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MOUTH-DISPERSING TABLET: AN EXCLUSIVE DOSAGE FORM RESERVED FOR SPECIFIC USES

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Abstract
Pharmaceutical scientists are learning more about the physicochemical and biological factors that affect drug delivery systems efficacy, which leads to an advancement in their sophistication.
The current state of science has led to intense competition, rapid advancement, and rising demand for medication delivery technologies. One such cutting-edge and distinctive drug delivery method that is quickly garnering significant attention in the realm of rapid dissolving technology development is the fast dissolving tablet (FDT). The oral route is the fastest and safest way to deliver pharmaceuticals since it may be used to administer a variety of medications. Fast dissolving tablets (FDTs), which dissolve or disintegrate quickly in oral saliva without requiring water intake, have recently been produced by researchers. Novel medicine administration methods like mouth dissolving tablets (MDT) or FDT have eliminated certain drawbacks such dysphagia and the inaccessibility of water when travelling. FDT can be a helpful substitute for traditional dose forms as well. The idea for a fast-dissolving tablet was first proposed in late 1970s, and its formulation and process are still being refined today. This review's objective is to learn more about variety of techniques for creating MDT, patented technologies, the superdisintegrant's mechanism, difficulties encountered, and evaluation criteria.

Keywords: Mouth Dissolving tablet, Dysphagia, Manufacturing technology, superdisintegrant, evaluation.

1. INTRODUCTION

In the pharmaceutical business, oral medication delivery is currently the gold standard since it is thought to be the safest, most practical, cost-effective, and patient-compliant route of drug delivery. [1]
The need for more patient-friendly and compliant dose forms has increased within the last ten years. The need to create new technologies has therefore been growing yearly. Pharmaceutical companies are currently concentrating on the development of new drug dosage forms for existing drugs with improved safety and

efficacy along with reduced dosing frequency, as well as the production of more cost-effective dosage forms, due to the high development costs associated with new drug molecules. [2]

Up to 50–60% of all dose forms are widely accepted as conventional forms, which include tablets and capsules. The most widely used conventional dosage form now in use is the tablet due to its exact dosage delivery, compact design, ease of self-administration, and ease of fabrication. One significant disadvantage of solid dose forms is that some patients, especially those who are young and elderly, may have dysphagia, or trouble swallowing or chewing. Due to hand tremors, dysphasia, fear of choking, underdeveloped muscular and neurological systems in younger people, and schizophrenia in patients, swallowing difficulties are a regular occurrence that impairs patient compliance.[3]

In addition to these conditions, swallowing difficulties with tablets and capsules can also arise from diarrhoea, allergies, bronchial infections, and coughing up the common cold. Swallowing problems affect about one-third of the population, primarily young and old. This causes poor adherence to oral tablet medication therapy, which lowers the effectiveness of therapy as a whole. Tablets that may quickly dissolve or disintegrate in the oral cavity have drawn a lot of interest because of these factors.[4]

Orodispersible tablets, fast disintegrating tablets, orally disintegrating tablets, mouth dissolving tablets, fast dissolving tablets, rapid dissolving tablets, porous tablets, quick melt tablets, and rapid melt tablets are other names for mouth dissolving tablets.[5]

According to the "Orange Book," an ODT is defined as "a solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue" by the US Food and Drug Administration's Centre for Drug Evaluation and Research (CDER).[6]The European Pharmacopoeia adopted the term "Orodispersible Tablet" to designate these dosage forms, emphasising their relevance. The phrase refers to a tablet that can be placed in the oral cavity and swiftly disperses before swallowing.[7]

According to recent market research, over 50% of patients prefer over-the-counter dose forms (ODTs), and the majority of consumers would either buy or ask their doctors for ODTs (70%), or prefer ODTs over conventional pills or liquids (>80%). [8]

The two primary methods used to make mouth dissolving tablets are the first is the use of super disintegrants such as crospovidone, sodium starch glycolate, and croscarmellose sodium. Using vacuum and freeze drying to maximise the tablets' pore structure is an additional technique. Direct compression is the recommended method due to its ease of use, speed, and affordability. [9],[10]

table 1: criteria for fast dissolving drug delivery system.[11],[12]

Sr.no	Parameters	Acceptance/Rejection
1	Water Required for swallowing	No
2	Fragility Concern	No
3	Leave Residue in oral cavity/Grittiness	No
4	Sensitive to Environmental factors (humidity, temperature)	No
5	Compatible with Taste Masking	Yes
6	Portable	Yes
7	Good Mouth Feel	Yes
8	Patient Compliance	Yes
9	Suitable for Conventional tablet processing and packaging	Yes
10	Economic	Yes

2. ADVANTAGES

- It is not necessary to take the tablet with water; it tastes and feels good in the mouth; it can be easily given to patients who are young, old, or intellectually challenged.
- After administration, there is no leftover in the oral cavity.
- Tablets can be delivered at a minimal cost by using standard processing and packaging equipment.
- Give high drug loading permission.
- A precise dosage in contrast to liquids could be offered.
- The medication dissolves and absorbs rapidly, resulting in a swift start to action.
- Better than fluid medication in terms of administration and transportation.
- The product differentiation will result in the creation of new commercial opportunities.

- The mouth dissolving drug delivery system's good tongue feel feature contributes to a shift in the general perception of pharmaceuticals.
- Also minimise the first pass metabolism.[13],[14]

3. TECHNOLOGIES USED FOR MANUFACTURING OF MDTs:

In the recent past, several new advanced technologies have been introduced for the manufacturing of MDTs with ideal properties like less disintegration time, pleasant mouth feel, exceptional taste masking and sugar free tablets for diabetic patients. The technologies used for manufacturing of MDTs broadly classified in two category one is patented another one is nonpatented technologies.

- Freeze drying/ Lyophilisation
- Tablet moulding
- Spray drying
- Direct Compression
- Sublimation
- Mass Extrusion
- Cotton candy process

1.1. Freeze-Drying or Lyophillisation

The process of sublimating water out of a frozen product is called freeze drying. With this method, an amorphous porous structure that dissolves quickly is produced. Here is a description of a common process used in the production of FDT utilising this method.

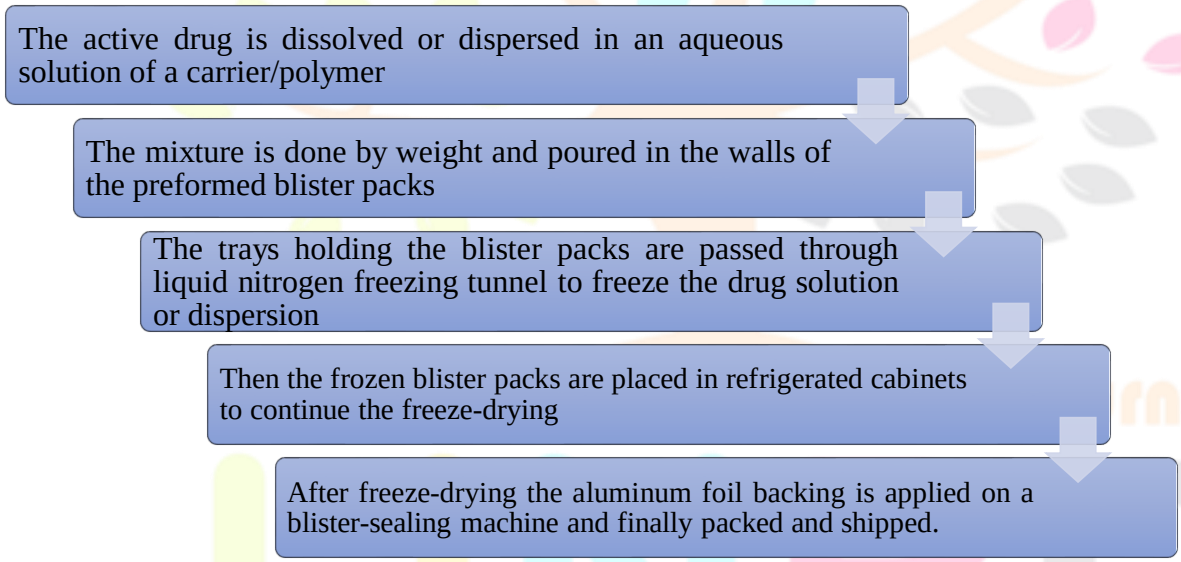

figure 1: steps by step procedure of lyophillisation of FDT

The process of freeze-drying has shown to boost bioavailability and improve absorption. The lyophillisation technique's main drawbacks are its high cost and lengthy processing time; also, these goods' fragility renders traditional packaging inappropriate for them, and their low stability under pressured circumstances.[14],[15]

1.2. Sublimation

Very volatile ingredients like ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, hydrocarbon, urea, ester, and anhydride could also be compressed along with alternative excipients into a pill in order to create a porous matrix. The formulation is then subjected to a method of sublimation. Sublimation is then used to remove this volatile substance, largely leaving a polymer matrix behind.[16],[17]

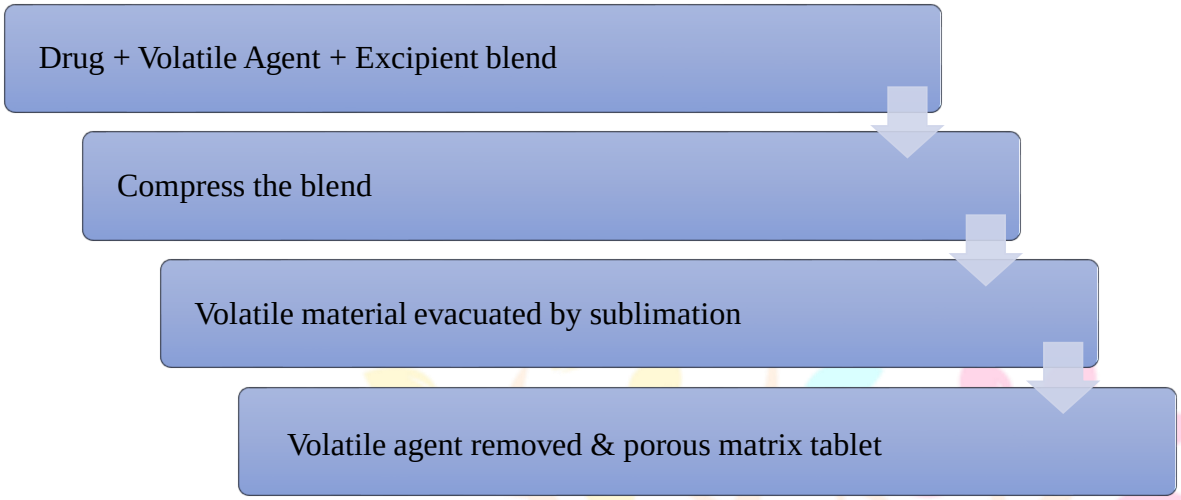

Figure 2: Systemic representation of sublimation

1.3. Direct compression

The simplest and most economical method of producing tablets is direct compression. Using this process, the medication and excipient mixture is compressed directly into tablets without any prior preparation. It is necessary for the mixture to be crushed to have good flow characteristics.[18]

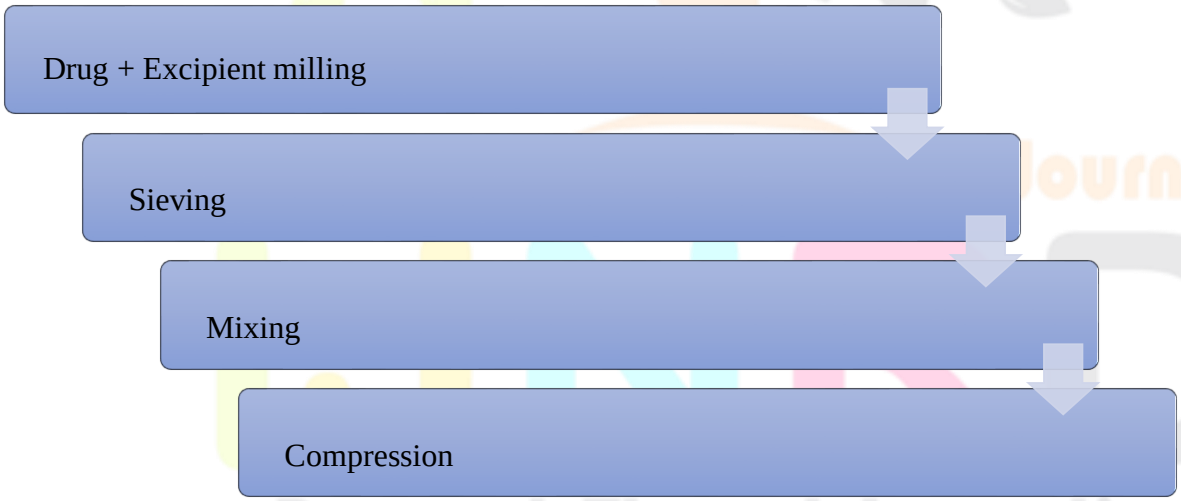

figure 3: steps involved in direct compression method

1.4. Tablet Molding

Molding process is of two types i.e., solvent method and heat method.

1.4.1. Solvent Method: -

By using a hydro-alcoholic solvent to moisten the powder blend, the solvent method compresses the mixture at low pressures into moulded plates to create a wetted mass (compression moulding). After that, the solvent is eliminated by air-drying. The tablets produced in this way have a porous structure that speeds up dissolving and are less compact than compacted tablets.

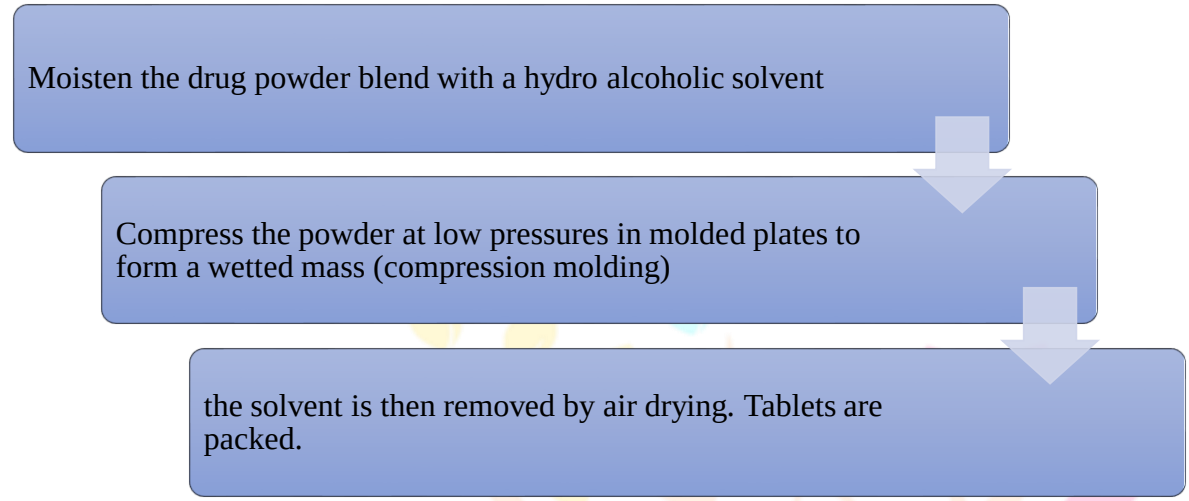

figure 4: procedure of solvent method.

1.4.2. Heat Method: -

In the heat moulding method, a suspension containing a medicine, agar, and sugar (such as lactose or mannitol) is prepared, then the suspension is poured into blister packaging wells, the agar is allowed to solidify at room temperature to create a jelly, and the mixture is dried at 30°C under vacuum. One major difficulty with moulded tablets is their mechanical robustness. It is necessary to include binding agents, which boost the tablets' mechanical strength.[19]

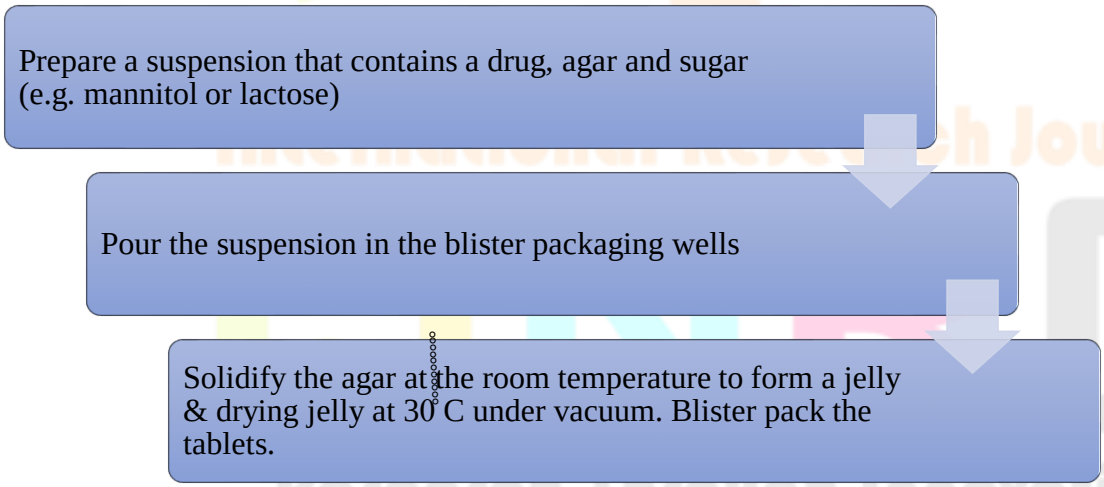

figure 5: procedure of heat method

3.5. Cotton candy process

The FLASHDOSE® is an MDDDS that is made with ShearformTM and Ceform TITM technologies to get rid of the medicine's bitter taste. Shearform technology is utilised in the creation of a "floss" matrix, which is composed of a blend of excipients, either in isolation or in conjunction with medications. The floss is a fibrous substance that resembles cotton candy fibres and is often composed of saccharides that range in temperature from 180 to 266 °F, including sucrose, dextrose, lactose, and fructose. But at a temperature that is 30–40% lower than sucrose, other polysaccharides, like polymaltodextrins and polydextrose, can also be converted into fibres. The safe addition of thermolabile medications to the formulation is made possible by this change. The resulting pills are extremely porous and provide a really pleasant experience. mouthfeel brought on by the sugars' quick solubilization in saliva.[20]

3.6. Spray drying

This method uses sodium starch glycolate, crosscarmellose, or crosspovidone as superdisintegrants, mannitol as a bulking agent, and gelatin as a matrix and supporting agent. It has been observed that tablets made from the spray-dried powder dissolve in an aqueous solution in less than 20 seconds. The composition included alkaline (sodium bicarbonate) and/or acidic (citric acid) chemicals together with bulking agents (lactose and mannitol), superdisintegrants (sodium starch glycolate & croscarmellose sodium), and When compacted into tablets, this spray-dried powder demonstrated improved solubility and quick disintegration.[21]

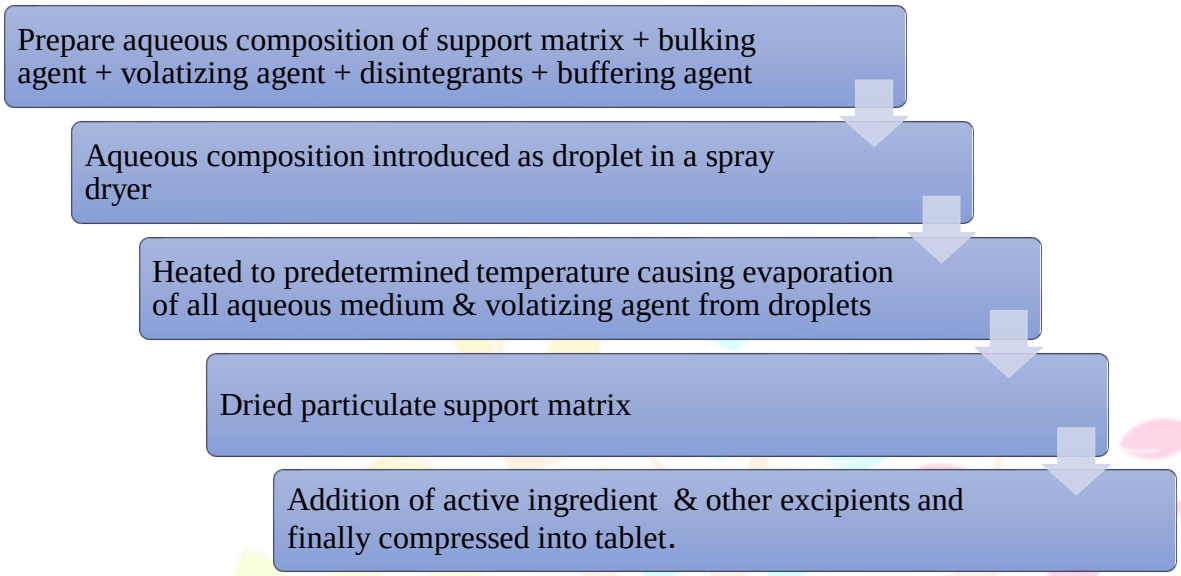

figure 5: steps involved in spray drying

1.5. Mass extrusion

To achieve taste masking, the dried cylinder can also be used to coat bitter medicine grains. Using a solvent mixture of water soluble polyethylene glycol and methanol, a mixture of active drug and other ingredients is softened. The softened mass is then forced through an extruder or syringe to create a cylinder of product, which is then divided into even segments with the help of heated blades to create tablets. The bitter flavour of medicine granules can be covered with the dried cylinder to disguise the bitter flavour. The product is obtained by extruding the softened bulk using a syringe or extruder, creating a cylinder that is subsequently divided into even pieces with a hot blade.[22]

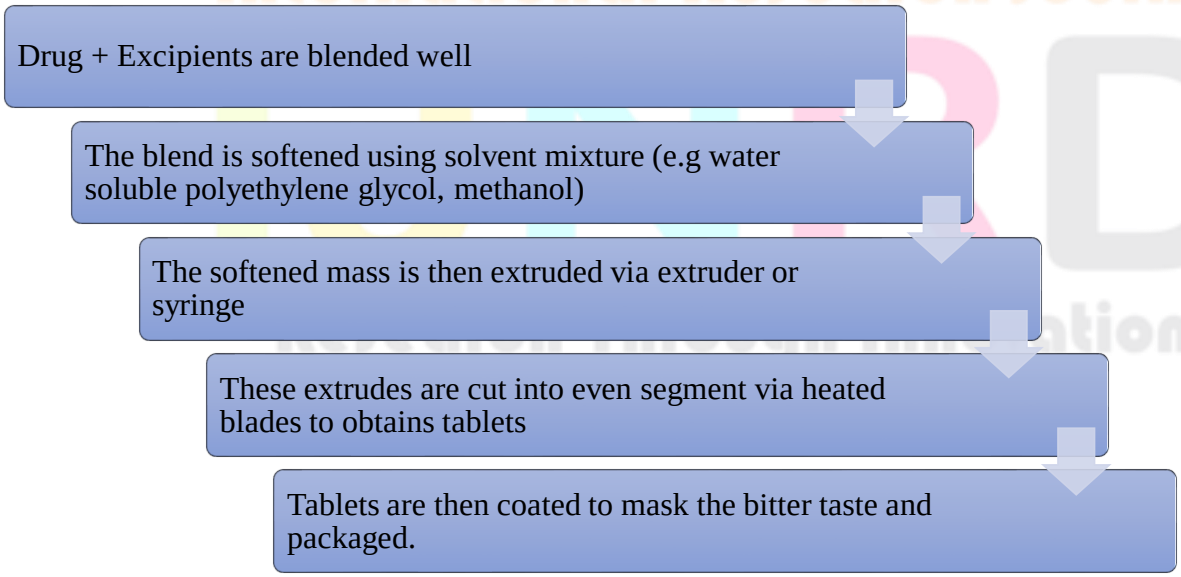

figure 6: procedure involved in mass extrusion

table 2: Promising Drugs to be incorporated In Fast Dissolving Tablets with their technology used

Drug(s)	Category	Technology used	Disintegration time (sec)
Chlorpromazine HCL	Antipsychotics	Direct compression	Less than 60
Sildenafil	Erectile dysfunction	Freeze drying	<30
Ascorbic acid, Cimetidine	Antihistaminic	Molding, Direct compression	31-37
Fexofenadine	Antihistaminic	Direct compression	15-20
Ondansetron	Antiemetic	Direct compression	10-15
Ibuprofen Indomethacin Naproxen Diclofenac	NSAID	Direct compression	8-15
Famotidine	Antihistaminic	Freeze drying	2-6
Clarithromycin or Cefixime	Antimicrobial	Extrusion spheronization	<60
Resperidone	Antipsychotics	Spray drying and compression	<30
Modafinil	CNS stimulant	Wet granulation	-
Aceclofenac	NSAID	Direct compression	12.2-27.5
Amlodipine Besilate	Antihypertensive	Direct compression	15-37.8
Granisetron HCL	Antiemetic	Direct compression	17.1
Capecitabine	Anticancer	Direct compression	50
Rizatriptan benzoate	Antimigraine	Direct compression	85
Ramipril	Antihypertensive	Direct compression	<30
Cinnarizine	Antihistaminic	Sublimation	25.3
Dicyclomine HCL	Anticholinergic	Direct compression	18-22
Omeprazole	Gastric acid suppressant	Wet granulation	<60
Fenofibrate	Hypolipidaemic	Sublimation	20-25
Allopurinol	Antigout	Direct compression	11-40
Olanzepine	Antipsychotics	Direct compression	<30

4. CHALLENGES IN FORMULATING MOUTH DISSOLVING TABLETS

4.1 Palatability

Since most medications are tasteless, FDTs typically include the medication in a form that masks its flavour. It dissolves or disintegrates in the patient's mouth after delivery, releasing the active components that come into contact with the taste buds. As a result, taste-masking pharmaceuticals becomes essential for patient compliance.

4.2 Mechanical strength

FDTs are either made of very porous and soft-molded matrices or compressed into tablets with very low compression force, which makes the tablets friable and/or brittle, difficult to handle, and frequently requiring specialised peel-off blister packing that may increase the cost. This allows the tablets to disintegrate in the oral cavity. The only tablet technologies that can make tablets hard and robust enough to be packed in multi-dose bottles are Wow Tab and Durasolv.

4.3 Hygroscopicity

Under typical temperature and humidity circumstances, a number of orally disintegrating dosage forms cannot preserve their physical integrity due to their hygroscopic nature. Because of this, they require humidity protection, necessitating the use of specialised product packaging.

4.4 Amount of drug

The amount of medicine that can be added to each unit dose restricts the deployment of FDT technology. Drug dosages for lyophilized dosage forms must be less than 400 mg for insoluble substances and 60 mg for liquid substances. This characteristic presents a significant challenge when creating oral films or wafers that dissolve quickly.

4.5 Aqueous solubility

Because they create eutectic mixtures, which induce freezing-point depression and the production of a glassy solid that may collapse upon drying due to loss of supporting structure during the sublimation process, water-soluble medications present a number of formulation issues. Using different matrix-forming excipients, like mannitol, which can cause crystallinity and provide the amorphous composite stiffness, might occasionally stop such collapse.

4.6 Size of tablet

A tablet's size affects how simple it is to take. It has been shown that tablets in the sizes of 7-8 mm are the simplest to swallow, whereas tablets larger than 8 mm are the easiest to handle. It is therefore challenging to create a tablet that is both convenient to carry and manage.

4.7 Mouth Feel

In the mouth, FDTs shouldn't break down into bigger particles. Particles formed following the FDTs' disintegration ought to be as little as feasible. Additionally, the oral feel is improved by the inclusion of flavours and cooling substances like menthol.[23]

5. AREA OF CONSIDERATION IN THE CHOOSING OF SUPER DISINTEGRANTS

- **Disintegration:** The disintegrant needs to wick saliva into the tablet quickly in order to create the necessary hydrostatic pressure and volume expansion for fast disintegration in the mouth.
- **Compatibility:** Strong tablets with less friability at a given compression force and suitable hardness are needed to reduce the need for specialised packaging and speed up production.
- **Mouth Feel:** Large particles may give you a harsh taste in your tongue. Particles that are small are advised. The tablet has a sticky flavour that many customers find unpleasant when it comes into contact with water and turns into a gel.
- **Flow:** Super disintegrants are usually added to tablet formulations at a rate ranging from 2 to 5 weight percent. With FDT formulation, the disintegrant amount can be substantially higher.

6. MECHANISMS OF SUPERDISINTEGRANTS

The degradation of MDTs in the mouth is explained by four major mechanisms.

6.1 By Molecular Breaking Down Technique (Particle Repulsive Force)

This method produced "un-swellable" MDTs. With the use of disgusting electric controls, the scientist Guyot-Hermann postulated the theory of molecular repulsiveness, which is based on perception and holds that non-expanding particles are what cause tablets to crumble. Water is needed for this operation in order to crumble tablets into smaller pieces, as seen in (Figure 8a).

6.2 Permeability and Capillary Behavior (Wicking)

This procedure is divided into phases and is predicated on the idea that tablets break down due to capillary action. When tablets are mixed with a suitable volume of liquid, the tablets penetrate the medication material and replenish any air that has been absorbed. Drug ingredients are degraded as a result of intermolecular interactions, which vary based on the hydrophilicity of the excipient and tablet circumstances. As seen in (Figure 8b), this process necessitates maintaining the permeable structure and low interface tension towards the watery liquid, which separates by merely forming a hydrophilic portion of medicinal substances in pieces.

6.3 Bloating (Swelling)

Because bloating causes tablets to swell, it should not be used excessively. The swelling and porosity of the coated polymer, as shown in (Figure 8c), determine whether or not tablets break into fragments.

6.4 Structural Deformation

The undissolved materials become deformed during the compression of the tablets and transform into a specific structure when they come into contact with the water. Starch swellability occasionally enhanced

granulation and controlled the structural deformation process. The tablet separates into smaller pieces as a result of this process, as seen in (Figure 8d). [24]

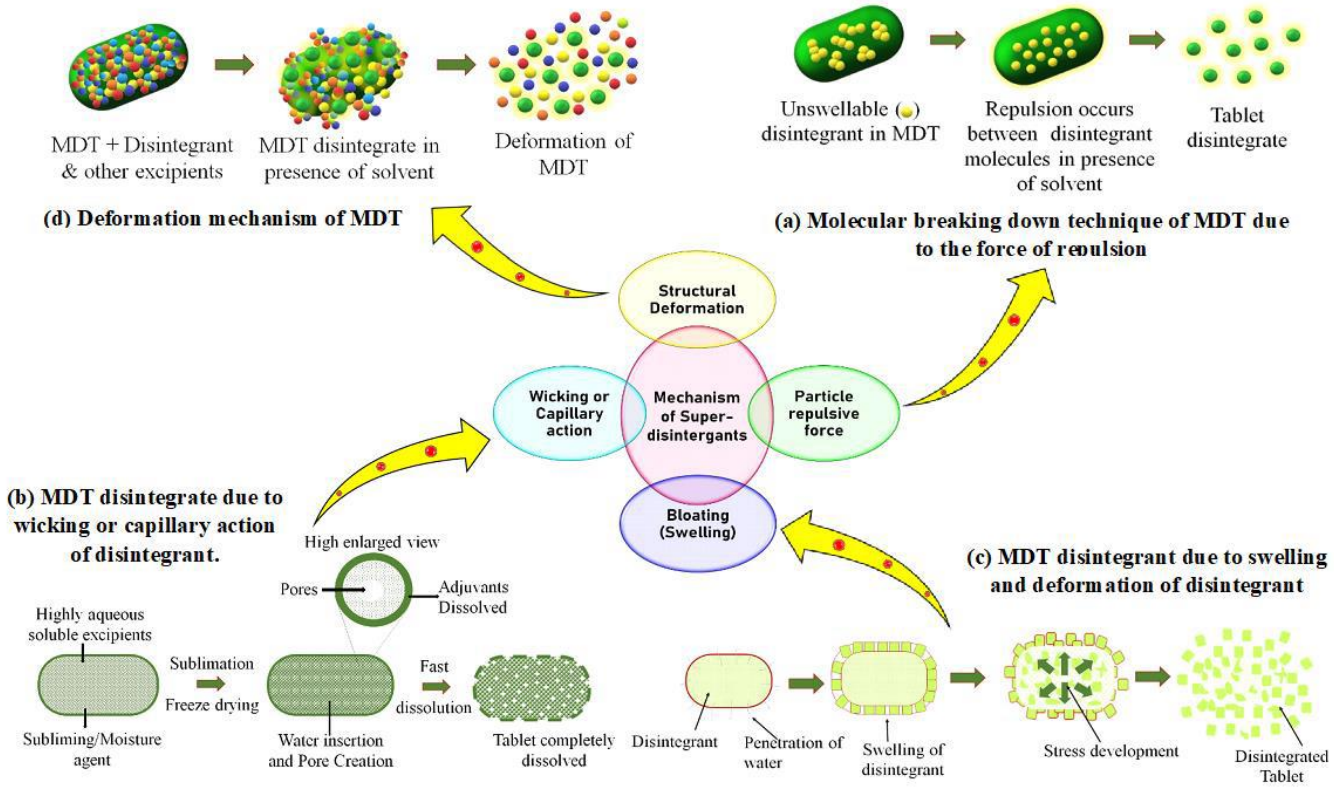

figure 8: mechanism of super disintegrants

Table 3: enlists various existing super disintegrants and also their mechanism of action

Superdisintegrants	Available grades	Mechanism of action
Cross-linked Alginic acid	Alginic acid, Satialgine	Rapid swelling in aqueous medium or wicking action
Cross-linked PVP	Kollidon, Polyplasdone, Crosspovidone	Swells very little and returns to original size after compression but act by capillary action
Cross-linked Starch	Primogel, Sodium starch glycolate, Explotab	Swells 7-12 folds in < 30 seconds.
Cross-linked Polymer of Polycarboxylic acid	Kyron T-314	Very high swelling tendency of hydration either in contact with water or G.I. fluid.
Cross-linked Cellulose	Croscarmellose, Ac-Di-Sol, Nymce ZSX, Solutab, Vivasol	Swells 4-8 folds in < 10 seconds. Swelling and wicking both
Pregelatinized starch	Starch 1500	Swelling
Micro crystalline cellulose	Avicel,Celex	Water Wicking

7. PATENTED TECHNOLOGIES FOR FAST DISSOLVING TABLETS

7.1 Zydis Technology:

Zydis formulation is a special method for making tablets that dissolve quickly. The medication ingredients are physically entrapped or dissolved within the matrix of quickly dissolving carrier polymers in this freeze-dried tablet technique. Water is not necessary for ingesting because the freeze-dried structure dissolves quickly in the mouth when the "zydis unit" is placed there. Zydis material is made up of a wide variety of materials to accomplish certain goals. Alginate and gelatin are added to polymers like dextran to give strength during handling. Good elegance, hardness, and crystallinity are achieved by including saccharides, such as sorbitol or mannitol. Glycine is typically employed as a collapse protectant in freeze-drying processes or long-term

storage to stop the shrinkage of "zydis units." The formulation needs to be sealed in a blister to keep moisture out of it.[25]

7.2 Durasolv Technology:

CIMA Labs' proprietary technique is called Durasolv. This method produces pills that have a lubricant, filler, and medication. Tablets are made with good stiffness and are manufactured with traditional tabletting equipment. These can be put into blisters or other traditional packaging systems. Durasolv is a suitable technology for products that need to have small concentrations of active substances.

7.3 Orasolv Technology:

Orasolv Technology has been created by CIMA labs. The active medication in this system is disguised by flavour. An effervescent disintegrating agent is also present. To reduce oral dissolution time, tablets are produced using a low compression force direct compression approach. The tablets are made using traditional blenders and tablet presses. The resultant tablets are friable and soft.

7.4 Flash Dose Technology:

Fuisz owns a patent on flash dosage technology. Biovail Corporation's first commercial product is a novel kind of ibuprofen called Nurofen meltlet, which is created using flash dosage technology and is meant to dissolve in the mouth like tablets. The "floss" in "flash dose" tablets is a self-binding shear form matrix. Flash heat processing is used to create shear form matrices.[4]

7.5 Wow tab Technology:

Yamanouchi Pharmaceutical Co. is the patent holder of the Wow tab technology. WOW stands for "Waterless." To create a powerful tablet that melts quickly, a combination of low and high moldability saccharides is used in this procedure. The low moldability saccharides, such as lactose, glucose, and mannitol, are combined with the active component, which is then granulated with the high moldability saccharides, such as maltose and oligosaccharides, and crushed into a table.[26]

7.6 Flash tab Technology:

The Flash tab technology is patented by Prographarm Laboratories. The active substance in the tablet made with this technology is in the form of microcrystals. The traditional methods of coacervation, micro encapsulation, and extrusion spheronization can be used to create drug microgranules. Every processing step made use of traditional tabletting technology.[4]

7.7 Pharmabust technology:

SPI Pharma is in the process of patenting pharmaburst technology. This method produces tablets that dissolve in 30 to 40 seconds. First, a dry mixture containing a medication, flavours, and lubricant is combined, then the mixture is compressed into tablets. This technology produces tablets that are strong enough to be packaged in bottles and blister packs.

7.8 Frosta technology (Akina):

Akina holds the patent for this invention. Frosta technology produces robust tablets with excellent porosity by utilising the fundamental idea of manufacturing plastic granules and compressing them at low pressure. The procedure is combining a water penetration enhancer with the porous plastic material, then granulating with a binder.[27]

7.9 Nanocrystal technology:

Elan's patented nanocrystal technology can facilitate formulation, enhance ingredient activity, and improve end product qualities for fast-dissolving tablets. Particle size reduction raises surface area, which speeds up the rate of dissolution. Nanocrystal technology can be used to accomplish this in a predictable and efficient manner. Small drug particles called nanocrystals, usually with a diameter of less than 1000 nanometers (nm), are created by grinding the drug material using a special wet milling method.

7.10 Oraquick technology:

With regard to this technology, K. V. S. Pharmaceuticals is patent holder. It makes use of a technique known as taste masking microspheres, or micromask, which offers a faster rate of product disintegration or dissolution, a substantial mechanical strength, and a better mouth feel than taste masking alternatives. The taste masking procedure does not use any type of solvent. As a result, it produces better and more quickly and efficiently.[28]

7.11 Advatab technology:

Advatab tablets dissolve quickly in the mouth—usually in less than 30 seconds—making it easy to take medications orally without the need for water. These tablets are particularly appropriate for people who have trouble swallowing pills and capsules. Advatab stands out from other FDT technologies because it may be paired with complementary particle technologies from Eurand, such as its DiffucapsR controlled release technology and its industry-leading MicrocapsR flavour masking technology.[29]

8. EVALUATION PARAMETERS:

8.1 Weight variation test:

Twenty tablets were chosen at random, and their individual weights as well as the average weight of the 20 tablets were calculated. Each tablet's deviation from the average weight was computed, and the results were compared to the standard values found in the Pharmacopoeia.[30]

table no 2: weight variation and accepted % deviation

Sr.no	Average weight of tablet	% Deviation
1	80 mg or less	10.0
2	More than 80 mg but less than 250 mg	7.5
3	250 mg or more	5.0

8.2 Tablet thickness:

When counting with filling equipment and replicating appearance, tablet thickness is a crucial factor. The tablets' consistent thickness is used by some filling machinery as a counting mechanism. A micrometre was used to measure the thickness of ten tablets.[31]

8.3 Friability:

The degree to which a tablet breaks under physically demanding circumstances, such as during packing or transit, is measured by its friability. Using a Roche friabilator, a sample of six randomly chosen tablets was assessed for friability for four minutes at 25 rpm. The total weight of six tablets is measured both before and after the procedure to determine the percentage of weight loss. The following formula can be used to get the percentage of weight loss:

$$\%\ Weight\ loss = \frac{\text{Total weight of tablet before} - \text{Total weight of tablets after}}{\text{Total weight of tablets}} \times 100$$

8.4 Mechanical Strength:

Tablets should have sufficient mechanical strength to withstand handling shocks throughout production, packing, and delivery. Friability and crushing strength are two crucial factors in determining mechanical strength.

8.5 Crushing Strength or Tablet Tensile strength:

It is crucial to remember that excessive crushing strength drastically shortens the disintegration period. Crushing strength is the force needed to break a tablet by compression in the radial direction. Pfizer hardness testers were used to measure the tablet's crushing strength. Three observations are averaged to calculate it. The formula for calculating tensile strength for crushing (T) is

$$T = 2F / \pi * d * t$$

where d and t stand for the tablet's diameter and thickness, respectively, and F represents the crushing load.[32]

8.6 Measurement of Tablet Porosity:

The porosity of tablets can be measured with a mercury penetration porosimeter. The following formula can be used to get the tablet porosity (ε):

$$\varepsilon = 1 - m / (\rho t V)$$

where m and V stand for the tablet's weight and volume, respectively, and ρt represents the real density.[33]

8.7 Wetting time:

For tablets that dissolve in the mouth, the two most important factors are the wetting time and the water absorption ratio. The following formula is used to determine the tablet's wetting time. A tiny petri dish filled

with a water-soluble dye solution was used to hold a piece of filter paper that had been sliced in a circular motion. Wetting time is the amount of time it takes for the dye colour to show on the tablet.
After placing the tablet on the paper, the amount of time needed to fully moisten it was calculated (Figure 7).A tissue paper folded twice was utilised by Bi Y. et al. and put in a small culture dish (i.d = 6.5 cm) with 6 ml of water.

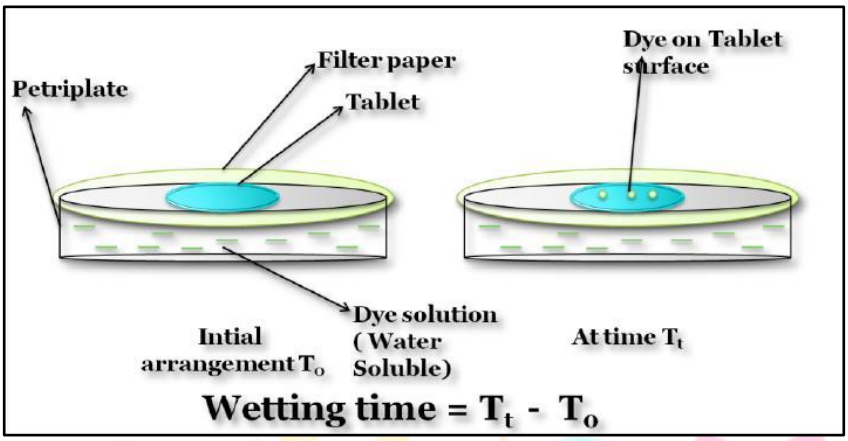

figure 7: the mouth dissolving tablet's wetting time.

8.8 Dissolution test:

When taste masking is not used, the disintegration processes for FDT are nearly the same as those for ordinary tablets. Drugs frequently have dissolving conditions similar to those in USP monographs. The same procedures as with regular tablets should be followed for evaluating FDT using pH 4.5, pH 6.8, and 0.1N HCl buffers. Because of the unique physical characteristics of the tablets, the USP 2 paddle apparatus is the most popular and appropriate option for the dissolution test of FDT tablets when compared to the USP 1 (basket) equipment. A typical paddle speed range for paddle devices is 25–75 rpm. Using slower paddle speeds can help generate a comparison profile because FDTs dissolve quickly under USP monograph conditions. Higher paddle speeds can help prevent the formation of a mound in the dissolution vessel caused by large tablets weighing more than one gramme.

8.9 Water absorption ratio:

Comparable to the process used to calculate the wetting time (Figures 8). However, in this case, the water absorption ratio was determined using the following method, which also computed the tablet's starting weight and final weight (after full wetting):

$$= \frac{\mathrm{Wa} - \mathrm{Wb}}{\mathrm{Wb}} \times 100$$

where Wa and Wb are the tablet weights before and after wetting, respectively, and R is the water absorption ratio.

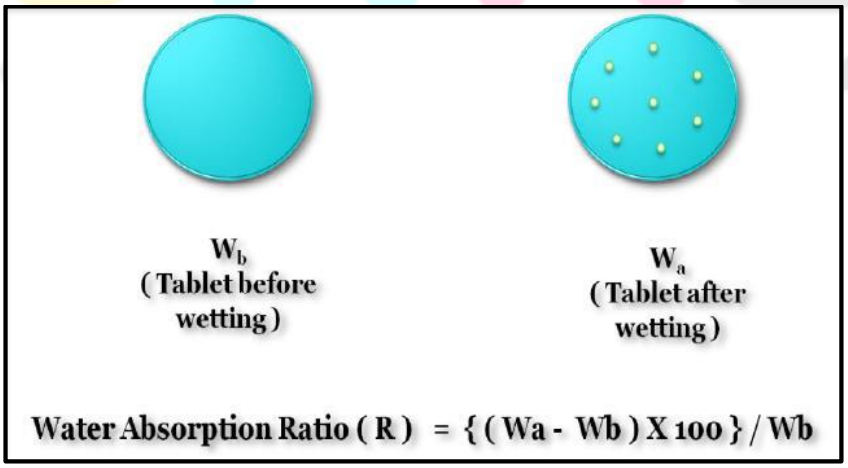

figure 8: water absorption ratio calculation

8.10 Disintegration time:

Using a disintegration test instrument, the disintegration time of six randomly selected tablets was determined. We computed the average disintegration time and compared it to standards.

8.11 Invitro dissolution studies:

Six randomly chosen tablets were utilised in USP dissolving device drug release investigations. A 900 ml dissolve medium volume was used, and a 37±0.5oC temperature was maintained. Up until 30 minutes, 5 ml of the sample was taken every 5 minutes and replaced with 5 ml of brand-new buffer solution. A UV spectrophotometer or an HPLC system was used to perform the drug assay after the samples had been filtered and appropriately diluted. Standard values were used to compare the outcomes.

Taste or mouth feel: The mouth feel of the tablet was assessed using volunteers who were in good health. One tablet's mouthfeel was assessed. Five members of the panel use the time intensity approach to assess mouth feel. A 40 mg sample was retained in the mouth for 10 seconds, and scores ranging from 1 to 10 were assigned to indicate the level of opinion. (0: good 1: tasteless, 2: slightly bitter, 3: bitter, 4: terrible).

8.12 Dissolution test:

When taste masking is not used, the disintegration processes for FDT are nearly the same as those for ordinary tablets. Drugs frequently have dissolving conditions similar to those in USP monographs. The same procedures as with regular tablets should be followed for evaluating FDT using pH 4.5, pH 6.8, and 0.1N HCl buffers. Because of the unique physical characteristics of the tablets, the USP 2 paddle apparatus is the most popular and appropriate option for the dissolution test of FDT tablets when compared to the USP 1 (basket) equipment. A typical paddle speed range for paddle devices is 25–75 rpm. Using slower paddle speeds can help generate a comparison profile because FDTs dissolve quickly under USP monograph conditions. Higher paddle speeds can help prevent the formation of a mound in the dissolution vessel caused by large tablets weighing more than one gramme.

8.13 Clinical studies:

According to in vivo investigations, FDT has an actual effect on the oral-esophageal tract in addition to having pharmacokinetic, therapeutic, and acceptability properties. The study employing gamma scintigraphy demonstrated how quickly fast dissolving dose forms were dissolved and cleared from the buccal cavity. The stomach emptying time and the esophageal transit time were similar to those of conventional dose forms, such as tablets, capsules, or liquid forms.[34][35]

8.14 Stability study (Temperature dependent):

The ICH guidelines for accelerated studies required a time of storage for the fast-dissolving tablets, which were kept under the following circumstances.

(i)40 ± 1 °C

(ii)50 ± 1°C

(iii)37 ±1 ° C and RH 75% ± 5%

After 15 days, the tablets were taken out and examined for physical characteristics such visual imperfections hardness, friability, disintegrations, and dissolution, among others. The kinetics of deterioration are ascertained by fitting the collected data into first order equations.

To calculate the shelf life at 25°C, accelerated stability data are shown using the Arrhenius equation.[36]

9. CONCLUSION:

Over the past 10 years, numerous manufacturers have shown interest in MDTs due to their potential benefits over traditional dosage forms. These benefits include enhanced patient compliance, convenience, bioavailability, and a rapid beginning of action. The MDT formulations produced using a few of these technologies are sufficiently strong mechanically and dissolve quickly in the mouth without the need for water. This market area presents a clear possibility for the introduction of new, improved oral solutions. Swallowing difficulties affect about one-third of the population, mostly the elderly and young. This leads to poor adherence to oral tablet medicine therapy, which lowers the overall efficacy of therapy. These pills are made to dissolve or break down quickly in saliva, usually in less than 60 seconds (with a range of 5 to 50 seconds). The creation of a fast-dissolving tablet offers the potential to expand the product line; a variety of medications, including those for erectile dysfunction, analgesics, cardiovascular medications, neuroleptics, and antihistamines, can be taken into consideration for this dosage form. Pharmaceutical manufacturers often develop a certain drug item in an enhanced dosage form when the drug's patent life is about to expire.

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