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## A Review on Fast Dissolving Tablet by Using Superdisintegrants



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### ABSTRACT

The most prescribable and appropriate route in terms of patient compliance is the delivery of drugs by the oral route. Improving patient compliance always presents a challenge for developing an oral drug delivery system. Over the last decade, fast disintegrating tablets (FDTs) have received ever-increasing demand, and the field has become a rapidly rising pharmaceutical industry. Fast dissolving Tablets are disintegrating and/or dissolve rapidly in the saliva without the need for water. Such tablets readily dissolve or disintegrate in the saliva generally within <60 seconds. Generally, superdisintegrants are used in the solid dosage form at a low concentration, typically 1–10% by weight relative to the total dosage unit weight. Different types of super disintegrants such as synthetic, semi-synthetic, natural, and co-processed blends, etc. have been used to establish successful mouth dissolving tablets and to resolve the limitations of traditional methods of tablet dosing. FDTs have benefits such as accurate dosing, easy portability, and manufacturing good physical and chemical stability and an ideal alternative for pediatric and geriatric patients. In addition to these benefits, dysphagia is the most common disadvantage of fast dissolving tablets benefits associated with numerous conditions such as sudden allergy exposure, mental disability, motion sickness, unconsciousness, water unavailability etc. To get rid of these problems several innovative drug delivery systems have been developed like Mouth Dissolving Tablets (MDT's). This article aims to address ideal properties, advantages, disadvantages, need for the formulation, superdisintegrants, patented technologies, and evaluation of FDTs.

## INTRODUCTION

Oral drug delivery is considered to be the safest, most appropriate, most cost-effective drug delivery. Due to ease of ingestion, accurate dosage, self-medication, pain prevention, the oral route of drug administration transformed common route for systemic impacts. Fast dissolving drug delivery system is concluded as a new drug delivery scheme for developing dosage forms, convenient to be manufactured and administered without water, providing instant release, improved bioavailability to obtain better compliance with patients [1].

It can be defined as a solid dosage form comprising active ingredient having the property of disintegrating rapidly as it comes in contact with saliva without water or chewing. Disintegrants are the agents that help break up tablets into their small particles or fragments as they come into contact with aqueous surroundings [2]. Quick dissolving drug delivery systems were first designed for pediatric and geriatric patients in the early 1970s as an alternative to traditional dosage forms. Such tablets are intended to dissolve or disintegrate rapidly into the saliva less than 60 seconds in total [3]. Pharmaceutical technologists have created a new oral dosage form known as orally disintegrating tablets or quickly disintegrating (dissolving) tablets (FDTs), mouth dissolving tablets (MDTs), instant release tablets that disintegrate quickly into saliva, generally within seconds, without the need to take water. Recent market studies show that over half of the population of patients prefer FDTs to other dosage forms. Quick dissolving tablets are primarily developed using two first-time techniques such as Croscarmellose sodium, sodium starch glycolate, crospovidone. Another method is to maximize the tablets' porous structure by freezing drying and drying vacuum. In all methods, direct compression is preferred because of its easy, quick procedure and cost-effectiveness [4].

But one important drawback of such dosage forms is 'Dysphagia' which means difficulty in swallowing. This affects almost 35 % of the overall population and is also linked with several condition such as:

- a. Parkinsonism
- b. Motion's disease
- c. Lack of consciousness

- d. Patients of old age
- e. Children
- f. People with mental disabilities
- g. Water is not available [5].

In this modern era, improved patient compliance is required. There is a need for a lot of cash, hardworking, and sufficient time to create a chemical entity. The focus is therefore on developing new drug delivery systems for current drugs, with increased efficacy and bioavailability, dose reduction, and dosage frequency to minimize side effects [6].

**ADVANTAGE OF FAST DISSOLVING TABLETS: [7-9]**

- Do not need to swallow the tablet with water.
- It can be administered easily to pediatric, elderly, and mentally disabled patients.
- Precise dosage compared to liquids.
- Rapid onset of action as dissolution and absorption of drug is fast.
- The metabolism of the first pass is reduced, thereby providing improved bioavailability and decreased side effects.
- Secure from the danger of suffocation due to physical obstruction, thus increasing protection.
- It is perfect for controlled and sustained release active.
- Allow high drug loading.
- Cost- effective.
- Have a good taste and a pleasant sensation for the mouth.
- No chewing necessary.
- Improved stability.

- Drug bioavailability is improved by mouth, pharynx, and esophagus intake.
- Rapid drug therapy intervention is possible.
- There is no need for particular packaging, it can be pushed through blisters.

**LIMITATIONS TO FDT: [10-11]**

- It is hard to formulate drugs with comparatively big doses into a fast dissolving tablet.
- Patients taking Anti-cholinergic medicines at the same time is not a good candidate for Fast dissolving tablet.
- The mechanical strength of tablets is generally inadequate. Therefore, careful packaging and handling are required.
- Unless correctly formulated, tablets may leave uncomfortable flavour and gritty in the mouth.
- Drugs with brief half-life and regular injection and requiring controlled or prolonged release are inappropriate applicants for tablets that dissolve easily.
- Fast dissolving tablets are very porous and smooth molded metrics or compressed in a small compression tablet, making the tablet friable and brittle which hard to manage.
- Bad taste drugs are hard to formulate as fast dissolving tablets, special care should be taken before such a drug is formulated.

**Ideal properties of fast Dissolving Tablets: [12-13]**

- It does not require water for oral administration, but in a matter of second, it dissolves, disperses, disintegrates into the mouth.
- It should have a pleasant feeling for the mouth.
- During manufacturing processes and after manufacturing handling, it should have an adequate hardness to resist rigors.
- After disintegration, it should leave minimal or no residue in the mouth.

- It should be low sensitive to circumstances such as temperature and humidity.
- It should be cost effective.
- Dissolve or disintegrate easily within a few seconds in salivary fluid.
- Be portable and transportable easily.
- The procedure for manufacturing is easy and low budget.

**Drug selection criteria:** [14-15]

The ideal characteristics of a drug for fast Dissolving tablet include:

- At the oral cavity PH, at least partially non-ionized.
- Have the capacity to spread and divide into the upper GIT epithelium.
- Good salivary solubility.
- Ability to permeate through the tissue of the oral mucosa.
- Dose below 50 mg.
- Molecular weight is small to moderate.
- Free from bitter taste.
- Drugs with a short half-life and frequent dosing.



**The Need for Development of fast dissolving tablets:** [16-17]

The requirement of non-invasive delivery systems persists due to the patients poor acceptance of, and compliance with, existing delivery regimes. The main objectives are pediatric and geriatric populations, as both groups discovered it hard to swallow conventional tablets.

The patient related factors for the development of fast dissolving tablets include the following:

- Pediatric and geriatric patients struggling to Swallow or chewing of the solid dosage form.

- During the oral administration of conventional formulations, the risk of suffocation due to physical obstruction was prevented, thus offering increased safety.
- Very elderly patients who may not be able to swallow an antidepressant daily dose.
- An eight-year-old with allergies who desires a dosage form that is more convenient than antihistamines.
- It may be too nauseous for a middle-aged female undergoing breast cancer radiation treatment to swallow her H2 blocker.

**The effectiveness factors are:**

- Increased bioavailability and quicker action are a major claim of these formulations. Because the tablets disintegrate within the mouth, drugs can be absorbed in the buccal, pharyngeal, and gastric areas.
- The absorption of pregastric drugs prevents the first pass metabolism and the dose of drugs can be lowered if a significant quantity of the drug is lost through hepatic metabolism.
- For drugs that produce large amounts of toxic metabolites mediated by first-pass liver metabolism and gastric metabolism, safety profiles may be improved.

**EXCIPIENTS COMMONLY USED FOR FDTs PREPARATION: [18]**

Excipients used in FDTs contain one superdisintegrant, a diluent/bulking agent, a lubricant and optionally swelling agent, permeabilizing agent sweeteners and flavourings agents.

**Table No. 1: Names and weight percentage of various major excipients**

Name of the excipients	Percentage used
Superdisintegrants	1–15
Binder	5–10
Antistatic agent	0–10
Diluents	0–85

**CRITERIA FOR EXCIPIENT USED IN FORMULATION OF FDTs: [19-20]**

- It must be able to disintegrate quickly.
- It should not have any interaction with drug and other excipients.
- When selecting binder (a single or combination of binders) care must be taken in the final integrity and stability of the product.
- The melting point of the excipients used should be in the range of 30-35°C.
- The binder may be in liquid, semisolid, solid, and polymeric.

**CHALLENGES IN FORMULATION OF FAST DISSOLVING TABLETS: [21-24]**

**Table 2: Challenges in the Formulation of Fast Dissolving Tablets**

<b>Challenges</b>	<b>Description</b>
Mechanical strength and disintegration time	FDTs are formulated to obtain disintegration time usually less than a minute. While doing so, maintaining a good mechanical strength is a prime challenge. Many MDTs are fragile and there are many chances that such fragile tablet will break during packing, transport or handling by the patients. It is very natural that increasing the mechanical strength will delay the disintegration time.
Taste masking	Many drugs are bitter in taste. So effective taste masking of the bitter drugs must be done so that the taste of the drug is not felt in the oral cavity.
Mouth feel	Tablets in the oral cavity should not disintegrate into larger particles. Particles generated after the FDTs have disintegrated should be as small as possible. After oral Administration, the tablet should leave minimal or no residue in the mouth.
Sensitivity to environment	Tablet will typically exhibit low sensitivity to environmental factors such as humidity and temperature, as most of the materials used in a tablet are intended to dissolve in limited water amounts.
Palatability	As most drugs are unpalatable, tablets should contain the medicament in a taste-masked form.
Aqueous solubility	Water-soluble drugs pose different formulation challenges because they form eutectic mixtures, resulting in freezing-point depression and the formation of a glassy solid that may collapse after drying due to the loss of supporting structure during the sublimation.
Size of tablet	It has been reported that the easiest size of the tablet to swallow is 7-8 mm while the easiest size to handle was one larger than 8 mm.
Fast Disintegration	FDTs should disintegrate in the mouth without additional water or with a very small amount (e.g., 1–2 ml) of water.

## **SUPER DISINTEGRANTS**

Disintegrants are the agents that help in the breakdown of tablets into their small particles or fragments as they come in contact with the aqueous environment. In case of FTDs dissolving tablets, fast disintegration is an essential step for faster drug release and quick action, thus superdisintegrants are added to facilitate faster disintegration. They are used in less concentration of 1-10% by weight relative to the total weight of dosage units [25].

### **Selection criteria for superdisintegrants: [26-27]**

- Particle size should be small.
- Should be non-toxic
- Compatible with other excipients and Drug.
- Good hydration capacity.
- Good flow property
- Good mouthfeel
- Effective in less quantity



### **Advantages of superdisintegrants**

- Required in less concentration.
- Does not affect compressibility and flowability [28].

### **Disadvantages of superdisintegrants**

- Sensitive to moisture leading to instability.



**Modes of Superdisintegrant addition:** [29-30]

**Table 3: Modes of Superdisintegrant addition**

<b>Modes</b>	<b>Inferences</b>	<b>Advantage</b>
Intragranular/Internal addition/During granulation	Together with other excipients, superdisintegrants are granulated which means they are added during granulation.	Easy to add and suitable for the direct compression method
Extragranular/External addition/Prior to compression	Superdisintegrants are added to already prepared granules before compression.	Suitable for wet granulation process.
Partially internal and external	Some amount of Superdisintegrant is added during granulation (internally) and parts are added after granulation.	More effective method and gives immediate disintegration of the tablet.

**Mechanism of Superdisintegrants:** [31]

The mechanism through which Superdisintegrants facilitate the quick breakdown of tablets into small fragments which results in faster dissolution and rapid onset of action are:

- Swelling
- Wicking (Porosity and capillary action)
- Heat of wetting
- Chemical reaction
- Particle repulsive force
- Deformation recovery
- Enzymatic reaction
- Combination action (Swelling and wicking)

**Classification of Superdisintegrants:** [32]

Based on their source of origin, Superdisintegrants can be categorized as:

1. Natural

2. Synthetic
3. Co-processed

### **1. Natural superdisintegrants**

Natural superdisintegrants are commonly used in tablet formulation which facilitates the disintegration of tablets. Examples of natural Superdisintegrants are Guar gum, gellan gum, Hibiscus rosa sinesis linn, Mango peel pectin.

#### **Advantages**

- Local accessible
- Eco-friendly and Bio-acceptable
- Low price as compared to a synthetic Superdisintegrant and renewable source

### **2. Synthetic Superdisintegrant**

Synthetic superdisintegrants are commonly used in tablet formulation which facilitates the disintegration of tablets. Examples of synthetic superdisintegrants are croscarmellose sodium, crospovidone, sodium starch glycolate, ion exchange resin.

#### **Advantages of synthetic superdisintegrants**

- Effective in low concentration as compared to starch.
- Have a low effect on compressibility and flowability.
- More effective intracranially.

#### **Limitations**

- Hygroscopic in nature and may cause problems with water sensitive drugs.

### **Co-processed superdisintegrants**

Co-processing excipients provide superior property compared to the physical mixture of individual excipient mixture. Examples of commercially available co-processed superdisintegrants are ludipress, starlac, starcap 1500, ludiflast.

### **Patented technologies for fast dissolving tablets: [33-46]**

Several technologies have been developed and patented by several pharmaceutical companies based on formulation aspects and different processes. The patented technology is described below:

#### **Zydis technology**

Zydis is a unique freeze-dried oral solid dosage form that can be swallowed without water as it dissolves in less than 5 seconds immediately on the tongue. The freeze-dried structure disintegrates instantly when zydis are placed in the mouth and does not require water to help swallow. Polymers such as gelatin, dextran, or alginates are incorporated to impart strength and resilience during handling. These form a glossy amorphous structure, which imparts strength.

#### **Advantages**

- Patients with difficulty swallowing oral medication due to dysphagia, stroke, or medical conditions like gastroesophageal reflux disease, multiple sclerosis or Parkinson's disease.
- Buccal pharyngeal and gastric regions are all areas of absorption from this formulation. Pre-gastric absorption prevents the first pass metabolism and can be an advantage in drugs suffering from hepatic metabolism.

#### **Disadvantage**

- The process of freeze-drying is a relatively expensive manufacturing process.
- The formulation is very lightweight and fragile, and therefore should not be stored in backpacks or the bottom of purses.
- It has poor stability at higher temperatures and humidity.

### **Limitations**

- The quantity of drug added for insoluble drugs should usually be less than 400 mg and less than 60 mg for soluble drugs.
- The particle size of the insoluble drugs should not be less than 50 $\mu$ m and not more than 200  $\mu$ m to avoid sedimentation during processing.

### **Orasolv technology (Cima Labs)**

In this system, the active medicament is taste masked. This includes the use of low pressure compressed effervescent disintegrating agents for the production of FDTs. The tablets are produced using conventional blenders and tablet machines. As tablets are prepared at low compression force, they are smooth and brittle.

### **Advantages**

- Taste-masking is two-fold, quick dissolution. This technology has been used for drug strengths in the range of 1 mg to 750 mg. Depending on formulation and tablet size, the disintegration time of the tablet can be designed in the range of 10 to 40 seconds.

### **Disadvantages**

- Because of the presence of the effervescent system, they are sensitive to moisture and must be packaged properly.
- Low mechanical resistance.

### **Durasolv technology**

Durasolv is the CIMA laboratory's patented technology. The tablets produced by this technology are drug, fillers and a lubricant. Tablets are prepared with good rigidity by using conventional tableting equipment. These can be packaged like blisters into the conventional packaging system. Durasolv is a suitable technology for products requiring small amounts of active ingredients.

### **Advantages**

- Durasolv technology is useful for tablets with small active ingredients (125 mg to 500 mg) and tablets are compressed to a higher hardness of 15-100 N, resulting in a more durable ODT. This technology allows flexibility in packaging as a result Tablets can be bottled and blistered.

### **Disadvantages**

- The technology is not compatible with higher doses of active ingredients due to high compaction pressure in the formulation.
- The drug powder coating in Durasolv may break during compaction and expose the bitter tasting drugs to the taste bud of the patient.

### **Wow tab technology**

Wow, tab technology is patented by Yamanouchi Pharmaceutical Co.

WOW means “Without Water”. In this process, a mixture of low mouldability saccharides and high mouldability saccharides is used to achieve a fast melting strong tablet. The Active ingredients are mixed with saccharides of low Mouldability and then granulated with saccharides of high mouldability and then compressed into tablets. The Wow tab product rapidly dissolves in 15 s or less.

### **Advantages**

- Adequate dissolution rate and hardness.
- In both conventional bottles and blister packs, the Wow tab product can be packed.

### **Disadvantages**

- There is no major change in bioavailability.

### **Flash does technology**

Flash dose technology has been patented by Fuisz Nurofen, allowing a fresh type of Ibuprofen to melt in mouth tablets, which is the first commercial product introduced by

Biovail Corporation using flash dose technology. Tablets with flash dose consist of self-binding shear that forms a matrix called floss.

### **Advantages**

- There is High surface area for dissolution.

### **Disadvantages**

- The high temperature needed to melt the matrix can limit the use of heat-sensitive drugs, sensitive to moisture and humidity.
- Only up to 600 mg of a drug can be used in the dosage form.
- Tablets produced are highly friable, smooth, and sensitive to moisture. Therefore packing is required.

### **Flashtab technology**

Prographarm laboratories have patented the Flash tab technology. This technology involves granulation of recipients by wet or dry granulation method and followed by tablet compression Tablet prepared by this system consists of a microcrystal active ingredient. In this formulation, a disintegrating agent and a swelling agent are used together with coated drug particles to produce a tablet that disintegrates in the mouth in less than one minute.

### **Oraquick technology**

K.V.S. Pharmaceuticals have a patent over this technology. It utilizes taste-masking microsphere technology called a micro mask, which provides superior mouth feel over taste masking alternatives, significant mechanical strength, and quick disintegration/dissolution of the product.

### **Advantages**

- Faster and efficient production, appropriate for heat-sensitive drugs.

### **Dispersible tablet technology**

Lek in Yugoslavia was issued patents for dispersible tablets of dihydroergotamine and cimetidine, which were claiming to disintegrate at room temperature in less than 1 minute when in contact with water. There was an enhanced dissolution rate of dihydroergotamine methanesulphonate with dispersible tablets containing 0.8-10% of organic acids, preferably about 4% by weight. It provides rapid swelling and/or good wetting capability to the tablets and thereby a quick disintegration.

### **Advatab technology**

Advatab tablets quickly disintegrate in the mouth, typically in less than 30 seconds, to allow for convenient oral drug administration without water. These tablets are particularly suitable for those patients who have trouble swallowing capsules and tablets. Advatab is different from other FDT technologies as it can be combined with Eurand's complimentary particle technologies such as world-leading MicrocapsR taste-masking technology and its DiffucapsR, controlled release technology.

### **Nanocrystal technology**

Nanocrystal technology can produce formulation and improve compound activity and final product characteristics. Decreasing particle size increases the surface area, resulting in a higher dissolution rate. Nanocrystal particles are small particles of drug substance, typically less than 1000 nanometres (nm) in diameter, manufactured using a proprietary wet milling method to mill the drug substance.

### **Nanocrystal Fast dissolving technology provides for**

- The pharmacokinetic advantage in the form of a rapidly disintegrating tablet matrix of orally administered nanoparticles (<2 microns)
- Differentiation of products based on a combination of proprietary and patent-protected technology elements.

### **Pharmaburst technology**

Pharmaburst technology is being patented by SPI pharma. The tablet manufactured by this method involves a dry blend of a drug, flavors, and lubricant then compression into tablets

that dissolve within 30-40 seconds. Tablets that have obtained have sufficient strength to be packed in blister packs and bottles.

### **Lyo (Pharmalyoc)**

Oil is prepared and placed directly into blister cavities in water emulsion followed by freeze-drying. During freeze-drying, Non-homogeneity is avoided by incorporating inert filler to increase the viscosity finally the sedimentation. A high filler proportion reduces the porosity of tablets due to which disintegration is reduced.

### **Sheaform technology**

The technology is based on floss preparing also known as matrix shear, which is manufacturing by using flash heat processing to subject a feed stock containing a sugar carrier. The sugar is simultaneously subjected to centrifugal force and a temperature gradient in this method, which increases the mass temperature to generate an internal flow condition that allows part of it to move the mass.

### **Ceform Technology**

Microspheres containing active ingredients are prepared in ceform technology. The essence of the manufacturing method of Ceform microsphere is to place a dry powder, containing significantly pure drug material or a special mixture of drug products plus other pharmaceutical compounds, and excipients into a precision designed and quickly spinning machine. The centrifugal force of the rotating head of the ceform machine throws the dry drug blend at high speed through small heated openings. The microspheres are then blended and/or compressed into the pre-selected oral delivery dosage format.

## **EVALUATION OF TABLETS**

Tablet formulation consists of two types of evaluation i.e. pre-compression studies and post compression studies.



**Pre-compression parameters: [47-49]**

**Angle of repose**

The angle of repose was determined using funnel method. The angle of repose was then calculated by measuring the height and radius of the heap of granules formed.

$$\theta = \tan^{-1} (h/r)$$

Where,  $\theta$  is the angle of repose and h is the height and r is the radius.

**Table 4: Relation between Angle of repose and type of flow and type of powder**

Angle of repose	Type of flow
< 25	Excellent
25-30	Good
30-40	passable
>40	Very poor

**Bulk density**

It is the ratio of total mass of powder to the bulk volume of powder. It is expressed in g/ml and is given by

$$D_b = M / V_b$$

Where, M is the mass of powder

$V_b$  is the bulk volume of the powder.

**Tapped density**

It is the ratio of total mass of the powder to the tapped volume of the powder. It is expressed in g/ml and is given by

$$D_t = M / V_t$$

Where, M is the mass of powder

$V_t$  is the tapped volume of the powder.

**Carr’s compressibility index (%)**

It indicates powder flow properties. It is expressed in percentage

$$I = (Dt - Db) / Dt \times 100$$

Where, Dt is the tapped density of the powder

Db is the bulk density of the powder.

**Table 5: Relation between % Compressibility and Flowability**

<b>% compressibility</b>	<b>Flow property</b>
15-12	Excellent
12-16	Good
18-21	Fairly passable
23-35	Poor
33-38	Very poor
<40	Very very poor

**Hausner’s Ratio**

Hausner ratio is an indirect index of ease of powder flow. It is calculated by the following formula,

$$\text{Hausner Ratio} = \text{Tapped Bulk Density} / \text{Loose Bulk Density}$$

**Table 6: Relation between Hausner ratio and type of flow**

<b>Hausner ratio</b>	<b>Type of flow</b>
<1.25	Good
1.25-1.5	Moderate
>1.5	Poor

**Post compression parameter: [50-62]**

**General appearance**

Tablets of different formulations were randomly selected and organoleptic properties such as color, odor, taste, shape, were evaluated.

### Tablet thickness

Ten tablets from each formulation were taken randomly and their thickness was measured with a digital screw gauge micrometer. The mean SD values were calculated.

### Tablet hardness

Hardness is also called crushing strength of the tablet, the force required to break a tablet in a diametric compression was measured using Monsanto tablet hardness tester. It is expressed by in kg/cm<sup>2</sup>.

### Friability (f)

Friability of the tablet determined using Roche friabilator. Friability is the loss of weight of the tablet in the container due to the removal of the fine particles from the surface. Compressed tablets should not lose more than 1% of their original weight.

$$F = \frac{Wt \text{ initial} - Wt \text{ final}}{Wt \text{ initial}} \times 100$$

### Weight variation

20 tablets are selected randomly from the lot and weighted individually to check for weight variation. Weight variation specification as per I.P.

**Table 7: Weight variation specification as per I.P.**

Average weight of the tablet	% Deviation
80 mg or less	±10
80 mg to 250 mg	±7.5
250 mg or more	±5

### Uniformity of Weight

Twenty tablets were taken as per IP and their weight was determined on a digital weighing balance, individually and collectively. For achieving weight variability the individual weights were compared with the average weight.

### **Wetting time**

A piece of tissue paper folded twice was placed in a small Petri dish (d = 5 cm) containing 6 ml of water, a tablet on the paper was put in. The time taken for water to hit the tablet's upper surface and to wet the tablet fully was noted as wetting time.

### ***In vitro* drug release**

The release of the drug in vitro was determined by using USP 2 Paddle apparatus at the temperature  $37\pm 0.5^{\circ}\text{C}$  rpm (50 or 100) as per their drug profile given in IP and by using specific 900 ml of phosphate buffer as per IP phosphate buffer.

### **Modified Disintegration test**

The standard technique for conducting the disintegration test for these dosage types has many drawbacks, and very short disintegration times are not appropriate for measuring. The disintegration time for FDT needs to be changed as disintegration without water is necessary, therefore the test should mimic disintegration into salivary material. A petri dish (10 cm diameter) was filled in for this reason.

### **Mechanical Strength**

Tablets should possess adequate strength to withstand mechanical shocks of handling in Manufacturing, packaging and shipping. Friability and crushing strength are two important parameters to evaluate a tablet for its mechanical strength.

### **Crushing Strength**

it is the force needed to split a tablet in the radial direction by compression; it is a significant Mouth formulation parameter dissolves tablets because of excessive resistance to crushing significantly decreases the time for disintegration.

### **Disintegration in the oral cavity**

The time required to completely disintegrate the tablets in the oral cavity was collected from the 6 safe participants, who were given tablets from the optimal formulation. Water absorption A piece of tissue paper folded twice has been placed in a small Petri dish with 6

ml of water. Tablet was put on the paper and the time required for complete wetting was measured. The wetted tablet was then weighed.

### **Stability studies**

The stability studies were studied at different temperature conditions according to ICH guidelines at  $25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C} / 60\% \pm 5\% \text{ RH}$  for real and at  $40\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C} / 75\% \text{ RH} \pm 5\%$  for accelerated stability studies. The samples were withdrawn at different time intervals as 0, 7, 15, 30, 60 and 90 days. The selected formulation was subjected to stability studies for 3 months. Samples were evaluated for colour, thickness, hardness, drug content, *in vitro* disintegration time, friability, and *in vitro* drug release studies.

### **CONCLUSION**

In recent days, oral disintegrating tablets have gained more importance when compared to the conventional dosage forms due to their varied advantages. FDTs are the type of dosage forms that can disintegrate within 60 sec without the need for water. They have many advantages like rapid absorption with increased bioavailability, improved efficiency of the drugs. It can also be administered for patients who are bedridden, pediatric, and geriatrics. The key principle of FDT is to have faster disintegration, dissolution. This can be achieved by adding superdisintegrants or producing a porous structured tablet matrix. There are different methods to formulate FDTs like freeze drying technique, direct compression, sublimation method, etc. Though they have pronounced advantages, they have minimal disadvantages like poor mechanical strength, they are hygroscopic. Apart from having disadvantages, they are used widely due to their better patients compliance. Due to the high market potentials, many drugs can be formulated as FDTs.

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