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Review Article

Fast Disintegrating Tablets: A Review on Novel Drug Delivery System

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ABSTRACT

Fast Disintegrating Tablets (FDTs) are a promising class of oral drug delivery tablets that dissolve or disintegrate quickly in saliva, offering a practical and patient-friendly alternative for various populations. These tablets dissolve quickly in the buccal cavity, allowing direct absorption through the mucosa, ensuring prompt therapeutic effects. They have advantages such as improved tongue feel, ease of administration, accurate dose, and comfort for bedridden or mobile patients. However, they also have drawbacks like brittleness, hygroscopicity, mechanical strength, and unpleasant scents. A balanced formulation strategy is needed to overcome these challenges. The article also explores non-invasive drug delivery methods, such as spray drying, tablet molding, and freeze-drying, to meet pharmaceutical industry demands.

INTRODUCTION

Despite a number of drawbacks, the oral route is the most effective way to administer drugs. [1,2,3,4] Over the past 20 years, several oral dose forms have been created to increase patient compliance, increase absorption, and lessen side effects. Since fast dissolving / disintegrating drug delivery systems (FDDDS) can dissolve quickly in the oral cavity when they come into contact with saliva, producing solutions or suspensions of the delivered medication, they have started to acquire recognition and appeal in this era.[5,6] The oral cavity is an excellent site for drug administration due to its high degree of vascularization, low enzymatic pool, and ability to circumvent hepatic metabolism, in addition to its advantageous anatomical and physiological characteristics that permit manipulation of drug penetration. The first FDDDS (Claritin Reditabs, Schering Plough, Kenilworth, NJ) to be approved in the US was the lyophilization-based Zydus (Catalent Pharma Solutions, Somerset, NJ) in 1996.[7] Fast disintegrating drug delivery methods have several advantages over traditional dose forms, including speedy medication therapy, rapid drug absorption, ease of administration, and patient acceptance, particularly for travelers, elderly, pediatric,

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dysphagic, and psychiatric patients. The benefits of traditional tablet formulations and liquid formulations are combined in these systems. Additionally, by providing innovative dosage forms, pharmaceutical businesses have discovered a way to differentiate their goods and prolong their product life cycle.[8] When a rapid peak plasma concentration is needed to produce the appropriate pharmacological response, these systems are more helpful. Pre-gastric absorption can occur from the buccal, pharyngeal, or stomach areas due to the drug's dispersion in saliva.[9] Since the majority of medications have a bitter taste, it is crucial to conceal their flavors in order to create an FDDDS that is acceptable.

Types Of Fast Disintegrating Drug Delivery System:

Fast disintegrating drug delivery systems are broadly classified into three categories.[10]

1. Orally disintegrating films and wafers,

2. Last disintegrating capsules and

3. Fast disintegrating tablets.

Fast Disintegrating Capsule's:

Conventional capsules are either perforated or vacuum-dried to create fast-dissolving capsules that can be administered in the oral cavity. Capsules offer a number of benefits over alternative rapidly dissolving dose forms, such as lyophilized spongus tablets. Haghe medication loading capacity and the lack of compression daring manufacturing are particularly significant.[11] In September 2004, a US patent was awarded for the creation of foambursa-based capsules that dissolve quickly. This technique creates a honeycombed structure in the film by blowing gas into it as it is developing. The filen's voids could be vacant, partially filled, or filled with various materials. The capsules' delicate honeycomb construction causes them to dissolve quickly in the mouth.[12]

Fast Disintegrating Tablet's (FDTs):

The most popular dose form in fast-dissolving medication delivery systems is fast-dissolving tablets. Many names have been given to these tablets, including melt-in-mouth, mouth dissolving, quick melting, orodisperse, and fast disintegrating tablets. Furopean Pharmacopocia states that orvudisperse tablets are those that dissolve quickly in the buccal cavity before being swallowed.[13]

Dysphagia And Fast Disintegrating Tablet's:

The idea behind the Fast Dissolving Drug Delivery System was to give patients a more traditional way to take their prescription drugs. Dysphagia is a prevalent issue that affects patients of all ages due to physiological changes that are particularly connected with the elderly and children. The pediatric and geriatric population, as well as other patients who prefer the convenience of easily swallowable dosage forms, can benefit greatly from solid dosage forms that can be broken down, dissolved, or suspended by saliva in the mouth, making swallowing easier. When this tablet is placed on the tongue, it instantly dissolves, releasing the medication that dissolves or spreads in the saliva.[14,15] The goal of oral fast-disintegrating tablets (FDTs) is to increase patient compliance and accetance. According to a Norwegian poll of 6158 general practitioners, over 26% of all patients do not take their recommended medication because they have trouble swallowing traditional tablets. The size, appearance, and flavor of the tablets are frequently the primary grievances.[16,17,18] Single unit solid dose forms known as fast melting tablets (FMT) or fast disintegrating / dissolving tablets (FDT) dissolve

or dissolve quickly (in a matter of seconds) in the mouth without the need for chewing or water. These dose forms are stable, simple to make, and easy for patients to handle. To some extent, it is also possible to achieve absorption of certain drugs across the oral mucosa directly into the systemic circulation, avoiding first pass metabolism and its subsequent side effects. In certain cases, the drug is readily available for absorption and is immediately released from the dosage form, improving its onset of action and bioavailability (soluble drugs). The product is available at any time and in any manner. It can be swallowed without liquid. It's prepared.[19,20]

Salient Features / Advantages Dissolving / Disintegrating Drug Delivery System [21,22]:

1)FDT offers all the benefits of solid dosage forms, including precise dosing, easy manufacture, high stability, and unite. simple handling etc.

2) Offers quick pharmacological therapy assistance.

3) There is no chance of physical blockage because of the dosing type.

4) The potential for increased bioavailability as a result of quicker absorption and action onset.

5) FDTs give medications that have reached the end of their patent life a fresh lease on life.

6) Ease of administration to patients, including children, elderly, mental, and disabled patients, who cannot or will not swallow a tablet.

7) Is water necessary for effective dissolving and disintegration of the dose form in the oral cavity?

8) The ability to utilize the benefits of liquid medication in a solid preparation form.

9) It can be made to have a nice mouthfeel and to leave little to no residue in the mouth after use.

10) Enables a high medication loading capacity.

11) By permitting pregastric drug absorption, FDTs help prevent hepatic metabolism and hence lower the necessary dosage of medication.

12) Adaptable to current packaging and processing equipment.

13) Economical.

Fast Dissolving Tablet's:

According to FDA definitions, FDTs are solid dosage forms that include an active ingredient or medication that dissolves or disintegrates quickly when applied to the tongue (FDA, 2009). Another name for fast-dissolving tablets is mouth-dissolving tablets or mouth-dissolving pills. The tablets either melt in the mouth or dissolve into tiny grains after being ingested, changing from a hard, solid form to one that resembles gel. The pills take a few seconds to over a minute to dissolve.[23] The creation of a suitable dosage form for the elderly is highly desirable due to the aging of the population. Current dose forms, such as capsules, are impractical due to changes in numerous physiological functions associated with aging, including difficulties swallowing. [24]

Fast Dissolving Films:

Solid dosage forms known as "fast-dissolving oral films" melt or disintegrate in the mouth in less than a minute without the need for chewing or water. By avoiding the first-pass metabolism, these drug delivery methods enhance the medication's bioavailability. [23,25,26]

Criteria Of Drug Selection:

When selecting a medication for a quick-dissolving system, the following considerations are important:
1) It is somewhat non-ionized at the oral cavity's pl.

2) How to manage molecular weight.

3) The medication must to be able to penetrate the oral mucosa.

4) The drug must be stable in both water and saliva and have the ability to diffuse and partition into the upper side of the GIT epithelial layer in order to be effective.

5) Medications with low bioavailability are a good fit for fast-dissolving systems.

6) Drugs that require frequent dosages and have a short half-life are not appropriate for fast-dissolving systems.

For medications having an unpleasant taste or odor, fast-dissolving systems are not the best option. Individuals who regularly take anticholinergic medications may experience developments. [23,27]

Ideal Properties FDT's [28,29,30,31,32,33]:

Suitable for standard tablet packaging and manufacturing methods Fragility Concern, Good Mouth Feel, Patient Compliance, Economical, and Taste Masking Compatibility.

Limitations Of FDT's:

The mechanical strength of tablets is one of the main drawbacks of FDTs.
1)FDT are soft, porous molded materials that can be compacted into a tablet with little compression, making the tablet fragile and easily handled.

2)Drugs with bad tastes are challenging to create as FDIT; extra care must be taken before formulating such a medication. Many IYTs require specialized packaging since they are hygroscopic and cannot maintain their physical integrity in typical humidity conditions.

3)People who have dry mouth from less saliva may not be appropriate candidates for these tablet formulations.

4)Overall bioavailability and the rate of absorption from saliva stability of drugs and dose forms.[34,35,36]

Standard Characteristics of FDT's:

One kind of tablet, known as a quick-breakdown or fast-disintegrating tablet, is designed to dissolve in the mouth when it comes into contact with saliva in less than a minute, ideally less than forty-five seconds, creating a suspension that is easy to swallow. The term "orodispersible tablets" is more widely used. According to estimates, 50% of people have trouble swallowing pills or capsules. Because of this issue, the recommended medication is not taken, which significantly reduces the effectiveness of the treatment. Therefore, urodispersible tablets are simple to provide to patients who have deglutition issues or to those who choose to take their medication without concurrently consuming liquids.[28,37,38] Current developments in new drug delivery (NDDS) seek to increase patient compliance and enhance the safety and effectiveness of therapeutic molecules by creating appropiate dose forms for each administration scenario. Oral disintegrating tablets (ODTs) are one such method. ODTs are solid unit dose forms that dissolve or disintegrate quickly in the mouth without the need for water, chewing, or swallowing. ODTs are designed with new developments in dosage form design that meet patient needs. without sacrificing its

effectiveness The ODTs meet the patient's needs, which include swallowing difficulties with traditional pills or capsules.[39,40]

Drugs Formulated As FDT's:

For medications to be formulated as Fast Dissolving Tablets, the following requirements must be met: low dosage, good mechanical strength, stability in aqueous media, and compatibility with excipients.[41,42]

Common Excipients Used For FDT'S Preparation:

The following are common excipients found in FDT at least one lubricant, diluent, disintegrant, swelling agent, permeabilizing agent, sweetener, and flavors.[43]

Name of the excipients	Percentage used
Disintegrant	1 to 15%
Diluents/Tillers	0 to 85%
Binder	5 to 10%
Antistatic Agent	0 to 10%

Fast Dissolving Tablet's Benefits:

1) Anywhere, at any time, without the need of water.

2) Appropriateness for elderly and young patients who have trouble swallowing, as well as for other populations that might have trouble with traditional oral dosage forms because they are mentally ill, developmental disabilities, uncooperative, on reduced liquid intake regimens, or have nausea.

3) Beneficial in situations requiring an extremely quick commencement of action, such as motion sickness, severe allergy attack episodes, or coughing.

4) Increased bioavailability as a result of these tablets' quick dissolving and disintegration, especially for insoluble and hydrophobic medications.

5)Stability for an extended length of time since the medication stays in its solid dose form until it is used. Thus, it combines the benefits of liquid and solid dosage forms in terms of bioavailability and stability, respectively.[28]

Mouth Dissolving Tablet's Limitations:

1) Usually, the tablets' mechanical strength is insufficient. Careful handling is therefore necessary.

2) If the tablets are not properly formed, they may leave an unpleasant taste and/or grittiness in the mouth. [28]

Techniques For Making of Fast Dissolving Tablet's [44]:

a) Lyophilisation,
b) Tablet moulding,
c) Mass extrusion,
d) Direct compression,
e)) Spray drying,
f) Sublimation .
g) Cotton candy process and
h) Nanonization.

A) Lyophilisation:

MDTS is made by taking advantage of the porous product that is created during the freeze-drying process. The process of lyophilization involves extracting the solvent from a frozen suspension or medicinal solution including additives that give it structure. The medicine and additives are freeze-dried to give the product a glossy, amorphous form that makes it lightweight and extremely porous. When placed on the tongue, the resulting tablet

melts and disintegrates quickly, and the freeze-dried unit dissolves immediately to release the medication. However, the lyophilized MDTs exhibit poor stability at higher temperatures and humidity levels, as well as limited mechanical strength.[29]

ADVANTAGES:

a) Increased fill weight management.
b) Sterility can be maintained
c) water can be removed at a low temperature
d) suitable for aseptic operation.[44]

DISADVANTAGES:

a) It is expensive and time-consuming
b) It is unstable under stress
c) Conventional packaging is not suitable for these products because of their fragility.[44]

b) Tablet Moulding Method:

A fast-dissolving drug delivery device is a tablet that dissolves or disintegrates in the oral cavity without the need for water or chewing. The majority of films for fast-dissolving delivery systems need to include additives that mask the flavor of the active ingredient. It is composed of hydro-alcoholic solvents and a water-soluble component. After that, the molding is done under specific pressure levels and with a variety of heating methods. Less pressure than is required for conventional tablet compression should be used. The figure 1 below shows the procedure.[23]

Different Techniques Used for Tablet Moulding Are:

i) Compression molding:

The powder combination is first soaked in a solvent, like water or alcohol, and the resulting wet mass is then forced onto the mold plate.

ii) Heat molding:

In this way, the drug is distributed throughout the molten matrix. [45]

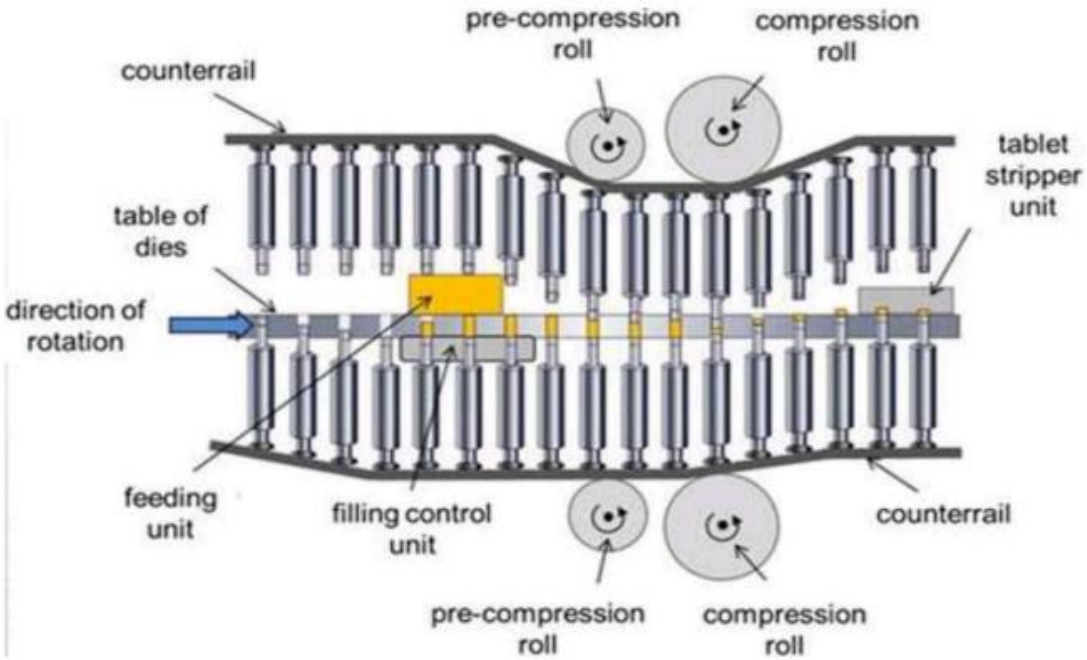

Fig. 1: Tablet Moulding Process.

ADVANTAGES:

a) It is the most lightweight and portable dose farm;

b) It is easy to administer;

c) It is easy to use;

d) It is more stable. [44]

c) Mass Extraction Method:

In order to create tablets, the active blend is softened using a solvent mixture of methanol and water-soluble polyethylene glycol. The softened mass is then extruded or syringed onto a product cylinder and cut into even segments using a heated blade. The dried material can be used to mask the taste of bitter drugs.[23] (Figure 2)

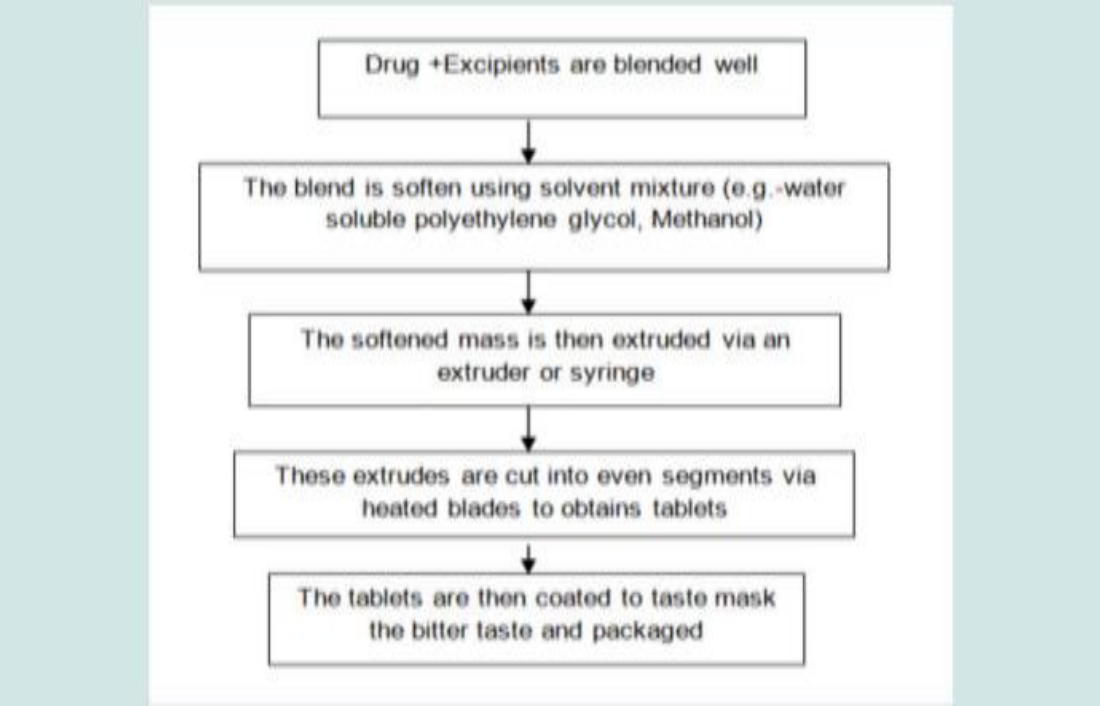

Fig. 2: Mass Extraction

d) Direct Compression Method:

In the past, a number of techniques, including direct compression, wet granulation, and dry granulation, were approved for the manufacturing of FDTs in tablet format.[46,47] Direct compression is the most straightforward method for producing tablets among all of these methods. This method's inexpensive production costs, well-known machinery, easily accessible excipient, and fewer operational processes make it a popular choice. The weight of the finished pill easily exceeds that of traditional manufacturing methods, and higher doses may be permitted. The activity of excipients, such as disintegrants, hydrophilic substances, and effervescent agents, either alone or in combination, determines the rate of disintegration and solubilization in the case of compressed tablets. For directly compressed FDTs to dissolve and disintegrate, super-disintegrants are essential. For a high disintegration rate and a pleasing tongue feel, selecting the appropriate type and grade of disintegrants is essential.[48]

ADVANTAGES:

i)Batch-to-batch differences are negligible because manufacturing procedures require fewer unit activities.

ii) Particle size consistency.

iii) The tablet's increased stability with age.

iv) API and excipient chemical stability issues would be avoided.[44]

e) Spray Drying Method:

Spray drying is a process that rapidly turns a liquid or slurry into a powder by employing a hot gas. For many products that are sensitive to heat, such food and medications, this is the recommended drying technique. Some industrial goods, like catalysts, require spray drying to attain a consistent particle size distribution.

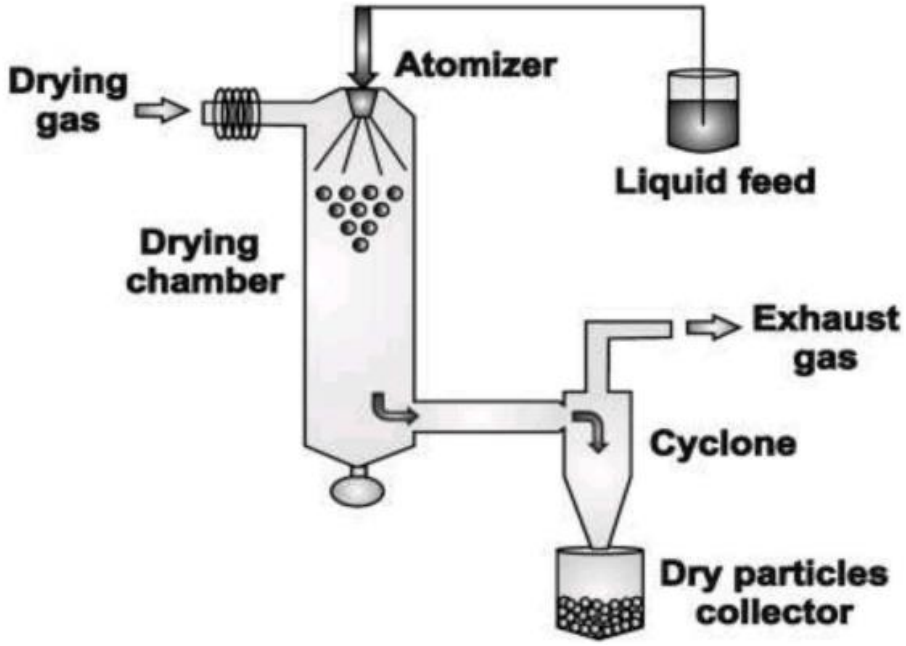

Fig. 3: Spray Dryer.

Nitrogen can be utilized if the liquid is a flammable solvent, such as ethanol, or if the finished product is oxygen sensitive, even though air is the hot drying medium. Every spray dryer disperses the liquid or slurry into a fine mist using an atomizer or spray nozzle. The figure 3 shows how this operates.[23]

ADVANTAGES:

a) A continuous, easily manageable process. b) Labor costs are low because the materials are dried in a single step without being handled. c) The dry power will have uniform particle size and shape.[44]

DISADVANTAGES:

a) Solid things cannot be dried by spray dryers.

b) A considerable amount of heat is lost during operation as a result of its low thermal efficiency. c) Cleaning after use is difficult. Equipment for spray drying is cumbersome and costly to install.[44]

f) Sublimation:

In order to achieve rapid disintegration and dissolution, inert solid components that volatilize capidly, such as urea, camphor urentomium carbonate, amenonium bicarbonate, & hexametnyiane-totramine, are formulated into porous moss mass. They were compressed after being combined with additional substances. By providing a slight temperature change and reducing pressure, the volatile substance is transformed into a porous mass. The sublimation method's properties include its porous nature and its compatibility with solvents such as cyclohexane and hensene. The figure 4 below provides an explanation of sublimation. [34,49]

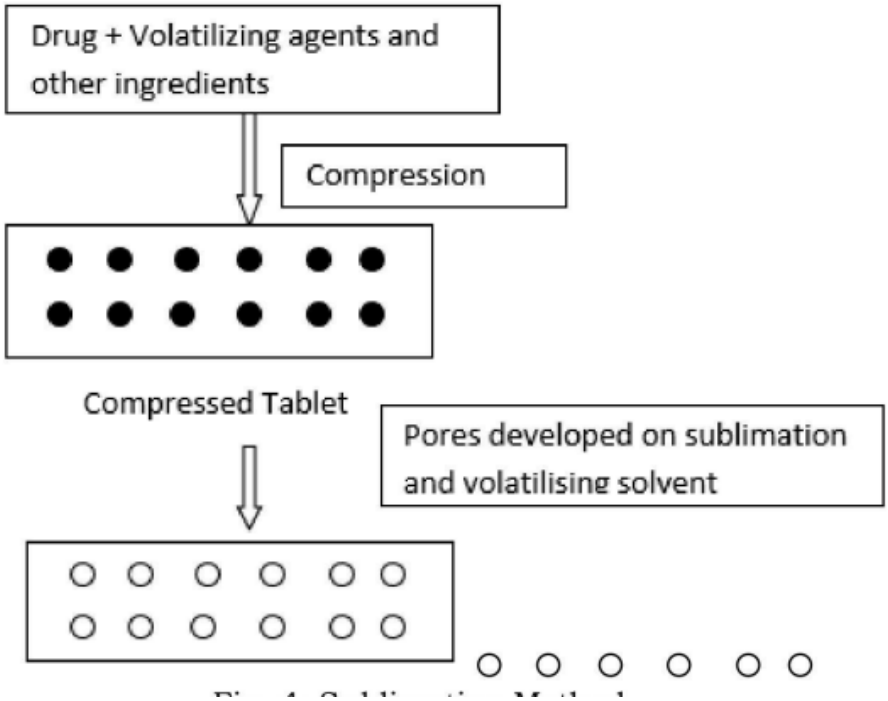

Fig.4 Sublimation Method

ADVANTAGES:

a) The use of sublimation in the purification process is its main advantage.
b) There are no solvents used.

c) The bare minimum of product is called Losa.[44]

DISADVANTAGES:

A non-sublimable material may decompose when heated.[44]

G) Cotton Candy Method:

The candy floss matrix is crushed and combined with excipients and active components to create an oral disintegrating tablet that has a higher mechanical strength and can contain larger medicinal dosages. A polysaccharide or saccharide matrix is produced when flash melting and spinning are carried out simultaneously. The flow and compressibility of the partially re-crystallized matrix have both improved.[23]

H) Nanotization:

In this method, the medicine is ground using a proprietary wet milling process to decrease the drug particles to nanoparticles. Particularly useful for drugs that are less soluble in water, surface adsorption of the nanocrystals stops agglomeration, which is then broken up and turned

into a tablet. The longer the disintegration time, the higher the drug's bioavailability.[23]

Super disintegrants:

Disintegrating agents are chemicals that are frequently added to tablet formulations to help break apart the compacted mass into the main particles so that the active ingredients can dissolve or be released more easily in a fluid environment. They support the tablet matrix's dispersion and penetration of moisture. Disintegrants' primary purpose is to counteract the tablet binder's effectiveness and the physical forces that give the tablet structure when it is compressed. To enhance the disintegration processes, new materials known as "superdisintegrants" have recently been created.[51] Another type of superabsorbing substance with customized swelling properties is called a superdisintegrant. These materials are designed to swell quickly rather than absorb large volumes of water or aqueous fluids. They are physically distributed throughout the dosage form's matrix and will swell up when it comes into contact with a moist environment.[52] With greater mechanical strength and disintegration efficiency, these more recent compounds work better at lower concentrations. In solid dosage forms, superdisintegrants are usually employed in small amounts, usually 1–10% by weight in relation to the dosage unit's total weight.[53] Their typically tiny and porous particles enable quick tablet dissolution in the mouth without the unpleasant mouthfeel that comes with gelling or big particles. Additionally, the particles can be compressed, which increases the tablet's friability and hardness.[54] Compressive strength is enhanced by efficient superdisintegrants. compatibility and do not adversely affect formulations containing highdose medications' mechanical strength. In general, 10–40 g of water or aqueous media are absorbed by one gram of superdisintegrant. Stress is produced upon absorption by swelling pressure and isotropic swelling of the superdisintegrant particles. concentrated regions where a mechanical property gradient will exist, causing the entire structure to shatter in a single portion.[50]

Types Of Super disintegrants:

Based on their availability, the Superdisintegrants can be divided into two groups[50]:

i)Natural Superdisintegrants

ii)Synthetic Superdisintegrants.

Plan And Work:

1)To investigate the hydrochlorothiazide preformulation factors, including the drug's solubility, melting point, pH, maximum, and standard calibration curve in phosphate buffer pH 7.8.
2)To investigate hydrochlorothizide using FTIR spectroscopy.
3)To investigate the parameters before compression.
4)Hydrochlorothizide fast-dissolving tablet formulation
5)To assess produced tablets using various post-compression metrics.
6)To investigate the dissolution of dissolving tablets in vitro. Phosphate buffer with hydrochlorothizide at pH 7.8.[50]

Preformulation Studies:

1)Drug solubility.
2)The coefficient of partition
3)Studies of UV Spectra.[50]

Isolation And Characterization of Polymers:

1) Natural polymer isolation: banana powder and isapghula.
2) Polymer solubility.

3) The Swelling Index.
4) Absorption of moisture.
5) Stability of heat.[50]

METHODOLOGY:

1)Manufacturing first formulations
2)Excipient Selection and Concentration Optimization
3)Preliminary batch formulation compositions.[50]

Characterization And Evolution of Formulation:

1)Precompression Specifications
2) Formulation optimization.[50]

Pre-Compression Parameters:

1)Angle of rest
2)Density of bulk
3)Carr's index
4)Hausner's ratio.[50]

Post-Compression Parameters[50]:

1)Thickness;
2)Wetting time;
3)Uniformity of weight;
4)Uniformity of drug content;
5)Hardness;
6)Friability;
7)Water absorption ratio;
8)Time of in vitro dispersion;
9)Time of in vitro disintegration;
10)Ultimate formulations' in vitro drug release.

Future Research Trends In Fast-Disintegrating Tablets:

As the table illustrates, FDT's technology and products encounter a number of difficulties. These difficulties are associated with new items and technologies. Several businesses will tackle some of these issues as these technologies advance and new goods are created. To distribute and transport drugs to the oral cavity quickly, a number of methods have been employed. This chapter covers his four FDT technologies: WOWTAB®, Zydis, OraSolve, and ShearformTM. For these various FDT approaches, formulation factors such as medication, excipient, packaging, and manufacturing process selection were compared. While each FDT method has advantages and disadvantages of its own, they are all characterized by quick disintegration and patient-friendly dosage. The performance of these goods must be examined using particular in vitro and in vivo test procedures. Although FDT's goods and technology are relatively new to the market, they face numerous obstacles, yet they are developing quickly to satisfy patient and medical needs as well as future problems, constantly enhanced to adapt to changes. All things considered, FDT goods have enormous economic potential that should come to fruition in the upcoming 10 years.[55,56]

Salient Characteristics Of FDDDS (Fast Dissolving /Disintegrating Drug Delivery System) :

1)Simple administration for children, elderly, and mental health patients who would rather not ingest medication.
2)Precise dosage, more practical than liquid forms.

3)It is convenient for those with epilepsy or depression because it doesn't require water.
4)Excellent mouth-taste qualities, especially for kids.

5)Accurate dosing, good stability, mobility, easy manufacture, and minimal package size are all provided by solid unit dosage forms. Quick medication absorption and breakdown results in quick action.
6)Drugs are quickly absorbed from the pregastric region (mouth, pharynx, and oesophagus),

reducing adverse effects, increasing bioavailability, lowering dosage, and improving clinical effectiveness.[57,58]

Challenges In Developing FDT's [57,59] :

a) Ensuring quick disintegration without sacrificing the tablet's mechanical strength is one of the main problems in FDT development.
b) A major issue in FDT formulation is striking a balance between the necessity to prevent excessive tablet expansion and the objective of quick disintegration.
c) The success of FDT depends on finding a compromise between obtaining quick disintegration and preserving sufficient tensile strength.

d) Designing FDTs that ensure a positive patient experience by leaving little to no residue in the mouth after administration is a problem.

e)Effective moisture protection techniques are necessary to address the hygroscopic characteristics of certain FITs in order to preserve stability and stop degradation.

f)One of the challenges in FDT formulation is creating packaging that is both protective and easy to administer.

g)Effective taste masking capabilities must be incorporated into FUTS in order to ensure patient acceptance, particularly for formulations that contain bitter medications.

CONCLUSION:

The main objectives of fast-dissolving/disintegrating tablets are to improve patient convenience and compliance. They are thought to be an excellent alternative to giving elderly and pediatric patients their drugs. These pills can be taken with or without water.

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