

# Fast Disintegrating Tablets Over Other Solid Dosage Form: A Comprehensive Review

<sup>1</sup>Apoorv Tripathi, <sup>2</sup>Dr Sameer Rastogi

Himt College Of Pharmacy Plot No.8, Knowledge Park-1 Greater Noida, Uttar Pradesh-201306.

**Abstract:** Such appliances are becoming an increasing amount more sophisticated as pharmaceutical researchers gain a better understanding of the physicochemical and biochemical features that are relevant to the efficacy of drug delivery systems. Fdt disintegrating tablets, also known as FDTs, have garnered a lot of attention over the past three decades as a preferred alternative to conventional tablets and capsules due to improved patient compliance. This is because FDTs disintegrate in the mouth instead of being swallowed whole. This is due to the fact that FDTs can dissolve in the mouth, meaning that they do not need to be swallowed. Oral disintegrating tablets, often known as FDTs, are solid dosage forms that, when put on the tongue, release their contents rapidly, typically in a few seconds or less. FDTs include active pharmaceutical substances. In the 1980s, FDT technologies first began releasing their products into the marketplace. Since then, there has been a consistent rise in the demand for these items, and FDT technologies are moving quickly to expand their product pipelines to meet this demand. The latest FDT technologies cater to a diverse range of requirements posed by both the pharmaceutical industry and individual patients. These needs span from improved life-cycle management to more convenient dose for paediatric, geriatric, and psychiatric patients who have difficulty swallowing. One example of the former of these needs is the necessity for patients with difficulties swallowing to be able to take their medication. As a result of this, a number of academic institutions as well as business companies have found the motivation to develop novel fdt disintegrating formulations and technological techniques in this sector. In this article, the development of FDTs, the challenges that were encountered during formulation, new FDT technologies and evaluation methodologies, the suitability of drug candidates, and the potential for the future will be discussed.

**Keywords:** Fast Disintegrating Tablet, Conventional Tablets, Conditional Process, Improve Bioavailability.

Over the course of the past decade, there has been a gradually growing demand for dosage forms that are more user- and patient-friendly. This demand has been continuously on the rise. As a direct result of this, the demand for the development of cutting-edge technological solutions has been consistently increasing over the course of the past year. Because the cost of producing a new medication molecule is so high, pharmaceutical companies are redirecting their efforts toward the production of more cost-effective dosage forms as well as the extension of alternative dosages for existing medicinal products. This is because the cost of developing a new drug molecule is so high [1]. These new dosage forms will have increased safety and efficacy, in addition to reduced dosing frequency, so they are really exciting. In addition, the development of these novel dosage forms will also take place for already existing medications [1, 2].

The vast majority of therapeutic medications that are used to induce systemic effects are typically taken by mouth, making oral administration the most common form of administration. This is owing to the multiple benefits that are offered by oral administration, as well as the high patient compliance that is offered by it in comparison to the majority of other routes of administration [3].

The majority of the medicine delivery systems that are currently available on the market consist of hard gelatin tablets and capsules. These forms of drug delivery are currently the most common. However, many patient groups, including the elderly, toddlers, and patients who are mentally challenged, uncooperative, nauseated, or on limited liquid-intake/diets have difficulties swallowing these dosage forms. Other patient groups that have difficulty swallowing these dosage forms include patients who are nauseous or who are on diets that limit the amount of liquid they consume [4]. Patients who are on diets or diet plans that limit the amount of fluids they consume are another patient group that has difficulties swallowing these dosage forms. People who are constantly on the go or who do not have convenient access to sources of water will also be affected [3, 5].

Fdt disintegrating tablets, also known as FDTs, are a revolutionary oral dosage form that was developed by pharmaceutical technologists. These tablets dissolve very quickly in saliva, usually in a matter of seconds, and the patient is not required to take them with water. This was done in order to fulfill the conditions that were established by the medical community. It's likely that the solubility and absorption of the medication, as well as the start of clinical action and the drug's bioavailability [6], will be significantly higher than what's seen with regular dose forms. Although tablets that can be chewed have been commercially available for some time, the fast disintegrating tablets (FDTs) that are currently on the market are in no way comparable to chewable tablet forms. Patients who have trouble chewing or who suffer pain when doing so will have no trouble using these new medications. youngsters who are missing part or all of their adult teeth but have not yet lost all of their primary teeth can be treated with FDTs, which is a handy choice for the treatment of these youngsters [7, 8].

The majority of customers are going to ask their healthcare provider for FDTs (70%), purchase FDTs (70%), or favor FDTs to conventional tablets or liquids (>80%), according to recent market research that reveal more than half of the individual's population prefers FDTs over other dosage forms [9].

An FDT is defined in the 'Orange Book' by the Center for Drug Evaluation and Research (CDER) of the United States Food and Drug Administration as "a solid dosage form containing medicinal substances that disintegrates rapidly, typically within a matter of seconds, when placed upon the tongue". The relevance of these dose forms is underscored by the introduction of the term "Orodispersible Tablet" by the European Pharmacopoeia. This phrase refers to a tablet that can be placed in the oral cavity, where it disperses quickly before being swallowed. This name was adopted to stress the significance of these dosage forms [10-12].

Building a suitable drug product to achieve optimized acceptance among patients and comfortable accessibility with improved bioavailability and effectiveness, dropping the dose, and reducing challenges in the Novel Drug Delivery System (NDDS) is a recent development that demonstrates an improvement and better result in the efficacy and safety of bioactive compounds that have been used in the past. This is accomplished by creating an appropriate drug product. The Fast Disintegrating Drug Delivery System, also known as the FDDDS, has earned a stellar name in the pharmaceutical sector thanks to the distinctive qualities it possesses [13]. Patients suffering with dysphagia or difficulty swallowing may benefit from using FDDDS, which comes in the form of a tablet that can dissolve in the mouth in a matter of seconds without the need for the addition of water. Tablets that can be broken up into smaller pieces quickly are in great demand these days because of the significant impact they have on patient compliance [14, 15].

Tablets that dissolve quickly in the mouth are called fast-disintegrating tablets, and they come in the shape of a solid dosage that can break up into very little particles. According to the formulation and the tablet size, the time required for disintegration for FDTs might last anywhere from a few seconds to several minutes [16].

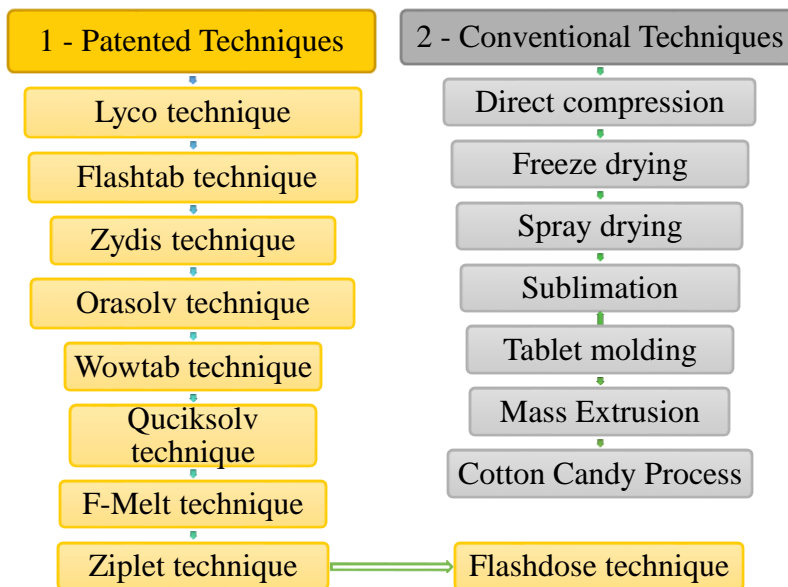
#### **Salient Features of Fdts:**

- ❖ The tablet can be swallowed without the need for water.
- ❖ As compared to liquids, tablets provide more convenience and effective dosing.
- ❖ The pleasant tongue taste of FDT helps to alter people's perceptions of medicine as "bitter medicine," which is especially beneficial for pediatrics.
- ❖ Patients who have difficulty swallowing tablets, such as geriatric and pediatric patients, along with mental patients, will find them simpler to give.
- ❖ As saliva goes down into the stomach, some medications are absorbed from the mouth and esophagus, resulting in enhanced drug bioavailability.
- ❖ Rapid drug disintegration, dissolution, and absorption can lead to a rapid onset of action.
- ❖ Ability to provide liquid medication advantages in a solid form.
- ❖ Pre gastric absorption can boost bioavailability and improve clinical efficiency by lowering the dose and decreasing unwanted side effects [18-21].

#### **FDT's Advantages:**

- ❖ Allows for a significant amount of drug loading space.
- ❖ It is possible to achieve high drug loading while yet achieving quick drug therapy action.
- ❖ Remedy for dysphagia Eliminates the requirement for water
- ❖ A pleasant flavor contributes to consistent behavior.
- ❖ The capability of incorporating, in a pill or other solid form, the benefits of liquid medical treatments.
- ❖ Have a pleasing flavor and a pleasant experience in the mouth.
- ❖ Improved patient enforcement [22-24].

#### **Techniques used in formulation of FDTs | 4, 25-28|:**



Technology	Innovation	Advantages	Disadvantages
Zydis	First to market, Freeze dried	Quick dissolution, Increased bioavailability	Inadequate stability, Expensive process.
Quicksolv	Freeze dried tablet, disintegrate in 10 Sec, blister packed,	Uniform porosity and adequate strength for handling.	--
Lyoc	Disintegrate in 10 sec, Freeze-dried wafer Blister packed	Lyoc tablets do not contain preservatives.	Low porosity that result in denser tablet.
Flashtab	Microcrystals of the medication in a compressed dose form	The only traditional tableting technique is required	--
Orasolv	Gently compressed, special taste-masking	Rapid dissolve and taste masking is accomplished two-fold.	Low mechanical strength
Flash Dose	A one-of-a-kind spinning mechanism that produces a floss-like crystalline structure, similar to cotton candy.	For dissolution, a large surface area is required.	High temperature requirement, sensitive to moisture and humidity.
Wowtab	Saccharides with low and high mold resistance. The smooth melt effect offers a better taste.	Hardness and appropriate dissolving rate.	No discernible difference in bioavailability.
F-Melt	Powder that has been co-sprayed and dried. Type C (appropriate for both pharmaceuticals and nutraceuticals), Type M (just for pharmaceuticals)	For nutraceuticals, a cost-effective, user-friendly royalty-free, and adaptable excipient system is available.	--

Ziplet	Water-insoluble, inorganic excipients are included for improved physical ability.	At a high dose (450 mg) and high weight (850 mg), good mechanical strength, operating challenges,	As the soluble component disintegrates,
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### **Complications With Rapidly Dissolving Tablet Formulation:**

#### **Palatability:**

The flavor of most pharmaceuticals isn't especially pleasant, which is why fdt disintegrating drug delivery systems usually involve masking the taste of the medication. It is vital to mask the taste of the active ingredients of a drug in order to ensure that patients take their medication as directed. This is because the active ingredients of a drug are released when the delivery mechanism of the drug dissolves or disintegrates in the mouth [13, 29].

#### **Mechanical strength:**

To be able to dissolve in the mouth, FDTs must either have a very porous and soft-molded matrix structure or be compressed to tablets with very low compression force. Either of these two options causes the tablets to be fragile and/or brittle, making them difficult to handle and occasionally expensive due to the requirement for specialized peel-off blister packaging. Tablets that are sufficiently hard and sturdy to be packaged in multidose bottles can only be manufactured using a select few technologies, such as Wowtab® by Yamanouchi-Shaklee and Durasolv® by CIMA labs [30-32].

#### **Hygroscopicity:**

Several of the pharmaceuticals that can be taken fdt dissolving are hygroscopic, which indicates that they are unable to maintain their structural integrity when exposed to circumstances of temperature and humidity that are considered normal. As a consequence of this, they have a demand for protection against moisture, which mandates the employment of particular packaging for the product in question [8, 15, 33].

#### **Amount of drug:**

The fundamental constraint that limits the applicability of the technologies that are used for FDTs is the quantity of medicine that may be incorporated in each individual dose. This is because FDTs are administered subcutaneously. When taking lyophilized forms of medication, the amount of the drug that is consumed should be no more than 60 mg for soluble pharmaceuticals and no more than 400 mg for insoluble pharmaceuticals. When it comes to the formulation of an oral film or wafer that dissolves quickly, this characteristic provides a difficulty that is particularly tough to overcome [21, 34, 35].

#### **Aqueous solubility:**

Since water-soluble drugs produce eutectic mixtures, their freezing point is lowered, and a glassy solid is generated. This glassy solid has the potential to collapse upon evaporation owing to the elimination of structural support that occurs during the sublimation process. This results in a wide array of difficulties with the formulation. When certain matrix-forming excipients are used, such as mannitol, they may induce crystallinity and, as therefore, impart rigidity to an amorphous composite, it is sometimes feasible to prevent the occurrence of collapse of the composite [7, 19, 36].

#### **Size of tablet:**

The larger a tablet gets, the more challenging it is to swallow, and this relationship holds true regardless of the tablet's shape. It has been asserted that a tablet with a thickness of 8 millimeters or more is the easiest to handle, while a tablet with a thickness of 7-8 mm is the easiest to swallow. The size of the tablet that is easiest to manage is one that is larger than 8 mm. As a result, it is difficult to design a tablet size that is both easy to take and easy to work with at the same time [29, 37].

#### **Mouth feel:**

The pill should not disintegrate into larger pieces while in contact with the oral cavity. After the Tablet has been broken up into its component parts, there should be the smallest possible particles left over. After being taken by mouth, the pill ought to leave behind either very little or nothing at all in the mouth [21, 33, 38].

#### **Taste masking:**

The taste of several drugs is described as being unpleasant. As a consequence of this, effective taste masking of bitter pharmaceuticals is necessary in order to ensure that the flavor of the drug is not picked up in the oral cavity [11, 25, 39].

**Sensitivity to environment:**

Since the majority of the components that go into a tablet are intended to dissolve in a limited quantity of water, the tablet itself should be relatively unaffected by environmental factors such as changes in temperature and humidity [14, 32, 40].

Sr.No	Organic polymer	Disintegration time	Concentration use (w/w)	Reference
1.	Guar gum	30 sec	1%	28, 41
2.	Gum karaya	17.10 sec	4%	14, 19, 40
3.	Agar and treated agar	20 sec	1-2%	30, 38
4.	Fenugreek seed mucilage	15.6 sec	4%	31, 36
5.	Gellan gum	155 sec	4%	26, 33
6.	<i>Lepidium sativum</i>	17 sec	10%	7, 39
7.	<i>Lepidium sativum</i> mucilage	17 sec	5-15%	9, 35
8.	Aegle marmelos gum	8-18 min	6%	18, 37
9.	Locust bean gum	13 sec	10%	30, 38
10.	Soy polysaccharide	12 sec	8%	15, 32
11.	<i>Mangifera indica</i> gum	3-8 min	6%	40, 42
12.	<i>Hibiscus rosa-sinensis</i> mucilage	20 sec	6%	22, 28, 41
13.	Dehydrated banana powder	15-36 sec	6%	4, 9, 42
14.	Chitin and chitosan	60 sec	3%	27, 33
15.	Mango peel pectin	11.59 sec	0.1-4%	19, 34

**Evaluation of FDT:**

The criteria that are outlined in pharmacopoeias can be utilized to do an evaluation of a material's capacity for breaking as well as its flexibility. However, there are certain examinations that require additional focus, and they include the following ones [43-45]:

**Wetting time:**

There is a link among the contact angle of dosage forms and the amount of time it takes for the forms to wet. It is essential to carry out an investigation in order to acquire the knowledge required to comprehend the disintegration properties of.

When it comes to tablets, a shorter wetting time means that the pill will break down more quickly than one with a longer wetting time would. In order to carry out this experiment, a tablet is placed on top of a piece of folded paper known as tissue, and then the complete apparatus is placed inside a little Petri dish that has an internal diameter of 6.5 centimeters and contains 6 milliliters of water. After then, the length of time that it takes for the tablet to get totally saturated with water is measured [22, 31, 46-48].

**Disintegration Time:**

FDTs normally disintegrate in a minute or two, and the actual duration of time it takes for a patient to go through the process of disintegration could range anywhere from five to 30 seconds. The traditional procedure that is utilized for the purpose of performing disintegration studies on these dosage forms entails a number of limitations, and it is not suitable for the evaluation of disintegration times that are exceptionally quick [49-51]. The process needs to be updated since FDTs require disintegration even in the absence of water; hence, the test needs to imitate disintegration in salivary contents. Due to the fact that FDTs need disintegration even in the absence of water, the process for performing the test needs to be updated. When the compendial method is used, an FDT that has a disintegration period that is too short to differentiate between tablets needs a modified dissolution equipment. This is because the compendial method was developed for tablets. This is due to the fact that the compendial technique necessitates a particular degree of accuracy. Within a container that holds 900 milliliters of water at a temperature of 37 degrees Celsius, a paddle is turned at a speed of 100 revolutions per minute, and a basket sinker that contains the tablets is positioned close to the surface of the water. The time at which the pill was able to disintegrate is determined once it has been completely dissolved and is able to pass through the display of the sinker [3, 42, 52].

Numerous researchers, collectively numbering, have come up with innovative in vitro processes that make it possible to obtain an accurate evaluation of the results of disintegration tests. A device called as a texture analyzer is utilized in the process of carrying out the disintegration test. In this particular test, a cylindrical probe with a flat end is placed into the disintegrating pill while it is being held in water. The results of this test are then analyzed. Regardless of the manner in which the tablet is shattering into pieces, the device is configured to continue providing a very low force for a predetermined amount of time. The disintegration characteristic of the tablets can be determined as a function of time by graphing some distance traveled by the probe and having the software that comes with the instrument do the plots for you. This will allow you to obtain the disintegration profile in a time-dependent manner. Because of the plot, it is now much simpler to ascertain where the starting and finishing points of the process of the tablet's disintegration are [34, 53].

**Dissolution test:**

The procedure that was used in the development of ways for the disintegration of FDTs is comparable to the one that was utilized for the disintegration of regular tablets, and the two procedures are extremely similar to one another. Scouting runs for a bioequivalent FDT should start with dissolution conditions for drugs that are published in a pharmacopoeia monograph. This information can be found in the monograph. It is advised that additional media, such as buffer (pH 4.5 and 6.8) and 0.1 M HCl, be assessed for FDT in a manner that is very similar to how their traditional tablet counterparts are reviewed. This is because the two types of tablets are extremely similar in terms of their composition [2, 31, 55].

There is evidence that the USP 2 paddle apparatus is the best and most common option for the manufacturing of fdt disintegrating tablets, and a speed of 50 revolutions per minute (rpm) for the paddle is commonly used in this process [56].

**Moisture uptake studies:**

In order to gain a better appreciation of the stability of the formulation, it is very necessary to conduct moisture uptake studies on FDT. This is because a lot of the excipients that are used in the formulation are hygroscopic. A desiccator is filled with calcium chloride and ten tablets of each formulation is placed inside. The mixture is then heated to 370 degrees Celsius for a 24-hour period. After that, each individual pill is weighed, and then it is stored for two weeks at the ambient temperature with a relative humidity of 75%. It is important to keep a saturated sodium chloride solution in the bottom of the desiccator for three days in order to achieve the level of relative humidity (RH) that is required, which is 75%. This can be accomplished by following the instructions provided by the manufacturer. In order to analyze the moisture absorption that is brought on by the other excipients, it is required to set aside one tablet to act as a control. This tablet should not include a superdisintegrant. After the pills have been weighed, a record is made of the percentage rise in weight that has occurred since the beginning of the process [26, 39, 57].

**Clinical studies:**

In-vivo studies have been carried out on oral fast-disintegrating dosage forms to investigate how they act in the mouth–esophageal tract, as well as their pharmaceutical kinetics effectiveness as therapies, and acceptability. Gamma-scintigraphy was performed in order to analyze the length of time that Zydis spent in both the mouth and the stomach in addition to its travel through the esophageal tract. This was done in order to determine how long Zydis remained in each of these locations. The rate at which it dissolved and cleared out of the buccal cavity was fast, but the rate at which it moved through the esophagus and the rate at which it emptied the stomach were both slow. The amount of time required for the stomach to empty was about the same as that required by traditional tablet, pill, or liquid form medications. There was also a decreased intersubject variability in the transit time, according to the reports that were received. Zydis also shown good therapeutic efficacy and patient acceptance, particularly in youngsters and in circumstances where simple administration and a speedy beginning of action were important (for example, in patients undergoing surgery). The fast-disintegrating forms that were studied had significantly better pharmacokinetic features as compared to the oral solid formulations that were utilized as a reference. Even though it contained the same amount of bioavailable acetaminophen as the most popular brand on the market, for example, the acetaminophen Flashtab had a significantly faster absorption rate. It was discovered that Lyoc formulations of a variety of drugs, such as phloroglucinol52, glafenine, spironolactone, and propyphenazone, exhibited higher bioavailability in addition to enhanced patient compliance.

When Zydis was used, there was an increase in the bioavailability of all pharmaceuticals, including those that can be absorbed through the buccal and esophageal mucosa. At the same time, the adverse effects of these treatments were greatly reduced. This is helpful in actives in general, but it is particularly advantageous in actives with significant first-pass hepatic metabolism<sup>44</sup>. At last, it was determined whether or not FDTs are appropriate for treatment over an extended period of time by conducting an inquiry. Patients who were suffering from gastrointestinal problems had a positive response to Lyoc formulations that contained aluminum [10, 17, 45, 58].

**FDT Counseling Concerns:**

As such, pharmacists are in a prime position to learn about these new tools and inform their patients on what to anticipate after receiving their first dose. Most people who are prescribed FDT formulations aren't familiar with them. Patients could be taken aback when medications start dissolving in their mouths. They might hope for the therapeutic effects to kick in sooner.

Asking the pharmacist for clarification can help eliminate any ambiguity. Most methods rely on the patient's own saliva, despite the fact that water is not necessary for the drug's rapid and effective distribution. The rate of disintegration/dissolution and the bioavailability of the substance may be slowed by a decrease in saliva volume.

Although chewable versions of pills have been commercially available for quite some time, the new oral disintegrating tablets (FDTs) are in a league of their own. Patients who experience difficulty or pain when chewing will find these novel tablet forms to be beneficial. FDTs are a convenient option for children who have lost some permanent teeth along with their baby teeth and are now lacking some permanent teeth.

Many individuals who use FDTs are under the impression that they are consuming effervescent tablets. It is possible that the pharmacist will want to stress that over-the-counter tablets (FDTs) are not the same as effervescent pills. The FDT formulations are more susceptible to the damaging effects of heat and moisture. A regular supply bottle is available for purchase, and it contains some of the most recent FDT formulations.

When distributing these types of preparations, pharmacists need to exercise extreme caution so that the medications do not become exposed to high levels of moisture or humidity. Patients ought to be warned against storing FDTs in the same locations as other medications, such as in the bathroom medicine cabinet.

New prescriptions for FDT formulations have been flagged for extra scrutiny by pharmacists. Most of these products come in the same dosage strengths as their more conventional counterparts. The dispensing of an FDT requires special note from the prescribing physician. Without naming a specific medicine, a doctor can be fooled into thinking the brand name is Zydis. It may be required in some situations, and can certainly help to clear up any confusion, to verify with the prescribing practitioner.

#### **Utilization in The manufacturing sector:**

- ❖ To create and experiment with disintegrants that can be taken fdt
- ❖ To improve upon the current FDT technology
- ❖ To achieve FDTs, it is necessary to optimize the combination of disintegrants or excipients.
- ❖ Product stability can be improved by using the right packaging material and method, which can also be used to reduce production costs.
- ❖ Improve patient adherence by developing and validating taste-masking agents and acceptable dose forms.
- ❖ In order to formulate FDTs, it is necessary to create disintegrants from a variety of polymers often employed as coating materials by making a few tweaks to their structure [23, 33, 47, 59].

#### **Outlook for the future:**

These dosage forms might be suitable for the oral delivery of drugs such as protein- and peptide-based therapies, both of which have a limited bioavailability when they are administered in the form of conventional tablets. When they enter the stomach, these chemicals frequently go through a period of rapid breakdown. It is possible that tablets may no longer be the format of choice for the administration of pharmaceuticals containing proteins or peptides if it turns out that the majority of the next generation of medications will be constituted of these two types of molecules.

Injections are often not favored for use by patients, unless they can be given with the assistance of technologically advanced auto-injectors. Patients generally prefer other methods of medication administration. However, the majority of chemical entities with low molecular weights have been generated so far as a result of the growing study into biopharmaceuticals that has been done so far. This is because of the research that has been done so far. Inhalation is one viable option that can be utilized as an alternate method for the delivery of these medications.

The latest developments in increased oral protein delivery technology using FDTs, which may release these drugs in the oral cavity, are very promising. These developments are particularly promising for the administration of high molecular weight proteins and peptides.

#### **The Outcome :**

Fdt disintegrating tablets have a higher patient acceptance rate and compliance rate when compared to standard oral dosage forms. Additionally, it is possible that fdt disintegrating tablets have enhanced biopharmaceutical properties, increased efficacy, and improved safety.

Initially, prescription over-the-counter (OTC) drugs were developed to assist patients who were afflicted with dysphagia, a condition that causes patients to struggle when attempting to swallow traditional tablet forms of medication. Patients of all ages, including children, the elderly, and those with mental illnesses, are included here. Over-the-counter (OTC) drugs are now more widely available, which means that FDTs can be used to treat a wider range of symptoms, including those associated with allergies, the common cold, and the flu.

The availability of cutting-edge technology, in conjunction with a substantial level of market acceptability and the demand from patients, makes the potential for such dosage forms look quite promising. By keeping a close eye on how technology is developing, pharmaceutical companies have the opportunity to utilize FDTs for the purpose of expanding their product lines or introducing new products to the market. Because of this, the enterprises are able to provide a wider variety of products. As a direct result of the ongoing research and production of novel pharmaceutical excipients, it is reasonable to predict the development of other revolutionary technologies for FDTs in the days and weeks that are to come.

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