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Fast Disolving Tablet Drug Delivery System- A Review

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Abstract

Fast dissolving tablets (FDTs) have revolutionized the pharmaceutical industry as a promising drug delivery system due to their ability to improve patient compliance. FDTs are designed to dissolve rapidly in the oral cavity without the need for water, making them ideal for patients with swallowing difficulties or on-the-go medication administration. They offer a rapid onset of action due to absorption in the pre-gastric area, leading to improved bioavailability. FDTs have advantages such as ease of administration, accurate dosing, improved patient compliance, and rapid onset of action, but also have disadvantages such as taste-masking issues and stability concerns. FDTs are prepared using two technologies: conventional technology and patented technology. Conventional technology includes freeze-drying or lyophilization, sublimation, spray drying, tablet molding, mass extrusion, direct compression, cotton-candy process, nanotization, fast dissolving films, and melt granulation. These techniques can be evaluated using various parameters such as shape, size, thickness, diameter, weight variation, friability, wetting time, hardness of tablet, in vitro/vivo disintegration time, dissolution test, stability study, and drug content.

Introduction

Tablet is one of the most commonly used oral dosage forms in medicine due to its wide acceptance, convenience in self-administration, compactness, and ease of manufacturing. However, conventional tablets have certain drawbacks, particularly for specific patient populations such as geriatric, pediatric, dysphasic, and mentally ill patients who may have difficulty swallowing or chewing. This can lead to issues with patient compliance. To address these challenges, scientists have developed an innovative and efficient drug delivery system known as fast dissolving tablets (FDTs)[1]. Fast dissolving tablets, also known as mouth dissolving tablets, rapid-dissolve tablets, rapimelt, fast melts, porous tablets, EFVDAS (Effervescent Drug Absorption System), Orosolv, Zydis, and others, are a novel type of drug delivery system that disintegrates or dissolves within a few seconds when placed under the tongue, without the need for water. According to the European Pharmacopoeia, these tablets should dissolve, disintegrate, or disperse in no less than three minutes. This formulation is particularly useful for bedridden patients and those who have difficulty swallowing conventional tablets or other medications[2]. The primary aim of fast dissolving tablets (FDTs) is to improve patient compliance by providing a dosage form that is easy to administer. FDTs offer several advantages, including rapid onset of action, increased drug bioavailability, improved stability, and the potential to become a popular choice in the current market[3].

Ideal properties of fast dissolving tablet[4]

The development of fast dissolving tablets (FDTs) involves several key considerations to ensure their effectiveness and patient acceptability. The following points discuss these considerations in detail:

1. Rapid Dissolution or Disintegration: FDTs should dissolve or disintegrate in the mouth within a few seconds upon contact with saliva. This property allows for easy administration, especially for patients who have difficulty swallowing conventional tablets.
2. No External Item Requirement: FDTs should not require the use of water or any other external item to facilitate their action. This characteristic enhances convenience and portability, making FDTs suitable for on-the-go administration.
3. Taste Masking and Pleasant Mouth Smell: FDTs should be compatible with taste masking techniques to mask the inherent bitterness or unpleasant taste of certain drugs. Additionally, they should possess a pleasing mouth smell to enhance patient acceptance.
4. Portability and Fragility Concerns: FDTs should be portable without concerns of fragility. This ensures that the tablets can be carried conveniently without the risk of breakage or damage during transportation.
5. High Wettability and Porous Network: The excipients used in FDT formulations should possess high wettability, allowing rapid wetting and subsequent disintegration upon contact with saliva. Furthermore, the tablet structure should have a porous network to facilitate rapid dissolution and drug release.
6. No Residues in the Mouth: After administration of the FDT, it should not leave any residues in the mouth. This characteristic enhances patient comfort and eliminates the unpleasant sensation of having residual tablet particles in the oral cavity.
7. Minimal Impact of Environmental Conditions: FDTs should be minimally affected by environmental conditions such as temperature and humidity. This ensures their stability and performance under various storage and usage conditions.
8. Rapid Drug Absorption: FDTs should enable rapid drug absorption from the pre-gastric area, leading to a rapid onset of action. This property is desirable for drugs that require quick therapeutic effects.
9. Sufficient Strength: FDTs should possess sufficient mechanical strength to withstand the rigors of the manufacturing process and subsequent handling. This ensures that the tablets maintain their integrity throughout production, packaging, and distribution.
10. High Drug Loading: FDTs should have the capability to accommodate a high drug loading. This allows for the delivery of an adequate therapeutic dose within a single tablet, reducing the need for multiple tablets or higher tablet volumes.

These considerations play a crucial role in the successful development of FDTs, ensuring their effectiveness, patient acceptability, and convenience. By addressing these factors, pharmaceutical scientists can design optimized FDT formulations that meet the specific requirements of various drugs and patient populations.

Advantages of Fast Dissolving Tablets[5]

Fast dissolving tablets (FDTs) have gained considerable attention in the pharmaceutical industry due to their numerous advantages over conventional tablets. The following advantages highlight the significance of FDTs in enhancing patient compliance, addressing specific patient populations, and improving drug delivery:

Improved Patient Compliance:

Patient compliance refers to the extent to which patients adhere to their prescribed medication regimen. FDTs offer a significant advantage in improving patient compliance due to their ease of administration. These tablets rapidly disintegrate or dissolve in the oral cavity without the need for water, making them convenient and easy to take. The elimination of the need for water or swallowing aids simplifies the administration process, particularly for patients with swallowing difficulties, pediatric patients, geriatric patients, and psychiatric patients.

Suitable for Specific Patient Populations:

FDTs are particularly useful for specific patient populations, such as pediatric, geriatric, and psychiatric patients. Pediatric patients often face challenges in swallowing conventional tablets, and FDTs provide a viable solution by offering a dosage form that can dissolve easily in the mouth. Similarly, geriatric patients may experience difficulties in swallowing due to age-related factors, making FDTs a preferable alternative. Psychiatric patients may also benefit from FDTs as they provide a non-invasive and easy-to-administer dosage form.

Rapid Onset of Action and Improved Bioavailability:

One of the key advantages of FDTs is their rapid onset of action. As these tablets dissolve or disintegrate quickly in the oral cavity, the drug is readily available for absorption into the bloodstream. This rapid dissolution can lead to improved bioavailability, ensuring that a higher proportion of the drug reaches systemic circulation and exerts its therapeutic effects. Additionally, FDTs can enhance drug stability by minimizing exposure to environmental factors that may degrade the drug.

Ease of Administration for Swallowing-Impaired Patients:

Patients who have difficulty swallowing conventional tablets, such as those with dysphagia or other swallowing disorders, can benefit from FDTs. These tablets dissolve or disintegrate in the mouth without the need for water, allowing patients to easily administer their medication. By eliminating the discomfort and potential choking hazards associated with swallowing large tablets, FDTs improve medication adherence among this patient population.

Convenience during Travel or Water-Scarce Environments:

FDTs offer convenience during travel or in situations where access to water is limited or not readily available. As these tablets dissolve without the need for water, patients can take their medication anytime and anywhere. This advantage is particularly valuable for individuals on-the-go or in situations where carrying water may be inconvenient or impractical.

Good Chemical Stability and Taste:

FDTs are formulated to provide good chemical stability, ensuring that the active pharmaceutical ingredient (API) remains intact throughout the shelf life of the tablet. Additionally, manufacturers often incorporate taste-masking techniques to improve the palatability of FDTs. This helps overcome any unpleasant taste associated with certain medications, enhancing patient acceptance and compliance.

Elimination of Measuring Required for Liquid Dosage Forms:

Liquid dosage forms often require precise measurement using measuring devices, which can be cumbersome and prone to errors. FDTs eliminate the need for measuring, simplifying the dosing process and reducing the risk of dosage errors.

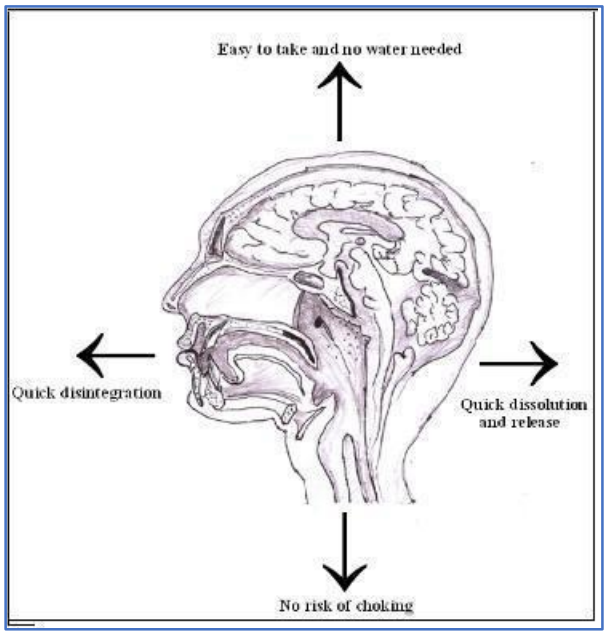


Fig 1: Diagram shows advantage of FDT

Disadvantages of fast dissolving tablets[6,7]

1) Fast dissolving tablets are hygroscopic in nature, requiring storage in a dry place to prevent moisture absorption.

2) Some individuals may experience an unpleasant mouth-feel when consuming fast dissolving tablets.

3) Fast dissolving tablets can be fragile and exhibit effervescent granule properties, which may affect their physical integrity.

4) Special packaging is necessary for fast dissolving tablets to ensure proper stabilization and safety of the product.

Salient feature of fast dissolving drug delivery system[8,9]

Fast dissolving drug delivery systems have several salient features that make them a promising alternative to conventional tablets. These features include:

1. Ease of administration: Fast dissolving drug delivery systems are particularly suitable for patients who have difficulty swallowing conventional tablets, such as the elderly, children, and patients with dysphagia.
2. No need for water: Unlike conventional tablets, fast dissolving drug delivery systems do not require water to be swallowed, making them a convenient option for patients on-the-go.
3. Rapid dissolution and absorption: Fast dissolving drug delivery systems are designed to rapidly dissolve or disintegrate in the mouth, leading to rapid absorption of the drug and quick onset of action. In such cases bioavailability of drug is increased and improves clinical performance through a reduction of unwanted effects.
4. Pre-gastric absorption of fast dissolving tablets can lead to improved bioavailability, allowing for reduced dosage and potentially enhancing clinical performance by minimizing unwanted side effects.
5. The risk of choking or suffocation during oral administration is eliminated with fast dissolving tablets, ensuring improved safety compared to conventional formulations.
6. Fast dissolving tablets present new business opportunities, including product differentiation, promotion, patent extensions, and life cycle management.
7. Fast dissolving tablets are particularly beneficial in cases where an ultra-rapid onset of action is required, such as in motion sickness, sudden allergic episodes, or coughing.

8. Fast dissolving tablets offer stability for a longer duration since the drug remains in solid dosage form until consumed. This combines the advantages of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability.
9. The good mouthfeel and palatability of fast dissolving tablets can change the perception of medication as a "bitter pill," especially for pediatric patients.
10. Fast dissolving tablets allow for high drug loading, enabling the delivery of a larger amount of medication in a single dose.
11. Fast dissolving tablets are cost-effective compared to other dosage forms, making them a viable option for pharmaceutical companies and patients alike.

Technology used in preparations of fast dissolving tablet:

Fast dissolving tablets (FDTs) are formulated using various techniques, including the use of super disintegrants such as cross carmellose sodium, sodium starch glycolate, and crosspovidone. These disintegrants help in rapid disintegration of the tablet in the oral cavity. Another method used for FDT preparation is maximizing the pore structure of the tablets by freeze drying and vacuum drying. These techniques create a porous structure that enhances the tablet's disintegration and dissolution properties.

FDTs offer several advantages over conventional tablets, such as improved bioavailability due to absorption of drugs in the oral cavity and pre-gastric absorption of saliva containing dispersed drugs that pass down into the stomach. Moreover, FDTs reduce the amount of drug subjected to first-pass metabolism as compared to standard tablets.

In recent years, some advancements have been made in the field of FDTs by considering their ideal properties. However, the technologies used for manufacturing FDTs can be broadly classified into two categories: conventional technology and patented technologies[10].

Conventional technology

Freeze drying or lycophylisation:

Freeze drying, also known as lyophilization, is a process that involves the sublimation of water from a product after freezing. This technique is used to prepare tablets with a highly porous open matrix network, allowing for rapid dissolution upon contact with saliva in the mouth. In addition to the active ingredients and matrix, freeze-dried formulations may include other excipients such as suspending agents, wetting agents, preservatives, antioxidants, colors, and flavors.

Ideal drug characteristics for freeze drying formulations include being water-insoluble, low-dose, chemically stable, having a small particle size, and being tasteless. One major advantage of freeze drying is that pharmaceutical substances can be processed at non-elevated temperatures, eliminating adverse thermal effects. However, there are some disadvantages to consider. The high cost of equipment and the time-consuming nature of the lyophilization process make it relatively expensive. The fragile nature of freeze-dried products can also pose challenges in terms of conventional packaging, and they may exhibit poor stability during storage under stressful conditions[11].

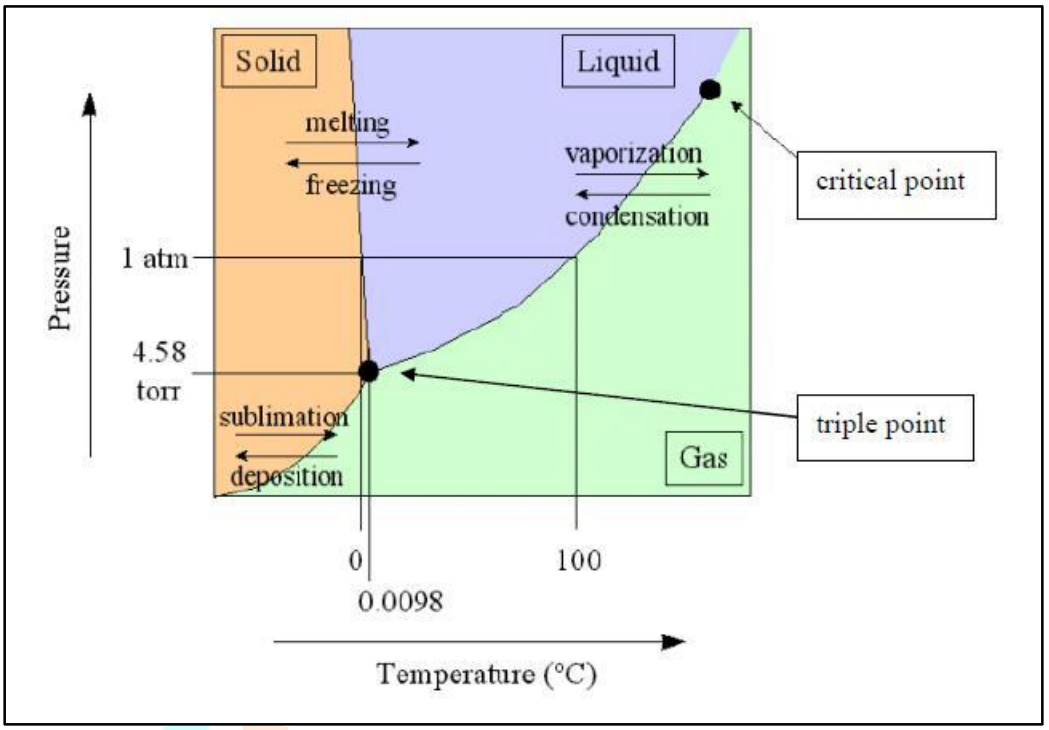


Fig 3: Graph of Freeze drying or lycophilisation

Sublimation:

One of the key factors for the rapid disintegration of fast dissolving tablets (FDTs) is the presence of a highly porous structure in the tablet matrix. However, conventional tablets with highly water-soluble ingredients often fail to disintegrate rapidly due to low porosity. To address this issue, volatile substances like camphor can be used in the tableting process, which sublimates from the formed tablet. Researchers have developed FDTs using camphor, a subliming material that is removed from compressed tablets prepared using a mixture of mannitol and camphor. After the preparation of tablets, camphor was sublimated in vacuum at 80°C for 30 minutes to improve the tablet's porosity[12].

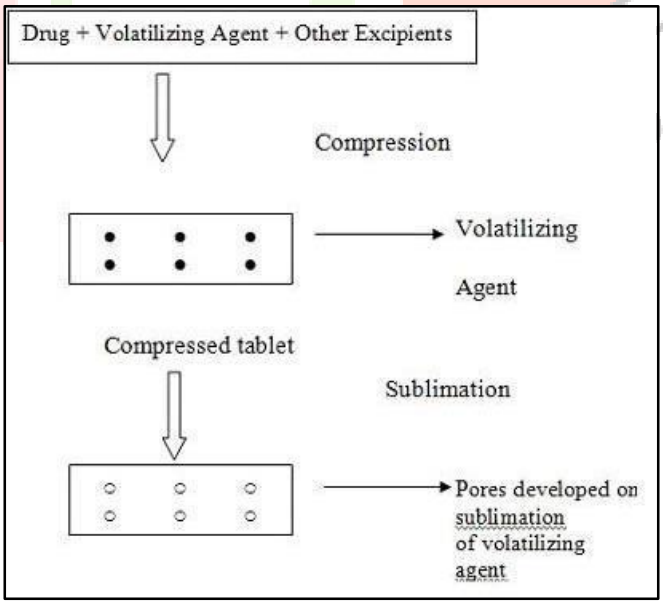


Fig 4: Step involved in sublimation

Spray drying method

The spray drying method is commonly used for the preparation of fast dissolving tablets. In this technique, hydrolyzed or non-hydrolyzed gelatins are used as supporting agents, while mannitol serves as the bulking agent. To promote disintegration and dissolution, disintegrating agents such as sodium starch glycolate or crosscarmellose sodium are incorporated. Additionally, the inclusion of acidic materials like citric acid or alkali materials like sodium bicarbonate can further enhance the disintegration and dissolution properties of the tablets.

One example of a fast dissolving tablet prepared using the spray drying method is Hyoscyamine Sulfate ODT. Another example is Resperidone, which is formulated as a fast dissolving tablet.

It is important to note that the characteristics of tablets prepared using the spray drying method include rapid disintegration within approximately 20 seconds when placed in an aqueous medium[13].

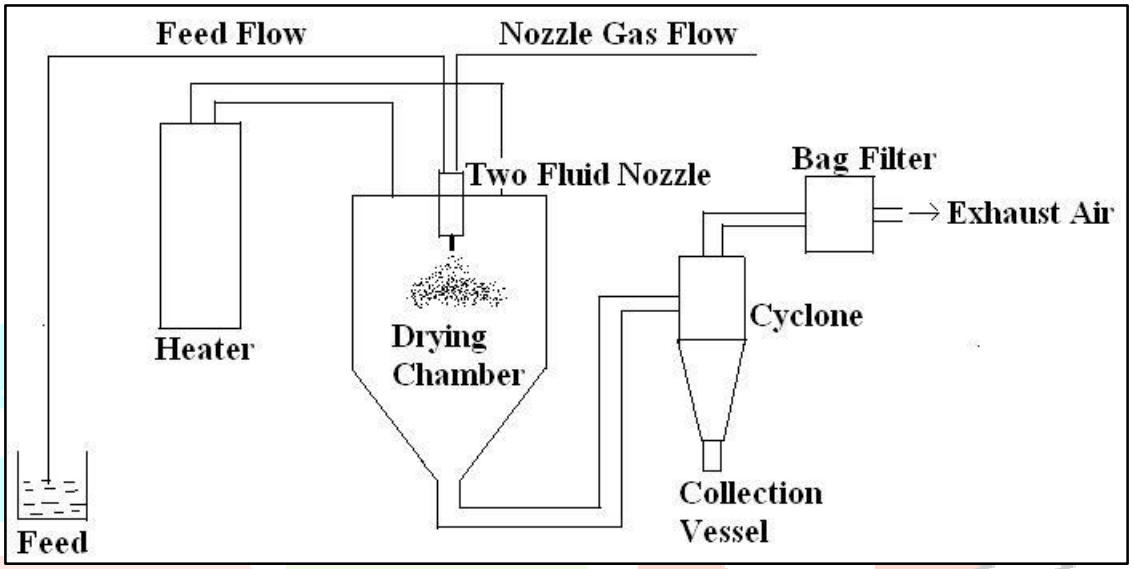


Fig 5: Spray drying method

Tablet moldings method:

Tablet molding method is a technique used to prepare tablets that dissolve or disintegrate rapidly and completely. Water-soluble ingredients are utilized in this method. The process involves moistening the powder with a hydro-alcoholic solvent and then molding it into tablets under low pressure compared to conventional dosage forms. The tablets are then air-dried to remove the solvents. It should be noted that the addition of substances like sucrose, acacia, or PVP K30 can enhance the mechanical strength of the tablet.

Advantages of tablet molding method include very rapid disintegration, typically taking 5-15 seconds. However, there are some disadvantages associated with this method, such as the requirement for high doses and the high cost of production. The mechanical strength of the tablets produced through this method is relatively weak, and there may be limitations in terms of stability.

Characteristics of molded tablets include their less compact nature compared to compressed tablets. This porous structure facilitates faster disintegration, dissolution, and ultimately, increased absorption of the active ingredients[14].

Mass extrusion

Mass extrusion is a manufacturing technique used to produce fast dissolving tablets. In this technique, a blend of active drug and other ingredients is softened using a solvent mixture of water-soluble polyethylene glycol and methanol. The softened mass is then extruded through an extruder or syringe to obtain a cylinder of product. The cylinder is finally cut into even segments with the help of heated blades to produce tablets.

One of the advantages of mass extrusion is that the dried cylinder can be used to coat granules of bitter-tasting drugs, thereby masking their bitter taste. This characteristic makes mass extrusion a suitable technique for developing fast dissolving tablets of drugs with unpleasant taste.

Examples of drugs that can be formulated using mass extrusion include Zolmitriptan, Clarithromycin, and Cefixime.

An example of drugs that can be formulated using the tablet molding method are Diclofenac and acetylsalicylic acid[15].

Direct compression[16]

Direct compression, also known as the disintegrant addition technology, is a highly preferred technique for manufacturing tablets. It offers several advantages:

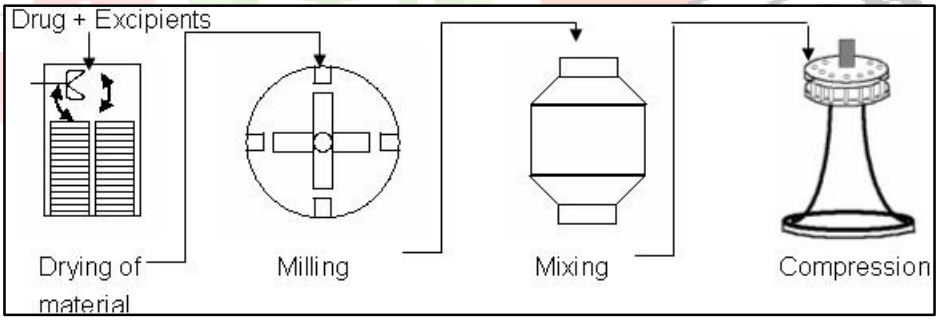
Accommodation of High Doses: Direct compression allows for the accommodation of high doses, and the final weight of the tablet can exceed that of other methods.

Ease of Manufacturing: It is the easiest way to manufacture Modified-Release (MDT) tablets.

Utilization of Conventional Equipment and Excipients: Direct compression utilizes conventional equipment and commonly available excipients, making it a convenient choice.

Limited Processing Steps: The manufacturing process involves a limited number of processing steps, simplifying the overall production.

Cost-Effectiveness: Direct compression is recognized as the most cost-effective tablet manufacturing technique.



Fast dissolving films:

Fast dissolving films are a promising drug delivery system that offers rapid drug release and improved patient compliance. These films are made by preparing a non-aqueous solution containing a water-soluble film-forming polymer such as pullulan, carboxymethylcellulose, hydroxypropyl methylcellulose, hydroxyl ethyl cellulose, hydroxyl propylcellulose, polyvinyl pyrrolidone, polyvinyl alcohol or sodium alginate, along with the drug and other taste masking ingredients. After solvent evaporation, a film is formed. For bitter drugs, resin adsorbate or coated micro particles of the drug can be incorporated into the film.

Fast dissolving films have several characteristics that make them an attractive option for drug delivery. These include their small size (less than 2x2 inches), rapid dissolution (within 5 seconds), instant drug delivery, and

flavored aftertaste. Overall, fast dissolving films offer a convenient and effective means of delivering drugs to patients[17].

Evaluation of fast dissolving tablet

General Appearance:

Tablet's visual identity and overall aesthetic appeal play a crucial role in its consumer acceptance. This includes factors such as the tablet's size, shape, color, surface texture, and any physical flaws. The presence or absence of an odor or taste can also impact the consumer's perception. Additionally, the legibility and consistency of any identifying markings are important factors to consider[18].

Size, Shape, Thickness and diameter

The dimensional description, monitoring, and control of the size and shape of tablets play a crucial role. The thickness of tablets holds significance not only in terms of appearance but also in the counting process using filling equipment. Certain filling equipment relies on the tablets' uniform thickness as a counting mechanism. To assess the thickness, ten tablets were selected, and their measurements were taken using a vernier caliper[19].

Weight variation

20 tablets were selected randomly from the lot and weighted individually to check for weight variation. Weight variation specification as per I.P.

Friability[20]

Friability is a test that evaluates the impact of friction and shocks on tablets, which can cause them to chip, crack or break. To conduct this test, a Roche friabilator device is used, which subjects a number of tablets to a combination of abrasion and shock. The device consists of a plastic chamber that rotates at 25 rpm and drops the tablets at a distance of 6 inches with each revolution. A pre-weighed sample of tablets is placed in the friabilator, which is then operated for 100 revolutions. After the test, the tablets are dusted and re-weighed. The compressed tablets should not lose more than 1% of their weight, which is expressed as a percentage using the following formula:

% Friability = (initial weight - final weight) / initial weight x 100

Wetting time

Wetting time is a crucial factor influenced by tablet structure and excipient hydrophilicity. Washburn E.W (1921) proposed an equation stating that the rate of water penetration into the powder bed is proportional to the pore radius and affected by powder hydrophilicity. The equation is as follows:

$dl/dt = r \Upsilon \cos\theta /(4\eta l)$

In the equation, l represents the penetration length, r is the capillary radius, Υ is the surface tension, η is the liquid viscosity, t is the time, and θ is the contact angle. It is evident that as compression force increases or porosity decreases, pore size reduces and wetting time increases. Wetting time exhibits a linear relationship with disintegration time, highlighting its significance in the disintegration process[21].

Hardness of tablet/ crushing strength

A significant advantage of orally disintegrating tablets (ODT) is their unique manufacturing process and specialized ingredients. The lower range of crushing strength for ODTs allows for quick disintegration in the mouth. The tablet's crushing strength can be measured using conventional hardness testers.

Dissolution test

For the dissolution test, the USP 2 Paddle apparatus was utilized with a paddle speed of 50 rpm, which is commonly used. The dissolution medium used was 900 ml of phosphate buffer (pH 6.8). Samples were withdrawn at proper intervals of 0.5 min, 1 min, 2 min and 5 min, and proper sink conditions were maintained. The samples were analyzed using a UV-Spectrophotometer. Typically, orally disintegrating tablets dissolve quickly under USP monograph conditions, so slower paddle speeds can be used to obtain a profile. However, for large tablets that approach or exceed one gram and contain relatively dense particles, a mound in the dissolution vessel may be produced. This can be prevented by using higher paddle speeds, which expands the suitable range to 25-75 rpm[22].

Future trend of fast dissolving tablet

Mouth dissolving tablets offer several biopharmaceutical advantages over conventional dosage forms. One such advantage is improved efficiency, as they require smaller amounts of active ingredient to be effective. Additionally, they offer better drug bioavailability and improved absorption profiles compared to regular tablets and capsules. However, there are still many aspects of FDT formulations that need improvement. For instance, formulating drugs with bitter taste and moisture-absorbing nature poses a challenge for formulation scientists. Moreover, when the drug dose is large, it can cause an increase in disintegration time. To overcome these challenges, formulation scientists must shorten the disintegration time while keeping other parameters like friability, taste, mouthfeel, and tablet strength within the accepted range. This can be achieved by using taste masking agents and super disintegrating agents without significantly increasing the weight and volume of the final dosage forms. Furthermore, there is a scope to develop better packaging systems to make FDTs more stable during handling[23].

Conclusion

fast dissolving tablets (FDTs) are a promising drug delivery system that has revolutionized the pharmaceutical industry. FDTs offer several advantages over conventional tablets, including ease of administration, improved patient compliance, rapid onset of action, and increased bioavailability. FDTs also have specific benefits for patients with swallowing difficulties, pediatric, geriatric, and psychiatric patients. The ideal properties of FDTs include rapid dissolution or disintegration, taste masking, high wettability and porous network, and rapid drug absorption. However, FDTs also have some disadvantages, including hygroscopic nature, unpleasant mouth-feel, fragility, and special packaging requirements. Overall, FDTs present new business opportunities and are particularly beneficial in cases where an ultra-rapid onset of action is required. By addressing key considerations during the formulation process, pharmaceutical scientists can design optimized FDT formulations that meet the specific requirements of various drugs and patient populations.

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