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A review article on fast dissolving tablets

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Abstract--For the majority of patients, oral administration is the preferred method of drug delivery. Tablets and capsules are the most often used oral solid dose forms all over the world. Around 30% of patients have had trouble swallowing tablets and capsules, according to reports. When spit comes into contact with the dose frames, they swiftly degrade, releasing the medication, reducing the amount of water required throughout the organisation. These distinguishing characteristics appeal to both paediatric and geriatric patients. Gulping difficulties with standard pills and containers are frequent in people of all ages, but especially in the elderly and dysphagia patients. [1] Furthermore, robust oral conveyance frameworks do not necessitate sterilisation. The rapid dissolving drug delivery system has played an important role in adapting and meeting the needs of patients. The oral course organisation is the most important method that has been credited with having a fundamental impact. The conventional tablet is widely recognised as the most popular pharmaceutical measurement shape because of its ease of transportation and low assembly cost. These structures break down fast in the mouth, increasing bioavailability. Mouth dissolving doses are a type of quick-dissolving measuring construction.

Keywords--oral delivery, bio availability, excipients, dissolution test.

Introduction

Drug distribution by oral route is chosen by the vast majority of patients. Oral solid dosage forms such as tablets and capsules are widely utilized around the world. According to statistics, almost 30% of patients have difficulty swallowing tablets and capsules. As soon as the dosing frames come into touch with spit, they begin to disintegrate, releasing the medication and lowering the overall water consumption. These unique features appeal to a wide range of patients, including

children and the elderly. Many people of all ages, but especially the elderly and those with dysphagia, have trouble swallowing regular tablets and containers (Hannan PA et., al 2016). Using sterile materials is unnecessary when using strong oral conveyance frameworks.

Fast dissolving tablets

FDTs are defined by the FDA as "a solid dosage form containing the medicinal ingredient or active component that rapidly disintegrates or dissolves when placed on the tongue" (FDA, 2009). Fast-dissolving tablets are sometimes known as mouth-dissolving tablets or mouth-dissolving pills. When swallowed, the pills dissolve into tiny grains or melt in the mouth from a hard solid structure to gel-like shape. A few seconds to more than a minute pass 1,2 before the pills dissolve.

Fast dissolving films

Fast-dissolving oral films are solid dose forms that disintegrate or dissolve in the mouth in under one minute without the need for water or chewing. These drug delivery systems allow the medication to circumvent the first-pass metabolism, resulting in increased bioavailability. (Agarwal J et., al 2011, Jeong, S.H et., al).

Criteria of drug selection (Bhowmik D et., al 2019)

The following are the factors for choosing medicine for a quick-dissolving system:

- At the pH of the oral cavity, it is moderately non-ionized.
- How to keep molecular weight in check.
- The medicine should be able to pass through the oral mucosa.
- To be effective, the medication must be able to diffuse and partition into the GIT epithelial layer on the upper side.
- The medication should be stable in both water and saliva.
- Fast-dissolving systems are a suitable fit for drugs with limited bioavailability.
- Drugs with a short half-life and frequent doses are not suited for fast-dissolving systems.

Fast-dissolving systems are not ideal for drugs with a bitter taste or odour. Patients who take anticholinergic medicines on a regular basis may developed.

Manufacturing Techniques For FDDDS:(Seager H et., al 1998, S.L.Nail, L.A et., al 1993)

- Lyophilization
- Direct Compression
- Tablet Moulding
- Cotton Candy process
- Mass Extrusion
- Spray Drying
- Nanotization

- Sublimation

Lyophilization

Lyophilization, also known as freeze-drying, is a method that involves removing water from a frozen product and placing it under a vacuum, allowing the ice to transition directly from solid to vapour without passing through a liquid phase. Freezing, primary drying (sublimation), and secondary drying are three different, unique, and interrelated processes (desorption). The advantages include the ease of processing a liquid, which facilitates aseptic handling, the increased stability of a dry powder, and the ease of processing a solid. Water removal without overheating the product, improved product stability in a dry state increased handling and processing time, as well as the need for sterile diluent during reconstitution, are all disadvantages. Lyophilization mechanism is explained by the following figure 1

Lyophilizer

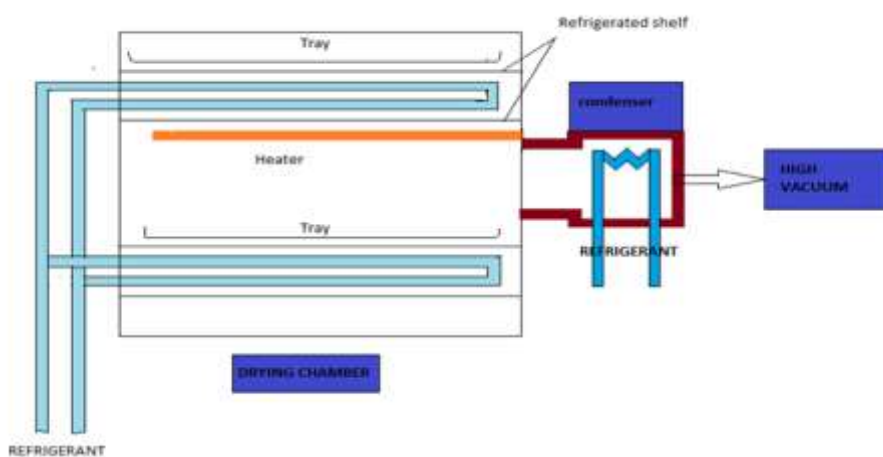


Fig-1: Lyophilisation Technique

Direct Compression Method

“A solid dosage form containing medical material or active component that disintegrates fast, usually within a matter of seconds when placed over the tongue (Deshmane SV et., al 2010), manufactured by direct compression method,” according to the United States Food and Drug Administration (FDA). The compressibility of a tablet determines its strength.

Tablet Moulding method

A tablet that dissolves or disintegrates in the oral cavity without the need for water or chewing is known as a fast-dissolving medication delivery device. Most fast-dissolving delivery system films must contain ingredients that hide the active ingredient's flavour. It's made with a water-soluble component and hydro-alcoholic solvents. The moulding is then carried out using various heating

techniques and under certain pressure settings. The pressure used should be less than that used for traditional tablet compression. The method is depicted in Figure 2 below.

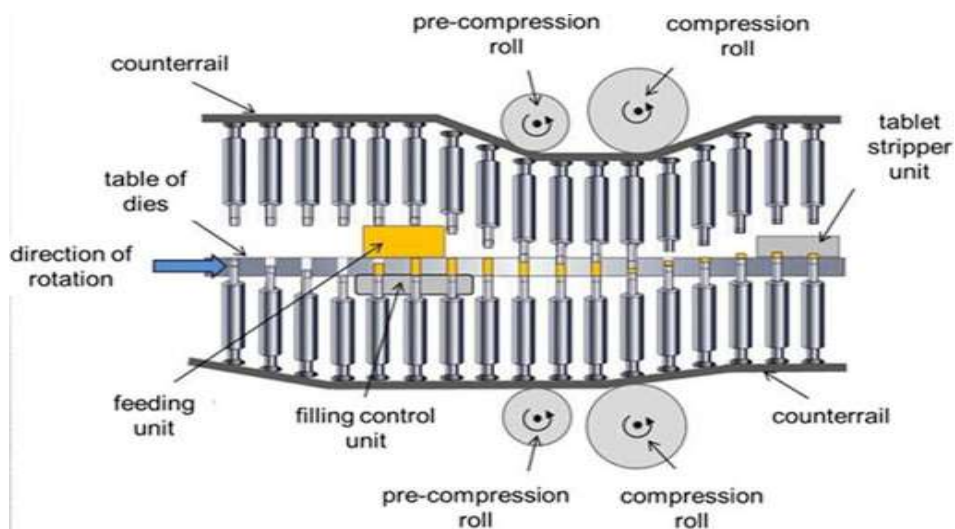


Fig – 2: Tablet Moulding Process

Cotton Candy Method

In order to make an orally disintegrating tablet with greater mechanical strength and the ability to hold larger pharmaceutical dosages, the candy floss matrix is crushed and mixed with active ingredients as well as excipients. When flash melting and spinning are done at the same time, a polysaccharide or saccharide matrix is created. The partially re-crystallized matrix's flow and compressibility have both improved.

Mass Extrusion Method

This process comprises softening the active blend with a solvent mixture of water-soluble polyethylene glycol and methanol, then extruding or syringing the softened mass into a cylinder of the product and cutting it into even segments with a hot blade to produce tablets. The dried substance can be used to cover bitter-tasting medications to hide their taste.

Spray Drying Method

When using spray drying, a hot gas is used to quickly turn a liquid or slurry into a powder. This is the preferred drying method for many thermally sensitive items, such as food and pharmaceuticals. It is necessary to spray dry certain industrial products, such as catalysts, in order to achieve a uniform particle size distribution. Although air is used as the hot drying medium, nitrogen can be used if the liquid is a flammable solvent like ethanol or if the final product is oxygen-sensitive. All spray dryers use an atomizer or spray nozzle to disperse the liquid or slurry into a fine mist. Figure 3 illustrates how this works.

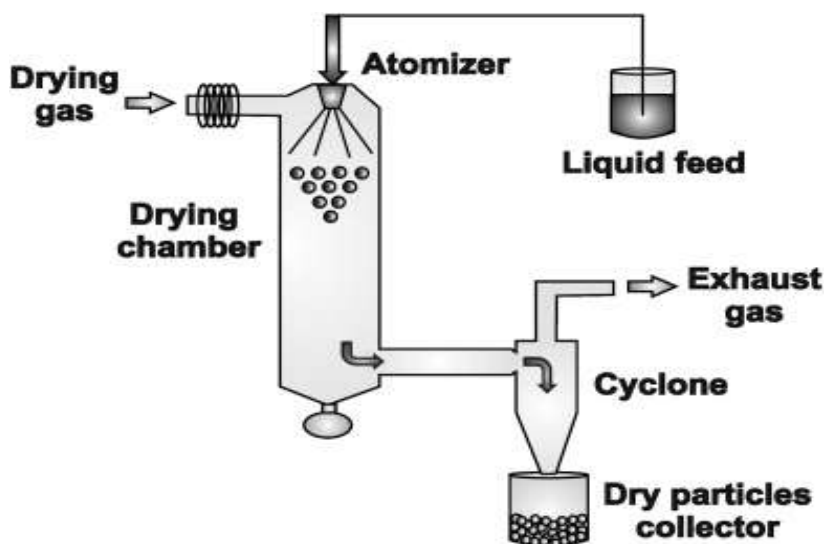


Fig - 3: Spray Dryer

Nanotization

The drug particles are reduced to nanoparticles in this procedure by grinding the drug in a patented wet milling process. Surface adsorption of the nanocrystals prevents agglomeration, which is subsequently crushed and transformed into a tablet, which is particularly effective for medications that are less water-soluble. The drug's bioavailability is increased as the disintegration time is significantly reduced.

Sublimation

Sublimation is a method for creating high-porosity, fast-dissolving tablets. By compressing a mixture of excipients with volatile substances such as urea, urethane, naphthalene, and camphor into a tablet, a porous matrix is created. Sublimation generates pores in the tablet structure, allowing the tablet to dissolve when it comes into contact with saliva. As pore generating agents, a variety of solvents such as cyclohexane, benzene, and others can be utilised. This approach was used to create oral dispersible tablets with a porous structure and excellent mechanical strength. Sublimation is explained in figure 4 given below.

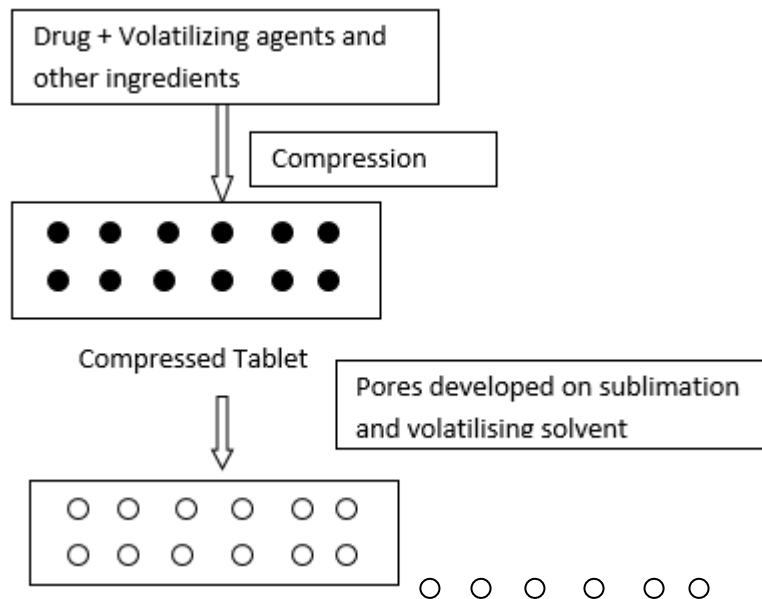


Fig -4: Sublimation Method

- A key aspect of a fast-dissolving drug delivery system is the ease with which it can be administered to patients who are unable to swallow.
- The dose form can be swallowed without the use of water.
- The medicine will dissolve and absorb quickly, resulting in a speedy commencement of effect.
- As saliva goes down into the stomach, some medications are absorbed from the mouth, pharynx, and oesophagus (pregastric absorption).
- In such circumstances, the drug's bioavailability is enhanced, which enhances clinical performance by reducing undesired side effects.
- It has a pleasant mouth sensation.
- Physical blockage reduces the danger of choking or suffocation during oral delivery of traditional formulation.
- It's useful in situations when there's a lot of movement.

Excipients used to prepare FDTs:(Forms-Parenteral Medications et., al 2009, K. A. Coppens et., al 2005)

Super disintegrants

Cross povidone contains microcrystalline cellulose, sodium starch glycollate, sodium carboxy methyl cellulose, pre-gelatinized starch, calcium carboxy methyl cellulose, and modified corn starch. Sodium starch glycollate has a higher Flowability than croscarmellose sodium. Cross povidone has a fibrous and compactable structure.

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Flavours

Peppermint oil, clove oil, bay oil, anise oil, eucalyptus oil, thyme oil, bitter almond oil, peppermint flavour, cooling flavour, flavour oils, and flavouring aromatic oil, peppermint oil, clove oil, bay oil, anise oil, eucalyptus oil, thyme oil, bitter almond oil, peppermint flavour, cooling flavour, flavour oils, and flavouring aromatic oil, peppermint oil, clove oil, bay Flavouring agents include vanilla, citrus oils, and fruit essences.

Sweeteners

Aspartame, Sugar's derivatives.

Fillers

Mannitol, Sorbitol, xylitol, calcium carbonate, magnesium carbonate, calcium phosphate, calcium sulphate, pre-gelatinized starch, magnesium trisilicate, and aluminium hydroxide are all spray dried and directly compressible.

Surface active agents

Sodium doecyl sulphate, sodium lauryl sulphate, polyoxyethylenesorbitan fatty acid esters (Tweens), sorbitan fatty acid esters (Spans), and polyoxymethylene stearates.

Binders

Polyvinylpyrrolidone (PVP), Poly vinyl alcohol (PVA), Hydroxypropyl methylcellulose (HPMC).

Colour

Sunset yellow, amaranth etc.

Lubricants

Magnesium stearate, zinc oxide, calcium oxide, talc, polyethylene glycol, liquid paraffin, magnesium lauryl sulphate, colloidal silicon dioxide.

Evaluation Parameters(R.P. William et., al 2010, Han Jung H, Floros John et., al 1997)

Pre compression parameters

Prior to compression into tablets, the blend was evaluated for properties such

Angle of repose θ

The angle of repose is used to calculate frictional forces in the case of loose powder. It is defined as the greatest possible angle between the surface of a powder pile and the horizontal plane. The funnel method is used to determine it.

Angle of repose was calculated using the formula:

$$\tan \theta = 2h/d$$

$$\tan \theta = h/r$$

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

Where,

θ = angle of repose

H =height of the pile (cms)

r=radius of heap (plane surface occupied by the powder)

Table :1 Angle of repose is used to determine the flow characteristics of powders.

S. No	Angle of repose (°)	Type of flow
1	< 20	Excellent
2	20-30	Good
3	30-40	Passable
4	> 40	Very poor

Bulk density (D_b)

It's the mass to volume ratio (M/V) of the total mass of powder (V). The apparent bulk density was calculated by measuring the volume and weight of a pre-sieved medication excipient blend poured into a graduated cylinder. The bulk density (in gm/ml) was determined using the following formula: $D_B = M/V_{ibe}$

Where M = mass of the powder

V/b = bulk volume of powder

Tapped density (D_t)

It is the ratio of the total mass of powder to the volume of taped powder. It was determined by mechanically tapping a graduated cylinder carrying a known mass of drug-excipient combination. The cylinder falls from a height of 10 cm to a hard surface at 2-second intervals. The tapping was continued until the volume remained constant. The following formula was used to determine the tapped density (in gm/ml).

$$D_t = M/V_t$$

Where,

M = Mass of the Powder

V_t = Tapped volume of the powder

Carr's Index (Carr's Consolidation Index)

It indicates the powder flow properties. It is expressed in percentage and is given by formula: % compressibility (I) = $[\text{Tapped density} - \text{Bulk density} / \text{Tapped density}] \times 100$

Table:2 Relationship between% compressibility and flowability

S. No	% Compressibility	Flowability
1	5-12	Excellent
2	12-16	Good
3	18-21	Fair passable
4	23-35	Poor
5	33-38	Very poor
6	<40	Very very poor

Hausner ratio

(Kuchekar BS and Arumugam V, et., al 1993, Bess WS, Kulkarni N et.,al 2006) It is an indirect indicator of the ease with which powder flows. It is calculated using the following formula:

Hausner ratio= Tapped density/ Bulk density

Lower Hausner ratio (<1.25) indicates better flow property than higher ones (> 1.25)

Porosity

Porosity ϵ is defined as the ratio of the packaging's void volume to its bulk volume. The powder's porosity is determined as follows:

$$\epsilon = \frac{v_b - v_p}{v_p} = 1 - \frac{v_p}{v_b}$$

Porosity is frequently expressed in percentage and is given as

$$\% \epsilon = \left(1 - \frac{v_p}{v_b}\right) \times 100$$

Evaluation of Fast Dissolving Tablets: (Han Jung H et., al 1997, Patel Zinkal Ket., al)

The following quality control tests were performed on tablets from all formulations.

General appearance

A tablet's entire appearance, visual identity, and overall elegance all play a role in customer adoption. Additionally, it indicates the tablet's size, shape, colour, and scent, as well as any physical defects, uniformity, and legibility of the tablet's identification markings.

Size and shape

Dimensionally describing, monitoring, and controlling the tablet's size and shape is possible.

Tablet thickness

When filling equipment is employed, tablet thickness is a significant aspect in replicating the appearance and counting of tablets. Certain filling machines count

tablets based on their uniform thickness. A micrometre was used to determine the thickness of ten pills. The thickness of the tablet is measured in mm using Vernier callipers.

Uniformity of weight

The I.P. process was followed to ensure weight homogeneity. Twenty pills were weighed individually and collectively using a digital weighing balance. The aggregate weight was used to determine the average weight of one tablet. The weight variation test would be an acceptable method for determining the uniformity of the medication content.

Table:3 Average weight of tablets and their %deviation

S.No.	Average weight of tablets (mg)	of Maximum % difference allowed
1	130 or less	±10
2	130-324	±7.5
3	more than 324	±5

Tablet hardness

The amount of force required to break a tablet across its diameter is known as the tablet's hardness. The hardness of a tablet under storage and handling conditions determines how resistant it is to chipping, abrasion, or fracture before use. The hardness of the tablet in each formulation was measured using hardness testers from Monsanto or Pfizer. There are kilocalories in one square metre.

Friability

Friability refers to the weight loss of a tablet in a container as a result of the removal of microscopic particles from the surface. Friability testing is used to determine the tablet's resistance to abrasion during packing, handling, and transportation. The Roche friabilator was used to determine the tablets' friability. Twenty tablets of each formulation were weighed and placed in a Roche friabilator set to 25 revolutions per minute for four minutes. The tablets were washed and weighed once more. The weight loss percent was adjusted. Weight loss was measured as a percentage using the following formula:

$$\% \text{friability} = [(w_1 - w_2) / w_1] \times 100$$

Where,

W1= Weight of tablet before test (Initial Weight)

W2 = Weight of tablet after test (Final Weight)

Thus, it is necessary that this parameter should be evaluated and the results are within bound limits (0.1-0.9%)

Wetting time

Five circular tissue papers were placed in a 10-cm-diameter Petri dish and were then incubated. 10 ml of water was dissolved in eosin, a water-soluble dye, and applied to the Petri plate. Researchers used a dye solution to see when the tablet surface was totally saturated. A tablet was carefully placed on top of the tissue paper in the Petri dish. After water had reached the tablets' upper surface, the soaking time was determined by their total time in water. To be certain of their accuracy, these tests were run six times in a row. The amount of time that each area was wet was measured with a stopwatch.

Water absorption ratio

A folded piece of tissue paper and 6ml of water were placed in a little petri dish. A tablet was placed on the paper, and the time required to completely soak it was calculated. The wetted tablet was reweighed once it had dried. To determine the water absorption ratio, we utilised the following formula:

R is equal to 100 times $W_a - W_b / W_b$.

W_b denotes the tablet's weight prior to water absorption.

W_a is the weight of the pill after it has absorbed water.

Moisture uptake studies

To determine the formulation's stability, moisture uptake investigations on FDTs are required. 10 tablets of each formulation dried in 24 hours at 37°C in a desiccator with calcium chloride. Following that, two weeks of storage at 75% relative humidity with the pills' weight were required. A three-day saturated sodium chloride solution was poured at the bottom of the desiccator to maintain the right humidity level. One of the excipients was utilised to evaluate moisture absorption, while another served as a control (without super disintegrants). We calculated the percentage rise in weight experienced by those who took weight-loss drugs.

***In-vivo* Disintegration test**

Six tablets were subjected to the test using the equipment specified in I.P 1996. The disintegration medium was distilled water at a temperature of 37°C±2°C, and the time necessary in seconds for the tablet to completely disintegrate with no particle matter remaining in the instrument was determined.

***In-vitro* dispersion time**

The time required for in vitro dispersion was evaluated by dropping a tablet into a beaker containing 50 ml of Sorenson's buffer pH 6.8. Three tablets from each formulation were chosen at random for invitro dispersion time.

Dissolution test

When FDT does not contain taste masking chemicals, the dissolve procedure is nearly identical to that used for ordinary tablets. Dissolving situations described

in the USP book can occur often with drugs. FDT should be tested with several buffers, such as 0.1NHcl, pH 4.5, and pH 6.8. Using the USP 2 paddle apparatus and a paddle speed of 50 rpm is the most typical method for dissolving FDT pills, according to experience. However, due to the tablet's distinctive physical characteristics, the USP 1 (basket) equipment is used less frequently for FDT. The inside top of the basket near the spindle can become clogged by tablet fragments or disintegration tablet masses, resulting in ineffective or unpredictable stirring and a varying dissolving pattern.

Patented Technology Tablets

Patented Technologies for Fast Dissolving Tablets

It is generally accepted that the fast disintegration of FDT is due to the rapid penetration of water into the tablet matrix. Several pharmaceutical businesses have created and patented a number of technologies based on formulation characteristics and various processes. Listed below is information on patentable technologies.

- | | | |
|----|----------|------------|
| 1. | Zydis | technology |
| 2. | Durasolv | technology |
| 3. | Orasolv | technology |
| 4. | Wow tab | technology |

Zydis technology (Seager et., al 1998, Shangraw et., al 1980)

Catalent Pharma holds the patent for Zydis technology, which is best known among the quick dissolving/disintegrating tablet formulations. This is a unique freeze-dried tablet in which the medicine is encased or dissolved in the matrix of fast-dissolving carrier material. When zydis units are swallowed, the freeze-dried structure disintegrates instantly and does not require water to aid in swallowing. Multiple materials make up the zydis matrix, which is intended to accomplish several goals with one ingredient. Polymers such as gelatin, dextran, or alginates are used to add strength and elasticity to the product during handling. With their shiny amorphous structure, they add strength. mannitol or sorbitol are used to achieve crystallinity, elegance and toughness. Porous units are produced in the manufacturing process using water to ensure quick disintegration, while different gums are employed to avoid the sedimentation of medication particles. Protectants like glycine can prevent the shrinkage of zydis units during freeze-drying or long-term storage of the product. Zydis medicines are packaged in blister packs to preserve the formulation from moisture in the environment.

Orasolv Technology (Patel Zinkal K et., al, Seager et .,al 1998, Keshari R et., al 2015)

First-to-market fast-dissolving/disintegrating dosage form, OraSolv, was developed by Cima in 2007. In contrast to Zydis, OraSolv technology disperses in the saliva by a very undetectable effervescence. Because of its rapid disintegration, the tablet matrix of ThenOraSolv technology can be compared to a fast-disintegrating tablet. The OraSolv formulation provides two types of flavour masking. Instead of just adding sweets or tastes to disguise an unpleasant

medicine flavour, OraSolv uses coating the powder and effervescence to achieve the same result. Over-the-counter medicines frequently utilize this technology as well. As a result, a drug's active ingredient is disguised. An effervescent disintegration agent is used as well. A modest compression force is used in the production of tablets using the direct compression technique in order to speed up oral dissolve time. To make the tablets, blenders and a tablet machine are used. Soluble and friable tablets are created.

Durasolv Technology (Nautiyal U et.,al 2014)

This is Cima's second generation of quick dissolving/disintegrating tablets, DuraSolv. DuraSolv is made in the same manner as OraSolv, but it has a substantially higher mechanical strength because of the higher compaction pressures used during tableting. Thus, the DuraSolv product is produced more quickly and at a lower cost. Because DuraSolv is so long-lasting, it doesn't matter whether it's packaged in blisters or vials.

Wow tab Technology (Boddeda et., al 2019)

Yamanouchi Pharmaceutical Co. has a patent on the Wow tab technology. "Without Water" is the acronym for WOW. To make a robust tablet that melts quickly, a mixture of low- and high-mouldability saccharides is employed in this procedure. Lactose, glucose, mannitol, and other low-moldability saccharides are combined with the active component, which is then granulated with high-moldability saccharides (such as maltose and oligosaccharides) and compacted into tablets. As a result of WOWTAB's success in Japan, this tablet formulation has been around for several years.

Conclusion

Improved patient compliance, efficacy, and biopharmaceutical characteristics have been demonstrated with fast dissolving drug delivery systems. Some of these technologies can access FDT dosage forms, which have sufficient mechanical strength and dissolve quickly in the mouth. Patients who are mad, chronic (like diabetes, thyroid, and cancer), geriatric, or paediatric, or who may not approach water, or who are voyaging, should have FDTs performed. Allergies, asthmatic episodes, and heart attacks necessitate prompt treatment. To get around these issues, scientists have created the FDT, or a new type of drug delivery system.

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