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Review Article

Review On Fast Dissolving Tablets

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ABSTRACT

The fast dissolving tablet (FDT) is a new and unique drug delivery system that is rapidly focusing major attention in the reasearch field of fast dissolving technology. In recent times, a few solid dosage forms, such as tablets and capsules, are dealing with issues such dysphagia, which causes difficulties swallowing and leads to a high rate of non-compliance, ultimately causing the therapy ineffective.Fast dissolving tablet are disintegrating or/and dissolve quickly without the need of water. These tablets are designed to dissolve or break down in saliva in the mouth, usually in less than 60 seconds.These fast dissolving tablet having many advantages such as easy portability and manufacturing, precise dosage, superior chemical and physical stability, and an excellent substitute for both pediatric and elderly patients.For a drug to be formulated as a Fast Dissolving Tablet, it must satisfy four criteria: high stability in aqueous media, low dose, appropriate mechanical strength, and compatibility with excipients. As day's passes, demand for the faster disintegrating formulation is increased. So, the pharmacist needs to formulate disintegrants i.e. super disintegrants which are effective at low concentration and have greater disintegrating efficiency, and they are more effective intragranular.This review describes the various advantages, excipients used,super-disintegrate employed,drugs eligible for FDTs, different techniques used for preparing FDT, various patented technologies, evaluation parameters.

INTRODUCTION

Fast dissolving tablets is the most frequently used dosage form available today due to its easy manufacturing, small approach and convenient self-administration. The inability to swallow is a typical occurrence in older adults because of dysphasia (speech disorder), hand tremors, and choking fear. It is also common in younger people because of underdeveloped muscular and nervous systems, and in patients with schizophrenia because it poor patient compliance. Swallowing problems influences about one-third of the population, mainly seniors and younger individuals. This causes a lack of compliance to

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oral tablet medication therapy, which lowers the efficacy of therapy as overall. Because of this, there has been a lot of interest in tablets that dissolve or disintegrate quickly in the oral cavity.[1] The fast dissolving tablet (FDT) is defined by the United States Food and Drug Administration (USFDA) as "a solid dosage form containing a medicinal substance or active ingredient which disintegrate rapidly usually within a matter of seconds when placed upon the tongue".[1] In order to provide pediatric and elderly patients with an alternative to conventional dosage forms, fast-dissolving drug delivery systems were first developed in the late 1970s. These tablets are made to dissolve or disintegrate in saliva—typically in less than 60 seconds.[2] Compared to conventional tablets, mouth dissolving tablets exhibit superior bioavailability, effectiveness, and biopharmaceutical qualities, as well as increased patient compliance and acceptance.[3] The benefits of fast dissolving dosage forms are becoming increasingly accepted in business and academic circles.[4] There are various synonyms for mouth dissolving tablets like orally disintegrating tablets, fast dissolving tablets, fast melting tablets etc. According to the European Pharmacopeia, a "orodisperse" tablet is one that dissolves in the mouth fast and doesn't require water.[5] The two primary methods used to make mouth-dissolving tablets are the first is the use of super disintegrants such as croscarmellose sodium, sodium starch glycolate, and crospovidone. Using vacuum and freeze drying to maximize the tablets' pore structure is an additional technique.[2] Direct compression is recommended over all other methods because to its convenience of use, speed and cost effectiveness.[6]

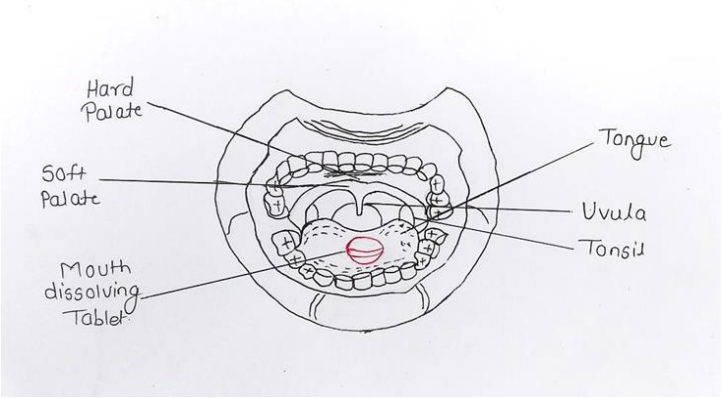


Fig.1: Administration of Mouth Dissolving Tablet

Mechanism of FDT'S:

To obtain the fast-dissolving characteristics:

1. For the tablet to dissolve instantly and disintegrate rapidly, water must get into the tablet matrix quickly.
2. Using highly water-soluble excipients or the proper disintegration agent in the tablet formulation

These are a few of the less discussed mechanisms that cause the drug suspension in the tablet to break.[7]

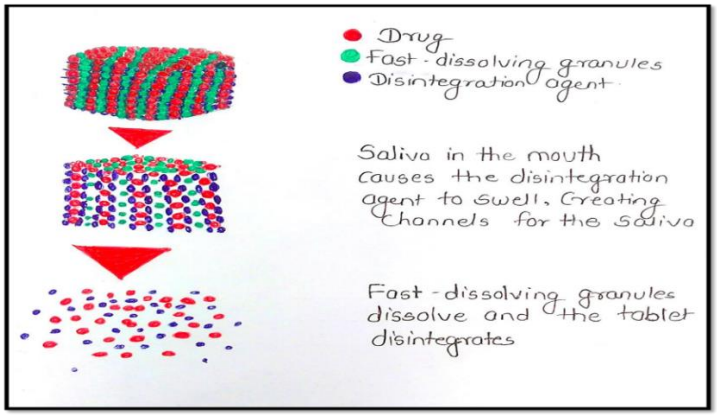


Fig.2: Conceptual Diagram of Fdts.

Advantages Of Fast Dissolving Tablets [9,10]

- To swallow the tablet there is no need of water.
- Patients with mental disabilities, senior citizens, and children can all get FDTs with easily.
- Precise dosage in comparison to liquids.
- Fast absorption of drugs and dissolution offer a rapid onset of action.
- Drug bioavailability is enhanced because saliva travels down the stomach's digestive tract to absorb certain medications from the mouth, throat, and esophagus.
- More effective in terms of administration and transportation than liquid medications.
- Reduction of first pass metabolism provides enhanced bioavailability, which in turn lowers dosage and adverse effects.
- Providing enhanced safety.
- Appropriate for controlled or sustained release actives;
- Permits high drug loading.

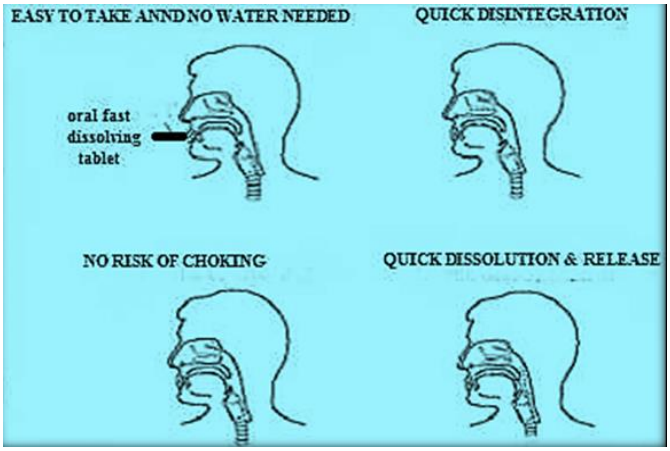


Fig.3: Advantages of Fdt

Excipients Used In Fdt Preparation [2,18]

Excipients used in FDTs include at least one super disintegrant, a diluent, a lubricant and optionally a swelling agent, a permeabilizing agent, sweeteners and flavouring agents.

Table 1: Name and weight percentage of various excipients in FDTs

S. No.	Name of the excipients	% used
1.	Super disintegrants	1-15%
2.	Binders	5-10%
3.	Antistatic agents	0-10%
4.	Diluents	0-85%

A] Super disintegrants [11, 15]

As time goes on, need for the faster disintegrating formulation is increased. Therefore, the pharmacist must formulate disintegrants, i.e. super disintegrants that work well at low concentrations, and have greater disintegrating efficiency, and they are more effective intragranular. These super disintegrants act by swelling and due to swelling pressure applied externally or radial direction, it causes the tablet to burst or the accelerated absorption of water leading to an extremely increase in the volume of granules to promote disintegration.

• Factors to be considered for selection of super disintegrants [2,14,19]

1.Disintegration

The disintegrant needs to absorb saliva into the tablet fast in order to create the hydrostatic pressure and volume expansion required for rapidly disintegration in the mouth.

2.Compactibility

It is preferable to have FDT with sufficient hardness and minimal friability at a given compression force to make durable tablets without requiring special packaging and to maximize manufacturing speed.

3.Mouthfeel

Large particles may cause the mouth to feel porous. Smaller particles are therefore preferred

If the tablet forms a gel-like consistency on contact with water, however, it produces a gummy texture that many consumers find uncomfortable.

4.Flow

Super disintegrants typically make around 2–5% weight percentage of the tablet formulation. Disintegrant level can be much higher when using FDT formulation.[14]

B] Bulking materials [10,19]

Bulking materials play a crucial role in the production of fast dissolving tablets. They serve as a filler, diluent, and reducing costs agent. In addition to providing volume and lowering the concentration of the active ingredient in the formulation, bulking agents improve the texture of the tablets, which further enhances the disintegration in the mouth. For better awareness of sensation and increased aqueous solubility, the bulking agents for this dosage form should be more sugar-based, such as mannitol, polydextrose, lactose derivatives such directly compressible lactose (DCL), and starch hydrolysate. Because of its negative heat of solution, Mannitol especially has high aqueous solubility and good sensory perception, as it provides a cooling effect. Bulking agents are added between 10% and around 90 %of the final product's weight.

The descending order of brittleness of excipients is ranked as microcrystalline cellulose>alpha lactose monohydrate>spray-dried lactose>anhydrous beta lactose>anhydrous alpha lactose>> dicalcium phosphate dihydrate.

Sugar based excipients can be categorized according to dissolution rate and moulding:

Type 1 saccharides: (lactose and mannitol), which have a high rate of dissolution but a low moldability.

Type 2 saccharides: (maltose and maltitol), which have a low rate of dissolution but a high moldability.

C]Emulsifying agents [2, 19]

The use of emulsifying agents in the formulation of fast-dissolving tablets is important because they promote rapid drug release and disintegration without the need for chewing, swallowing, or water consumption. Emulsifying agents also improve bioavailability and stabilize immiscible combinations. Various emulsifying agents such as lecithin, sucrose esters, propylene glycol esters, and alkyl sulfates are used in formulations of fast-dissolving tablets. These can be incorporated in the final formulation in an amount ranging from 0.05% to around 15% by weight.

D]Lubricants [2,20]

These are not mandatory excipients; however, they can help to make the tablets taste better once they dissolve in the tongue. Lubricants help the transportation of drugs from the mouth to the stomach and decrease grittiness.

E] Flavors (taste masking agents) and Sweeteners [2, 19]

Patients find the products more pleasant and pleasing when they include flavors and taste masking agents. By adding these compounds, some actives' unpleasant tastes and bitterness can be minimized. Natural as well as synthetic flavours can be used to enhance the organoleptic characteristics of fast dissolving tablets. There is a large variety of sweeteners available, such as sugar, fructose, and dextrose, as well as non-nutritive sweeteners including sucralose, aspartame, sodium sucrose, and sugar alcohols The addition of sweeteners imparts a pleasant taste as well as bulk to the formulation.

Drugs Eligible For Fast Dissolving Tablet's:

Drugs must meet four requirements in order to be eligible for formulation as Fast Dissolving Tablets: low dose, acceptable mechanical strength, good stability in aqueous media [21], and compatibility with excipients. [22,23]

Table 2

Class of drug	Drug
Analgesic/Anti-inflammatory Agents	Piroxicam, Ibuprofen, Mefenamic Acid
Anti-Bacterial Agents	Erythromycin, Tetracycline, Doxycycline, Rifampin
Anti-Emetic	Ondansetron, Dolasetron, Granisetron, Promethazine
Anti-Fungal	Griseofulvin, Miconazole
Anti-Malarial	Chloroquine, Amodiaquine
Anti-Gout	Allopurinol, Probenecid
Anti-Hypersensitive	Amlodipine, Nifedipine
Anti-Coagulant	Glipizide, Tolbutamide
Anti-Protozoal	Benznidazole, Tinidazole
Anti-Thyroid	Carbimazole
Cardic Inotropic Agents	Digitoxin, Digoxis
Gastro-Intestinal Agent	Omeprazole, Ranitidine, Famotidine
Nutritional Agent	Vitamin A, Vitamin B, Vitamin D, etc
Oral Vaccines	Influenza, Hepatitis, Polio, Tuberculosis, etc.

Techniques For Preparing Fast Dissolving Tablets:

Several techniques to formulate orodispersible or fast-dissolving tablets have been documented. The main methods that are frequently employed in the formulation of these tablets have been discussed here. [24, 25]

1. Freeze drying / lyophilization
2. Tablet Moulding Method
3. Mass Extrusion
4. Melt Granulation
5. Direct Compression
6. Sublimation
7. Spray Drying

1.Freeze drying / Lyophilization

Freeze drying is the process in which water is sublimed from the product after it is frozen. This method produces a, amorphous porous structure that can dissolve quickly. A typical process used in the manufacturing of FDT using this technique is mentioned here.[26]

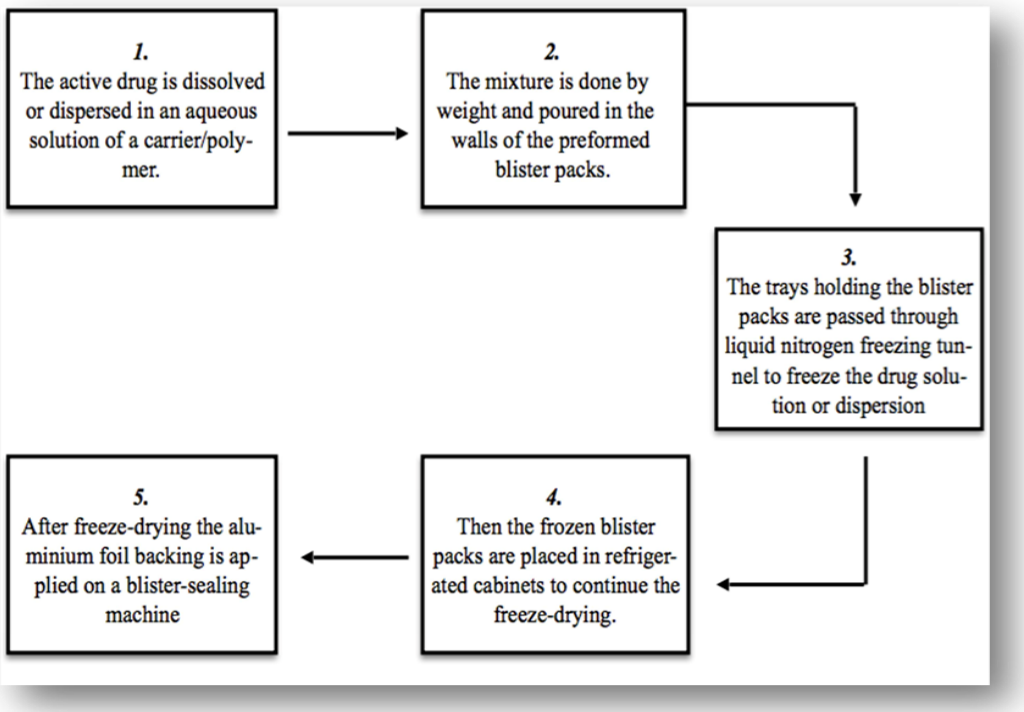


Fig.4 Step by Step Procedure of Lyophilization of FDT

The process of freeze-drying has shown to raise bioavailability and improve absorption. The primary drawbacks of the lyophilization process are its high cost and time consuming; also; delicate nature makes conventional packaging inappropriate for these products, and their low stability under pressure. [27,28]

2.Tablet Moulding Method [17]

Hydrophilic substances are used in the design of tablets in order to achieve maximal the drugs disintegration. The powder mass is compacted into a dosage form after being wetted with a hydroalcoholic solvent. After then, the solvent system is allowed to evaporate. Spray-congealing a molten mixture that includes hydrogenated cottonseed oil, sodium carbonate, lecithin, and polyethene glycol with an active ingredient into a lactose-based tablet triturate develops the taste of the drug particles. The molding process has particularly porous characteristics since the solvents are eliminated by drying, leaving behind porous bulk that encourages quick disintegration.

3.Mass Extrusion [17]

This process involves softening the active blend with a solvent mixture of polyethylene glycol and water-soluble methanol. The softened mass is then expelled through a syringe or extruder to create a cylinder product, which is then cut into even segments using a heating blade to make a tablet. In order to achieve taste masking, the dried cylinder can also be used to coat granules for bitter drug.

Formulation by Mass Extrusion:

Drug+Excipients are blended well.

⇩

The Blend is softened using solvent mixture (e.g. water-soluble polyethylene glycol, methanol).

⇩

The softened mass is then extruded via an extruder or syringe.

⇩

These extrudes are cut into even segment via heated blades to obtain tablets.

⇩

The tablets are then coated to mask the bitter taste and packaged.

4.Melt Granulation [29]

Using the melt granulation technique, a meltable binder effectively agglomerates the pharmaceutical powders. Compared to a traditional granulation, this method has the advantage of not requiring the use of organic solvents or water. Compared to wet granulation, this technique uses less energy and takes less time because there is no drying step. It is a technique beneficial to improve the dissolving rate of poorly water-soluble medicines, such as griseofulvin.

5.Direct Compression [30]

Due to a few benefits, the disintegrant addition technology (direct compression) is the method of tablet manufacturing that is most recommended:

• Higher dosages can be used, and the tablet's final weight can be greater than it would be using other technique

• The simplest method for producing the tablets.

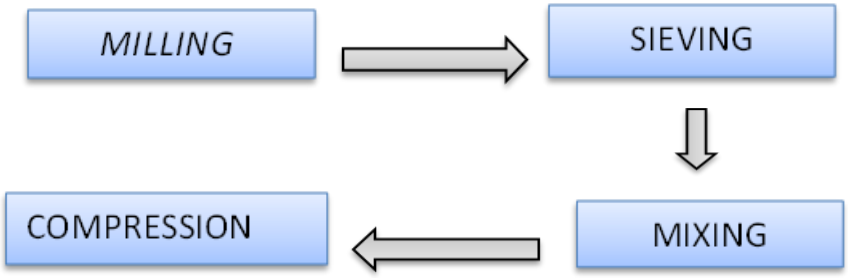
• conventional equipment and widely accessible excipients are used.

• Economical viability.

• A limited no. of processing steps are involved.

The disintegrant effectiveness is highly influenced by the size and hardness of tablets. Disintegration times for hard and large tablets are longer than normal. Tablets that are tiny and extremely soft have poor mechanical strength. To get fast disintegration and high dissolving rates, an optimal kind and concentration of disintegrant should be used. But the disintegration time stays approximately constant or even increase above the critical concentration point.

Process of Direct Compression:[8]



6.Sublimation [16]

Ammonium bicarbonate, urea, camphor ammonium carbonate, and hexamethylene-tetramine are examples of inert solid substances that volatilize quickly and can be quickly formulated into a porous mass for rapid disintegration and dissolution. They were compressed after being combined with additional components. By lowering the pressure and gradually raising the temperature, the volatile substance is evolved, leaving the mass porous. The sublimation method's characteristics include their porous nature and the use of solvents such as benzene and cyclohexane.

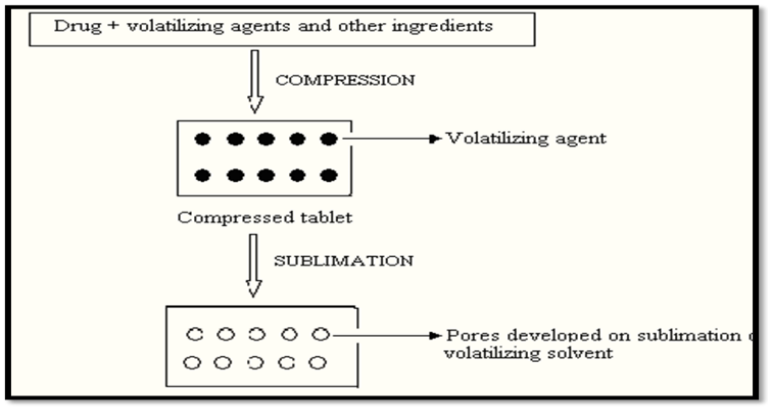


Fig.5: Schematic Diagram of Sublimation Techniques for Preparing FDT's[29]

7.Spray Drying

In this technique Using gelatin as a matrix and supporting agent, mannitol as a bulking agent, and super disintegrants such as sodium starch glycolate, crospovidone, or croscarmellose. It has been observed that in an aqueous media, tablets made from spray-dried powder including bulking agent, super disintegrant, acidic component (citric acid), and/or alkaline ingredient (sodium bicarbonate) dissolve in less than 20 seconds. When this spray-dried powder was crushed into tablets, it disintegrated quickly and dissolved better.[31]

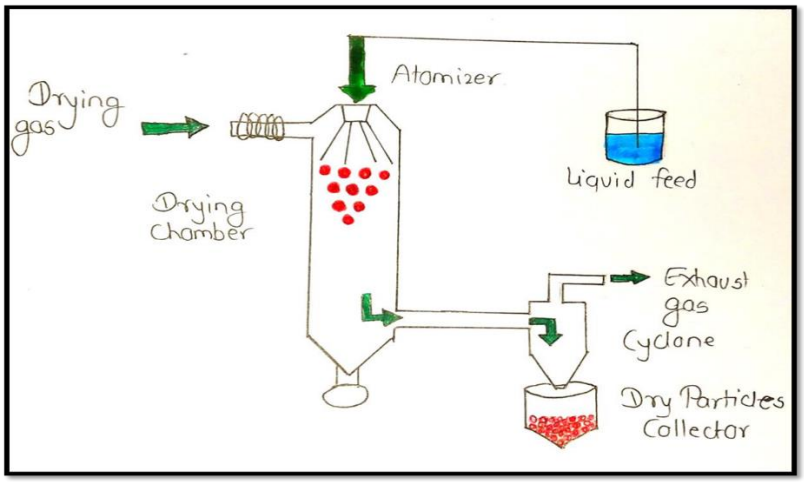


Fig.6: Spray dryer

Patented Technologies For Fast Dissolving Tablets:

1.ZYDIS Technology [32]

Zydis is a unique type of freeze-dried tablet where the medicine is physically dissolved or entrapped in a matrix of rapidly dissolving carrier material. The freeze-dried structure of zydis units dissolves instantly in the mouth and doesn't need water to make it easier swallowing. The zydis matrix is made up of numerous components that are intended to achieve various goals. Alginates, gelatin, and dextran are examples of polymers that are added to provide strength and resilience during handling. These combine to produce a strong, glossy, amorphous structure.

Advantages

- The Zydis formulation is self-preserving due to the freeze-dried product's final water concentration being too low to support microbial development.
- This formulation can be absorbed in the gastric and buccal pharyngeal regions.
- Pre-gastric absorption prevents first-pass metabolism and may be advantageous for

medications that undergo significant hepatic metabolism.

Disadvantages

- The formulation is very lightweight and delicate in nature, so it shouldn't be kept in backpacks or the bottom of handbags;
- It has poor stability at higher temperatures and humidities;
- The freeze-drying method is a highly expensive manufacturing procedure.

2.Orasolv Technology [2,33]

CIMA Labs is the company that invented Orasolv technology. The active medication in this method is taste-masked. The effervescent disintegrating agent is also present. To reduce the amount of time that tablets take to dissolve in the mouth, they are created using a low compression force direct compression method. The tablets are made using standard blenders and tablet machines. The resulting soft and friable tablets are packaged in a pick and place system that was specifically created for that purpose.

Advantages [32]

- Taste masking has a two-pronged disintegration. This method has been applied to pharmaceutical strengths ranging from 1 mg to 750 mg.
  The disintegration time of a tablet can be tailored to be between 10 and 40 seconds, depending on the composition and size of the tablet.

Disadvantages [32]

- Because of the effervescent mechanism, they are moisture-sensitive and must to be packaged carefully. inadequate mechanical strength.

3.Wow Tab Technology [2,30,32,34]

Yamanouchi Pharmaceutical Co. has a patent on Wow, tab technology. WOW stands for "Without Water." The goal of this procedure is to create a strong tablet that melts quickly by combining low and high moldability saccharides. To create tablets with the right amount of hardness, high and low moldability are combined.

Advantages

- Appropriate hardness and rate of dissolving. Wow, tab products can be packed in blister packs and regular bottles.

Disadvantages

- No significant change in Bioavailability.

4.Durasolv Technology [2,30]

Durasolv is the patented technology of CIMA labs. The medication, fillers, and lubrication that make up the tablets produced with this method. Tablets are developed with good rigidity and are manufactured with standard tableting equipment. These can be packed into blisters or other forms of conventional packaging. Durasolv is an appropriate technology for products requiring low amounts of active ingredients.

Advantages [32]

- Dura Solv technology compresses tablets to a higher hardness of 15–100 N, resulting in a more durable ODT. This technique works well for tablets with low amounts of active ingredients (125 mcg to 500 mg). This technology allows for flexible packaging; tablets can be blistered and bottled as a result.

Disadvantages [32]

- Larger doses of active substances are incompatible with the method because compaction subjects the formulation to high pressure. When Durasolv is compacted, the drug powder covering may break down, exposing the patient's taste buds to the bitter medication.

5.Flash Tab Technology

This method attempts to provide a flash dispersal tablet with ease of use, a microencapsulated medicine with effervescence, and a drug with rapid release in the gastrointestinal tract. For fast release, eudragit is usually the polymer in use. This technology follows the standard compression procedure with a conventional wet/dry granulation

strategy. Drug formulation involves the use of micro-granules of the medication, dissolving agents, taste masking agents, and swelling agents [35]. Because materials like polyvinyl chloride/aluminum foils provide superior moisture protection than standard polyvinyl chloride or polypropylene foils, these tablets are highly recommended for hygroscopic materials for blister packing due to their good physical resilience.

6.Pharmabust Technology [2,20]

SPI Pharma is patenting the pharmaburst technology. This method produces tablets that dissolve in 30 to 40 seconds by compressing a dry mixture containing a medication, flavoring, and lubrication. Because of their adequate strength, the tablets produced using this technique can be packaged in bottles and blister packs.

7.Oraquick Tecchnology

KV Pharmaceutical states that its patented flavor masking technique, known as Micro Mask, is a unique application of microsphere technology. It produces tablets faster and more effectively because it doesn't require any kind of solvent. Also it produces less heat, which is advantageous for medications that are heat-sensitive. This technology claims enhance tablet flavor masking and faster disintegration times. There are no other products on the market made using this technology, except from KV Pharmaceuticals. This technique evaluates things like stability, physical strength, flavor, pleasant mouthfeel, bioavailability, and rate of absorption and dissolution.[36]

Evaluation Parameters:

It is important to evaluate the formulated drugs in order to determine the quality of the tablet.The essential evaluation parameters are listed below.[37,38]

Table 3: Evaluation parameters of FDT

Parameters	Criteria
Hardness	Hardness of the tablet should be lesser than conventional tablet falling in the range of 3-4kg/cm^2
Friability	Friability should be within the range of 0.1-0.9%.
Weight variation	Weight Variation tests are carried out according to either USP, IP, BP.
Tablet Porosity	Tablet porosity is conducted (as per ICH guideline)
Mechanical Strength	Mechanical Strength Should possess adequate mechanical strength to absorb the transportation shock and avoid breakage of tablet
Wetting time and water absorption	Use of simulated saliva to check the wetting time of tablet as well as water absorption
Disintegration Studies	The time period at which the tablet starts to disintegrate in given aqueous media is determined
In-vitro Dispersion time	At optimum and fixed pH and temperature, time taken for dispersion of tablet in media is determined
Dissolution Studies	Dissolution Studies carried out according to USP, IP, BP
Stability Studies	Stability studies (including Accelerated Stability studies) are conducted according to the ICH guidelines
Content Uniformity	Content uniformity according to either USP, IP, BP.

CONCLUSION:

The newer technologies employed for the formulation of FDTs that provide more advantageous and minimally disadvantageous dosage formulations. Certain technologies have the ability to utilize FDT dosage forms, which possess adequate mechanical strength and rapidly dissolve in the oral cavity. Patients with mental illness, chronic conditions (such as diabetes, thyroid, or cancer), paediatric, geriatric, inability

to access water, or who are traveling should have FDTs performed. Scientists have developed the FDT, a novel kind of drug delivery device, to avoid these problems.

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