

## Fast dissolving tablets: Opportunity in herbal drug delivery system

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### Abstract

The polyherbal preparation's pharmacological and phytochemical properties have been used all over the world. Single or multiple herbs (polyherbal) are utilized for treatment in Ayurveda. The Sarangdhar Samhita, a work of Ayurvedic literature, emphasized the idea of polyherbalism as a means of enhancing therapeutic efficacy. Individual plants' active phytochemical components are insufficient to produce the desired therapeutic effects. The medicinal effects and toxicity are improved when different herbs are combined in a specific ratio.

Comforts of drug administration and patient compliance are given significant weight when designing dose forms. New and developing technology can be used to produce durable, adaptable tablets with exceptional flavor masking and controlled release. Orally disintegrating tablets (ODTs) are solid dosage forms that disintegrate in the mouth in less than 60 s, and are thus swallowed without the need for water. Rapid disintegration of tablet cause quick dissolution thus rapid onset of action. Polyherbal Fast dissolving Tablets disintegrates in mouth quickly and produces fast onset of action without use of water makes it suitable for special population like pediatrics, geriatrics, psychotic, dysphasic, bedridden patient and frequent traveller patient.

The current review article explains the features of active ingredients and excipient used in the formulation of ODTs, discusses multiple ODT formulation and preparation techniques with their merits and demerits, and also, offers remedies for problems associated with ODTs. Moreover, quality control steps and required considerations are presented.

**Keywords:** FDT; Techniques; Super-disintegrants; Evaluation parameters

### 1. Introduction

The most common route of administering drugs for disease is orally. Tablets are among the most extensively used form of medication due to its ease of administration, compactness, and ease of manufacture. However, elderly and pediatric patients struggle with swallowing traditional tablets, resulting in poor compliance among patients. To address this shortcoming, researchers created novel medication delivery devices known as "melt in mouth" or "a mouth dissolving (MD)" tablets. These are unique pills that disintegrate/dissolve/disperse in saliva. Their special benefits, such as being able to administer them absent the use of water, anyplace and at any moment, make them ideal for geriatric and pediatric patients. They are further appropriate for the mentally sick, the confined to a and people who do not have simple access to water. The advantages of compliance among patients, fast start of action, enhanced its bioavailability and excellent consistency makes the tablets acceptable as a dosage form preferred in the present marketplace. [1, 2, 3, 4]

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Hyperglycemia is treated using a variety of synthetic medicines. Synthetic medications can cause hyperglycemia at greater amounts, dermatology actions, liver issues, vomiting, nausea, generalized hypersensitivity responses, lactic acidosis, and diarrhoea, among other side effects. These diabetes medications also promote weight gain, which may hasten the progression of type 2 diabetes. Secondary consequences from the use of synthetic medications limit their usage and may provide problems in managing the symptoms of diabetes [5]. As a result, there's an imperative to create secure and cost-effective alternate diabetes therapies. As a result of their organic origins and lower side impacts, therapeutic plants are gaining popularity. The World Health Organization also promoted and endorsed the use of medicinal products, particularly in nations where modern diabetes therapies are unavailable. When contrasted with polyherbal compositions that comprise combinations of different plants, the pharmacological action of a single plant is lower. Polyherbal compositions provide more effective synergistic responses while also lowering the amounts of individual plants, so decreasing unwanted effects. [6]

Ayurveda meaning the "science of life and longevity" in ancient Sanskrit, is a therapeutic method that involves lifestyle, diet, and plants. Herbal remedies and minerals have been employed in one form or another for tens of thousands of centuries under indigenous traditions of digamous medicine such as the traditions of Ayurveda, Siddha, and Unani, in addition to natural items utilization of their pharmacological activities. ayurveda specialists prescribe many ayurveda powdered made by ayurvedic firms. [7]

Standardization refers to the process for developing guidelines for evaluating the quality as well as security of crude drugs. Herbal medications are examined using pharmacopeial and internal criteria. The FT-IR spectrum research was used for assessing the drug's acceptability with the excipient; this investigation was carried out to detect any modifications in the chemical makeup of the medication after mixing using the excipient. [8,9]

Most patients, particularly the elderly, have trouble swallowing medications such as capsules and tablets, resulting in a high incidence of non-compliance and inefficient medication. Compliance-oriented study has led in the development of numerous safer and newer drug delivery systems. Fast dispersing tablet are one example of rapid deconstruction or dissolve in the mouth using a small amount of liquid or even saliva.

Disintegrants, which may disintegrate more quickly, are included to a medicine composition to improve tablet dissolving. [10]

### **1.1. Criteria for Fast dissolving Drug Delivery System**

- The tablets should not require water to swallow, but rather break down or disintegrate in your mouth in a couple of seconds.
- Be compatible with taste masking.
- Be transportable without fear of breaking.
- Have a pleasing mouthfeel.
- After consumption, the drugs leave little to no residual in the mouth.
- Displays little sensitivity to external conditions such as moisture and temperature.
- Allow for the low-cost production of tablets utilizing normal manufacturing and shipping equipment. [11]

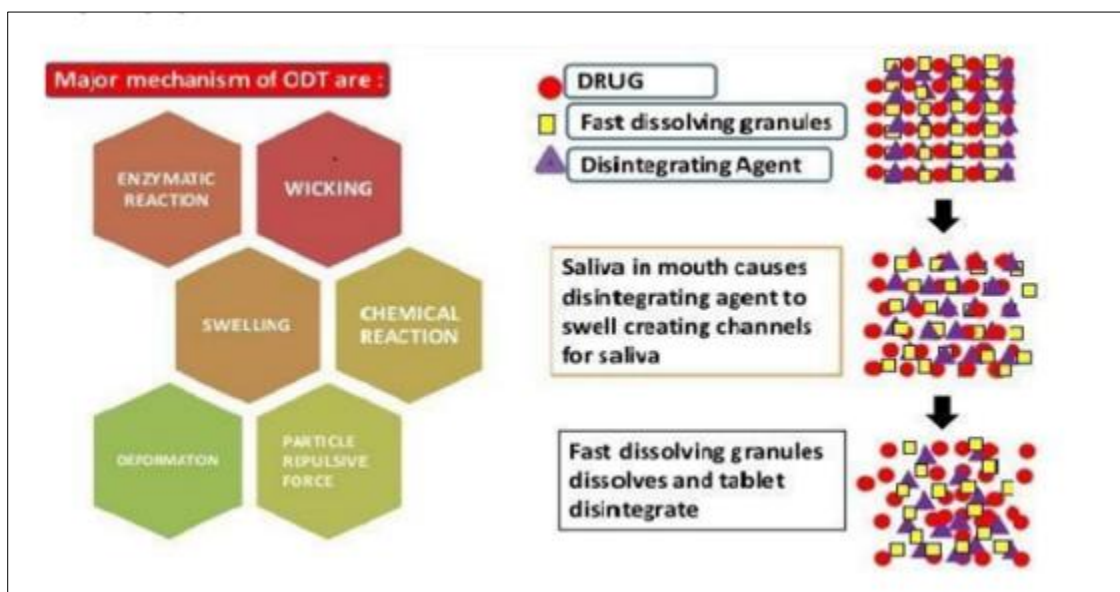
### **1.2. Salient features of Polyherbal FDT**

- The ease to take for patients who cannot swallow, including elderly people, stroke victims, bedridden patients, kidney disease patients, and those who fail to swallow, such as paediatric, elderly, and mental health patients.
- There is not a requirement for water to consume the dosage form, which is a very useful feature for people who are travelling and do not have easy availability of water.
- Rapid dissolving and administration of the medicine, resulting in a fast commencement of effect.
- As saliva flows down into the gastrointestinal tract, some medications are absorbed from the mouth, throat, and esophagus. In such circumstances, the drug's solubility is boosted.
- Pregastric digestion may result in increased absorption and lower dose.
- Enhance the clinical outcome by reducing side effects.
- The favorable tongue feel characteristic helps to transform what people think of medicine as a bitter pill, especially in pediatric patients. The risk of choking or suffocation during oral administration of conventional formulations due to physical impediment is reduced, giving increased safety. New business opportunity like product differentiation, product promotion, patent extensions and life cycle management.
- Beneficial in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra-rapid on set of action required.

- An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
- Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability. [12,13,14]

### 1.3. Drug Selection Criteria of FDTs

- Able to saturate the oral mucosa.
- Have the ability to diffuse and partition into the epithelium of upper GIT.
- BCS class-II class drug is good candidate for FDTs.
- At least moderately non-ionized at oral cavity pH.
- Molecular weight below 500 Dalton.
- Low dose drugs mostly less than 50 mg.
- Should have good stability in saliva and water.
- Should have lower bio availability are good candidates for FDTs.
- Short half-life and frequent dosing drugs are unsuitable for FDTs.
- Very bitter taste and undesirable odor drugs are unsuitable for FDT. [15]



Fast dissolving tablets also known as orodispersible tablets. Dissolution of tablet occur in presence of saliva (enzyme action) saliva in mouth causes superdisintegrants (swelling, wicking, deformation) to create channels for saliva penetration in tablet which leads to dissolution of tablet without use of water.

**Figure 1** Mechanism of fast dissolving tablet [16]

### 1.4. Benefits of Polyherbal fast dissolving tablets

- Administered without water, anywhere, any time.
- Suitability for geriatric and pediatric patients, who experience difficulties in swallowing and for the other groups that may experience problems using conventional oral dosage form, due to being mentally ill, the developmentally disabled and the patients who are un-cooperative, or are on reduced liquid intake plans or are nauseated.
- Beneficial in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra rapid onset of action required.
- An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
- Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability. [17]

### 1.5. Limitations of Fast Dissolving Tablets [18]

- The tablets usually have insufficient mechanical strength. Hence, careful handling is required.
- The tablets may leave unpleasant taste and/or grittiness in mouth if not formulated properly.

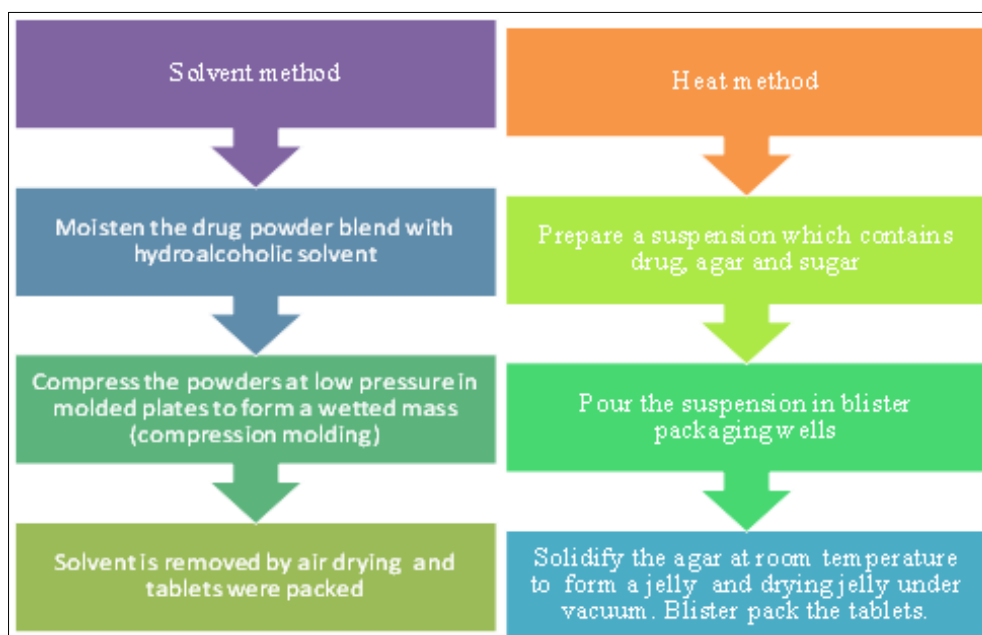
## 2. Technique for preparing fast dissolving tablets

- Freeze drying / lyophilization
- Tablet Moulding
- Spray drying
- Sublimation
- Direct compression
- Mass extrusion

### 2.1. Freeze drying / lyophilization

The method of freeze-drying is used to enhance the dissolution rate and bioavailability in the mouth of medications that have little solubility but a high permeability (biopharmaceutical system of classification Class II pharmaceuticals). Freeze drying (Lyophilization) is the method of removing water from an item after it has been frozen. The procedure can be carried out in a variety of ways to generate the same end product, for example, 1) the drug is physically encased in a soluble in water matrix (a water-soluble combination of sugars and polymers formulated to provide rapid distribution and physical strength), which is Freezing dried to produce a product that dissolves quickly when put into the oral cavity. These formulations need a chemically inert and insoluble in water medication with a single particle size of less than 50 m. Development of porous solids that are produced through freezing aqueous dispersion or solution with an active-containing matrices and eliminating water from it with a large amount of alcohol (solvent extraction), with the benefit that thermolabile drugs may be developed at non-elevated temperatures, thus preventing adverse thermal effects, and kept in a dry state with few shelf-life equilibrium problems;[19] A solid form lyophilized oil-in-water emulsion (porous solid galenic form) is deposited immediately in the blister alveolus.[20] The fundamental problem of these dosage forms is that, in addition to the high cost of manufacturing, they are unavailable.[21]

### 2.2. Tablet Moulding



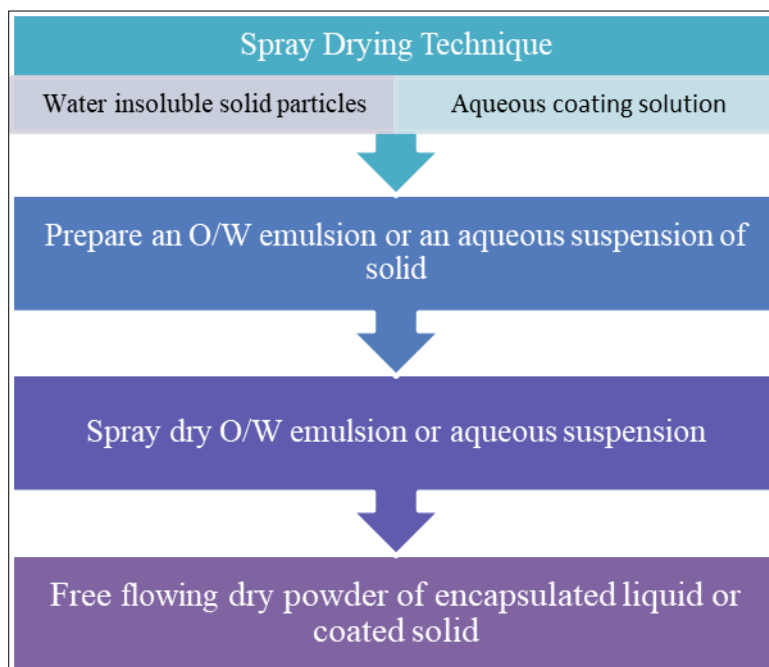
**Figure 2** Tablet molding [24]

Compression moulding is a method of producing tablets using soluble materials such as sugars by compressed a powder combination previously soaked with solvent (typically ethanol or water) into mould plates to generate a wetted mass.[22] Because moulded tablets are constructed of water-soluble carbohydrates, they disintegrate faster and have a better taste. Moulded tablets disintegrate faster and taste better because the dispersion matrix is formed of water-

soluble carbohydrates. When porous tablets or parts that have been physically transformed by the method of moulding are employed, these qualities are improved. In comparison to the lyophilization procedure, tablets manufactured via moulding technique are easier to scale up to an industrial scale. RDT produced by the lyophilization and moulding processes dissolve in about 30 seconds but have poor physical resistance and high friability. Direct compression tablets, on the other hand, are less friable yet degrade over a longer period of time. [23].

### 2.3. Spray drying

The microspheres were prepared by drying with spray. Spray drying is commonly employed in pharmaceutical manufacturing because it is a single-step procedure that is easy to regulate and scale up. Spray drying is common in the pharmaceutical and biochemical industries, and the final size of the particles can be controlled by a number of variables, such as the size of the nozzle utilized during the procedure. [16]



**Figure 3** Spray drying Technique

### 2.4. Sublimation

To create a porous matrix, volatile chemicals are added to the formulation, which is then sublimated. Extremely volatile substances such as ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, naphthalene, urea, urethane, and phthalic anhydride may be compacted into a tablet along with other excipients. This volatile substance is subsequently removed by sublimation, which leaving behind a very porous matrix. This approach has been claimed to produce tablets that disintegrate in 10-20 seconds. Strong solvents like as cyclohexane and benzene can be utilised as pore generating agents. [17,18]

### 2.5. Direct compression

Compression directly is the most basic and inexpensive tablet manufacturing method for Fast dissolving Tablets (FDT) because it can be done with standard tablet manufacturing and packaging machinery, as well as because tablet excipients with improved flow, elasticity, and disintegration real estate are available. [19,20]

### 2.6. Mass extrusion

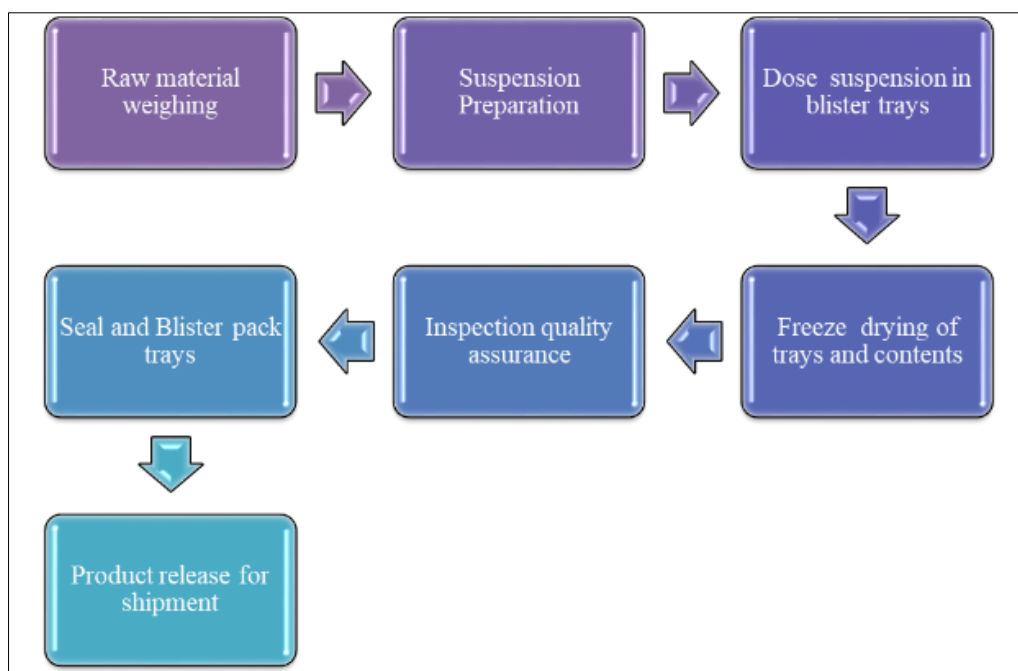
This process comprises relaxing the active mixture with a combination of solvents of soluble in water polyethylene glycol & methanol, followed by expulsion of the softened material through an extruder or syringe to create a cylinder of the product into even segments using a sharpened blade to make a tablet. The dried cylinder can also be utilized to coat particles for unpleasant medications, resulting in flavor masking. [21]

### 3. Important Patented Technologies for Fast Dissolving Tablets

#### 3.1. Zydis Technology

Zydis formulations is a one-of-a-kind freezer dried tablets in which the medicine is mechanically trapped or absorbed within a matrix of rapid dissolving carrier materials. When zydis units are placed in the mouth, the freeze-dried structure disintegrates instantly and doesn't need water to facilitate digestion. The zydis matrix is made up of various materials that work together to achieve a variety of goals. Polymers like gelatin, dextran, and alginates, or are used to add strength and resilience during handle. These combine to form a shiny crystalline structure that adds rigidity.

The sugars like mannitol or sorbitol are used to achieve crystallization, beauty, and toughness. Water is employed in the production procedure to assure the development of porous units for quick disintegration, while different gums are utilized to avoid the sedimentation of dispersed drugs in the process of production. Collapse protectants, such as glycine, prevent zydis units from shrinking during the freeze-drying process or long-term storage. Zydis medicines are packaged in blister packs to preserve their contents from moisture in the atmosphere.



**Figure 4** Zydis Tablet Manufacturing Process [22,23]

#### 3.2. Durasolv Technology

CIMA labs' distinctive equipment is called Durasolv. This method creates tablets that contain a medication, a filler, and a substance that lubricates them. Tablets are made with traditional machinery and have a high degree of stiffness.

These can be put in traditional packaging techniques such as blisters. Durasolv is a suitable method for products that require a little quantity of active chemicals.[24]

#### 3.3. Orasolv Technology

Orasolv Technologies was created by CIMA labs. The active medication is taste-hidden in this method. It also includes an explosive disintegration agent. To reduce oral dissolving time, tablets are produced using a direct compressive method with a low compressive force. The tablets are made using traditional blenders and tablet machines. The tablets formed are flexible and friable.[25]

### 3.4. Flash Dose Technology

fuisz is patenting flash dosage technique. Nurofen meltlet, an innovative version of ibuprofen as dissolve in oral tablets created with flash dosage technology, is biovail corporation's first market item. The self-binding shearing form matrix known as "floss" is used in flash dosage tablets. Flash heating is used to make shear form matrix.[26]

### 3.5. Wow tab Technology

Yamanouchi Pharmaceutical Co. is patenting Wow tab technology. WOW is an abbreviation for "Without Water." A mix of low mouldability sugars and high mouldability sugars is utilised in this procedure to create a quickly melting robust tablet. The active component is combined with a low mouldability saccharide (such as lactose, glucose, and mannitol) and granulated with an elevated mouldability oligosaccharide. (eg. Maltose, oligosaccharides) and compressed into tablet.[27]

### 3.6. Flash tab Technology

The Flash tab technology has been patented by Prographarm laboratories. This technology produces tablets with an active component in the form of micro crystals. Traditional procedures such as coacervation, micro encapsulation, and extrusion spheronisation can be used to create drug micro granule. All of the work was done using traditional tableting techniques.[28]

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## 4. Challenges in formulating FDTs: [29,30,31,32,33,34]

- **Palatability:** Most dissolved oral drug delivery methods disintegrate or dissolve in the mouth and throat of the patient, producing active chemicals that come into touch with the taste buds; consequently, flavor-masking of the medications becomes crucial to compliance among patients.
- **Mechanical strength:** To allow FDTs to break down in the oral cavity, they are constructed with a very small compression forces, resulting in the tablets friable and/or brittle, hard to handle, and frequently needing specialized peel-off blister wrapping, which may raise the cost. Only a few methods, such as Wowtab® by Yamanouchi the company Shaklee and Durasolv® by CIMA labs, can make tablets which are hard and robust enough to be put in multidose containers.
- **Hygroscopicity:** Many FDTs are hydrophilic and are unable to maintain their structural integrity in typical humidity and temperature settings. As a result, they require humidity protection, which necessitates specialized packaging for the goods.
- **Amount of drug:** For freeze-dried dosage forms, the drug dose must be lower than four thousand mg for insoluble medications and less than sixty mg for soluble drugs.
- **Aqueous solubility:** Water-soluble medications combine to generate eutectic compounds, which induce a decrease in the freezing point and the production of a glass solid, which may collapse upon drying due to loss of supporting structure during the process of sublimation.
- **Size of tablet:** It was previously stated that the simplest size of tablet to swallow is 7-8 mm, whereas the simplest size to handle is greater than 8 mm. As a result, it is challenging to obtain a tablet size that is both portable and manageable.
- **Superdisintegrants:** "Super disintegrants" are more efficient at lower concentration levels, with better disintegration effectiveness and mechanical durability. When super disintegrants come into interaction with water, they expand, hydrate, alter volume, or shape, causing an adverse effect in the tablet. Efficient super disintegrants enhance compression and compatibility while having no negative influence on the rigidity of compositions containing high-dose medicines. Super disintegrating agents outperform starch. [34]

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## 5. Mechanism of super disintegrants [35,36,37]

- **Swelling:** While not all efficient disintegrants swell when exposed to water, swell is thought to be a process by which some disintegrating substances (such as starch) give the disintegrating action. The adhesiveness of other compounds in a tablet is overcome by expansion in contact with water, causing the tablet to fall apart.
- **Porosity and Capillary Action (Wicking):** Efficient disintegrants which have no swelling are thought to disintegrate through permeability and capillary contraction. Fluid absorption into tablet is facilitated by tablet permeability. The disintegrant granules themselves (with low cohesion and compressibility) work to increase porosity and give these paths into the tablet. Through the process of capillary action, liquid is drawn up or "wicked" into these routes, rupturing the interparticle connections and causing the tablet to break apart.

- **Deformation:** Starch granules are typically regarded to be "elastic" in the natural world, which means that granules that are distorted when compressed will revert to their original form once the stress is released. However, due to the pressures of compression that occur during tableting, these particles are thought to be significantly damaged and have been described as "energy rich," with the energy leaking out upon exposure to water. In this case, the potential of starch grains to swell is greater in "energy rich" starch granules than in starch granules that have not been distorted under pressure. Most disintegrants are thought to work through many mechanisms. However, it is most likely the outcome of interactions between these primary systems.
- **Due to disintegrating particle/particle repulsive forces:** This disintegration process tries to clarify why tablets constructed with 'nonswellable' disintegrants expand. Guyot-Hermann presented the particle repulsion hypothesis based on his discovery that non swelling particles also induce tablet disintegration. The disintegration mechanism is the electric repulsive interactions between particles, and water must exist for it. The investigators discovered that repel comes second to washing.

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## 6. Evaluation Parameters of Polyherbal Tablets: [38,39,40,41,42,43,]

### 6.1. Precompression parameters

Before compression of powders in the form of tablets some precompression test of powders were performed such as Angle of repose, Bulk density, Tapped density, Compressibility index, Hausner's ratio.

### 6.2. Postcompression tests

After compression checks are carried out on the completed FDTs. Weight fluctuations, dissolving tests, wetting time, moisture uptake, water-absorption ratio, friability, hardness, weight, in-vivo and in-vitro disintegration time, thickness, and flavour assessment are examples of such testing .

#### 6.2.1. Weight variation method

The weight variation value is determined using the United States Patent procedure for both disintegration of tablets and FDTs. The weight of just one pill is calculated using Twenty tablets. The norm and comparative deviation values are calculated and calculated independently for each of the Twenty tablets. To be utilised efficiently by children, FDTs must be lighter than FDTs. The FDT weight variance values for paediatric uses, in specific, should be computed.

#### 6.2.2. Hardness

Hardness can be described as the force generated to the tablet's width. The hardness value of each tablet is determined via measurement of the standard deviation value. The thickness ranges from Tablet thickness are important because it affects the display and packing of tablets. According to statistics, the size of a total of 20 tablets is measured and analyzed.

#### 6.2.3. Friability

The total amount of pills determined is then weighed (initial weight) and loaded in a friabilator. The tablets have been rotated for 4 minutes at 25 rpm in the friabilator. The reduction in weight of tablets is calculated using friction and is displayed as a % . After the test, the tablets are weighed again. 'Value must be less than 1%', according to USP.

$$\text{Friability} = \frac{\text{initial weight} - \text{final weight}}{\text{initial weight}} \times 100$$

#### 6.2.4. Dissolution test

USP equipment one or two can be used for FDT dissolution investigations. If a tablets-forming portion is employed, Instrument 1 will bind the pores on the tablet as well as produce certain dissolution profile errors. This is why the paddle-based approach, also known as equipment 2, is extensively employed for FDT dissolution testing. The spin speed for masked FDT formulas can be up to 100 rpm.

Analytical techniques such as ultraviolet spectroscopy and liquid chromatography under high pressure are commonly used to determine the amount of soluble active ingredient. In accordance to the FDA, in DT products, at least 85% of the active ingredient should be absorbed within 30 minutes.



### 6.2.5. Wetting time

Wetting time indicates the internal construction of the tablet & the hydrophilic nature of the excipients. As a result, the angle of contact influences the wetting time of a dosage form. Tablets disintegrate faster with a shorter soaking time. The wetting time is determined by placing five circular paper towels 10 cm in diameter in a Petri dish 10 cm in diameter. In the Petri dish, 10 milliliters of water-soluble dye solution, such as eosin, is added. The tablet is gently placed on the surface of a tissue paper. The wetness time is the time it takes for water to get to the upper surface of the tablet. The weight of the pill before it is placed in the Petri dish is recorded ( $W_b$ ) to calculate the water-absorption ratio. The wetted tablet from the Petri plate is removed and reweighed ( $W_a$ ).  $R$ , the water-absorption ratio, can be calculated using the following equation:

### 6.2.6. Moisture-uptake studies

Moisture-uptake tests are performed to determine the device's stability. 10 pills have been stored in desiccators over  $CaCl_2$  for 24 hours at 37°C. The tablet forms were then weighed exposed to 75% percent humidity at ambient temperature for a period of two weeks. For three days, a saturated sodium chloride solution was set at the bottom of the desiccators to generate the needed humidity. One tablet was used as a baseline (without a super disintegrant) to measure moisture uptake caused by various excipients in Tabs were weighed, and the % increase in weight were noted.

## 6.3. Future Trends

Each FDT technology has its own advantages and disadvantages but common to all are their rapid disintegration and convenience of dosing to patients. Special *in vitro* and *in vivo* test methods to study the performance of these products are required. Although FDT technology and products face many challenges as they are fairly new in the marketplace, these technologies are rapidly evolving and continue to undergo improvement which will address the future challenges and changing patient and healthcare needs. Overall, FDT products have enormous commercial potential, which will be realized in the next decade as more effective FDT products are being developed to address the unmet needs of the patients.

Natural blend of pharmacologically active herbs shows promising action in improvement of activity following its formulation in FDTs carries high potential towards clinical translation.

### List of abbreviation

- FDT: Fast Dissolving Tablet.
- USP: United State Pharmacopoeia
- FDA: Food and Drug Administration
- DT: Dispersible Tablets
- rpm: revolution per minute
- mm: millimeter

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## 7. Conclusion

The FDT dosage forms are ideal for many groups of patients including geriatrics, pediatrics, and those people who have difficulty swallowing. An important benefit of FDT dosage forms is the ability to provide the advantages of a liquid medication in the form of a solid preparation. This feature enables the patient to take the dose as directed at any time without water and inconvenience. There is clear medical need and clinical benefits provided by these technologies and products.

Herbal fast dissolving tablets shows good disintegration property and dissolution rate.

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## Compliance with ethical standards

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### *Disclosure of conflict of interest*

Authors don't have any competing interest We wish to confirm that there are no known conflicts of interest associated with this publication

### *Statement of Ethical approval*

We confirm that the manuscript has been read and approved by all named authors and that there are no other persons who satisfied the criteria for authorship but are not listed. We confirm that the manuscript has been read and approved by all named authors and that there are no other persons who satisfied the criteria for authorship but are not listed. We further confirm that the order of authors listed in the manuscript has been approved by all of us.

### *Statement of Informed consent*

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### *Availability of data and material*

It is review article so content of this manuscript is based on thorough study of other research and review article.

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### *Author's contribution*

Content in manuscript has been drafted by Krishna after literature review and the article has been read and suggestion for correction in manuscript by Co-authors. All authors read and approved for final submission of manuscript.

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