [28]:

1. Enhanced patient compliance, especially for those with swallowing difficulties.
2. Rapid onset of action due to quick dissolution in saliva.
3. Convenient administration without the need for water.
4. Potential for improved drug bioavailability compared to conventional tablets.
5. Reduced risk of choking, making them suitable for pediatric and geriatric populations.
6. Flexibility in dosing regimens, including fractionated doses.
7. Opportunity for taste masking to enhance patient acceptance.

Disadvantages of Fast Dissolving Tablets [29]:

1. Limited drug loading capacity, particularly for high-dose medications.
2. Stability concerns, requiring careful formulation and packaging.
3. Complexity in manufacturing, leading to higher production costs.
4. Regulatory complexities regarding bioequivalence and dissolution testing.
5. Challenges in taste masking, potentially impacting formulation complexity and cost.
6. Moisture sensitivity, necessitating special storage conditions.
7. Limited compatibility for certain drugs and formulations.
8. Risk of dose dumping with rapid drug release, posing safety concerns.

CONCLUSION

When compared to traditional oral dose forms, fast-dissolving tablets have superior biopharmaceutical characteristics, effectiveness, and safety, and they are more readily accepted by patients. Modern manufacturing processes have made it possible to transform many medications into fast-dissolving tablets, bringing the convenience of liquid medicine in a solid form. FDT should be developed for a wide range of patients, including those with specific needs, such as those who are young, elderly, bedridden, psychotic, or who are often on the go and may not have access to water.

Clinical trials have shown that FDTs may enhance the bioavailability, shorten the time it takes for an effect to take effect and improve patient compliance. An additional commercial potential presented by the creation of fast-dissolving tablets is the possibility of expanding the product line to include a wider variety of medications. This includes medications for erectile dysfunction, neuroleptics, cardiovascular pharmaceuticals, analgesics, and antihistamines.

A further factor contributing to the proliferation of fast-solving/disintegrating products is the pharmaceutical industry's marketing efforts. It is usual practice for pharmaceutical companies to create an enhanced dosage form of an existing therapeutic item when its patent life approaches its expiration.

Many of the currently available sustained-release formulations are comparable to fast-solving/disintegrating tablet formulations. Increased revenue and access to treatment for underprivileged groups are both achieved via the extension of market exclusivity, which a fast-dissolving/disintegrating dosage form may give.

The customer is not being charged more for these customized dose forms, even though their manufacturing cost is higher than that of regular tablets. There is a need for better manufacturing processes for fast-dissolving tablets that are mechanically strong, easy to handle and package, and have production costs comparable to conventional

tablets.

This is because existing FDDT technologies have limitations, as mentioned earlier. The development of a new oral tablet dose form that dissolves quickly in saliva without the requirement for drinking water has been a significant endeavor by formulators to meet these medical demands.

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