ENHANCED ORAL DRUG DELIVERY WITH ORALLY DISPERSIBLE TABLETS: A COMPREHENSIVE REVIEW

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Abstract

Oral dispersible tablets (ODTs) have gained significant attention in the pharmaceutical industry as a unique dosage form that quickly disintegrates or dissolves in the mouth without requiring water. Their popularity has surged due to advantages such as improved patient compliance, easy administration, precise dosing, and pain avoidance. ODTs are especially beneficial for individuals with dysphagia, who have struggled to swallow oral tablets. This review explores several patented technologies, including Zydis, OraSolv, DuraSolv, Wowtab, Flashdose, and Flashtab, which use different mechanisms to achieve fast-dissolving properties while ensuring stability and taste masking. ODTs offer great potential in enhancing drug safety and efficacy, particularly for patients with physical or physiological limitations, children, geriatric individuals, and travellers. They provide a promising solution for non-invasive drug delivery and improved patient acceptance and compliance. However, the review also acknowledges challenges in ODT formulation and the need for advanced technologies to overcome these hurdles. Despite the challenges, the growing demand for ODTs in the pharmaceutical market is expected due to their rapid action, convenience, and patient-friendly characteristics. With ongoing advancements and increased patient demand, ODTs are likely to become a preferred choice in drug delivery systems.

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1. INTRODUCTION

The oral route is widely considered the most common and recommended method for drug delivery, involving both solid and liquid dosage forms. Solid dosage forms, particularly tablets and capsules, are favored for their ease of administration, accurate dosing, self-medication capabilities, pain avoidance, and high patient compliance. Despite their popularity, some individuals face challenges in swallowing pills and hard gelatin capsules, a condition known as dysphagia.[1] The United States Pharmacopoeia has granted a license to these dosage forms, designating them as orodispersible tablets. ODTs are solid unit dosage forms similar to conventional tablets, but they contain super disintegrants that enable them to dissolve in the oral cavity within a minute, facilitated by saliva, without any difficulty. This formulation offers various advantages, including administration without water, enhanced stability, precise dosing, ease of manufacturing, compact packing size, and easy handling.[2]

The pharmaceutical industry has developed oral disintegration tablets that rapidly disintegrate or dissolve in the mouth within a few seconds of placement, thereby maximizing the safety and efficacy of the medication. These tablets have gained significant popularity among a diverse population due to their ease of administration, especially benefiting patients with impaired physiological and physical capacities, geriatric individuals, children, and those suffering from dysphagia. Additionally, these tablets are particularly advantageous for traveling patients who may not have immediate access to water, as swallowing conventional solid oral dosage forms can be challenging in such situations.[3] The widespread acceptance of oral disintegration tablets stems from their ability to address the specific needs of diverse patient groups, ensuring convenient and effective medication delivery.

Novel drug delivery systems (NDDS) represent significant advancements aimed at enhancing the safety and efficacy of therapeutic molecules. These systems focus on developing dosage forms that offer ease of administration and improved patient compliance. Dysphagia, a common difficulty experienced across all age groups, poses a challenge with traditional solid dose forms like pills and capsules. Elderly individuals, who may have hand tremors and dysphagia, encounter difficulties in taking conventional oral medications. Similarly, children with underdeveloped muscular and neurological systems frequently face swallowing problems. In various instances, such as motion sickness, sudden allergic reactions, coughing, or dehydration, swallowing standard pills can be problematic. In response to these medicinal demands.[4] formulators have diligently worked to create innovative drug delivery systems tailored to address these specific challenges.

Furthermore, we delve into the potential challenges encountered during ODT formulation, including mechanical strength, taste optimization, environmental stability, and cost-effectiveness. Understanding these obstacles is vital for researchers and pharmaceutical companies seeking to optimize ODT development and ensure their successful integration into the market.[5] Disintegrants play a crucial role in the formulation of ODTs, as they promote the rapid disintegration of the tablet and enhance drug release for quick absorption in the oral cavity. The primary function of disintegrants in ODTs is to break down the tablet's structure into smaller particles when it comes into contact with saliva, promoting easy dispersion and subsequent swallowing. This is particularly important for patients who have difficulty swallowing traditional solid dosage forms, as disintegrants facilitate ease of administration and improve patient compliance.[6] The FDA (Food and Drug Administration) defines ODTs as "a solid dosage form containing medicinal substances or active ingredients that disintegrate rapidly when placed on the tongue, usually within seconds," In correlation, the European Pharmacopoeia (Ph. Eur.) describes them as "uncoated tablets intended to be placed in the mouth where they disperse rapidly before being swallowed, and as tablets that should dissolve within 3 minutes."[7]

Advantages and disadvantages:

1. They are simple to take and therefore useful for patients such as the elderly, victims of stroke, kidney failure patients, bedridden patients, and people who refuse to swallow, such as psychiatric patients, geriatric and pediatric.
2. Progastrin absorption increases bioavailability (rapid absorption).
3. Do not require water to ingest and are thus appropriate for patient compliance for bedridden patients, disabled, travelers and those who are continuously on the go and do not always have access to water.
4. Excellent mouth feel.
5. Increased safety as a result of the minimal danger of choking or asphyxia during oral administration.
6. Unappealing taste.
7. Manufacturing procedure that is expensive.
8. Typical blister packets lack physical resistance.

9. Restricted ability to integrate higher active drug concentrations.[8]

2. CHALLENGES IN FORMULATING ODTS

ODTs present a unique set of challenges in their formulation due to their specific characteristics and requirements. Some of the challenges in formulating ODTs include

2.1 Disintegration time and Mechanical Strength: The disintegration time refers to how quickly ODTs break down into smaller pieces when placed in the mouth, usually within a minute. On the other hand, the mechanical strength of ODTs relates to how sturdy and resilient they are, which affects their ability to withstand handling, packaging, and transportation without breaking or crumbling. Balancing these two aspects of quick disintegration while maintaining adequate mechanical strength can be a challenge in designing and producing ODTs.[9]

2.2 Taste and Palatability: ODTs are intended to be taken without water, so they need to have an acceptable taste and mouthfeel. Masking the taste of active pharmaceutical ingredients (APIs), especially those with bitter or unpleasant flavors, while maintaining drug stability can be difficult. In the oral cavity, ODTs should not break into bigger particles. The particles formed following ODT disintegration should be as tiny as possible. After oral administration, ODTs should leave little to no residue in the mouth. Furthermore, the inclusion of tastes and cooling substances such as menthol improves the mouth feel.[10]

2.3 Manufacturing Techniques: Conventional tablet manufacturing processes may not be suitable for ODTs due to their unique characteristics. Developing and optimizing manufacturing techniques that ensure uniformity, reproducibility, and stability of the final product can be challenging.[11]

2.4 Packaging and Moisture Protection: ODTs' rapid disintegration makes them susceptible to moisture, which can degrade the drug and affect shelf life. Developing appropriate packaging materials that provide moisture protection without hindering disintegration is a challenge.[12]

2.5 Stability: ODTs often have a larger surface area exposed to the environment, which can impact their stability. Developing formulations and packaging that maintain the stability of the drug over its shelf life can be a significant challenge.[13]

2.6 Excipient Selection: Choosing suitable excipients that aid in disintegration, enhance palatability, and ensure drug stability can be complex. Excipients must be carefully selected and their interactions understood to achieve the desired properties.[14]

2.7 Patient Variability: ODTs are often prescribed to a wide range of patients, including pediatric, geriatric, and patients with swallowing difficulties. Formulations need to account for variations in patient preferences and physiological conditions.

2.8 Cost-effectiveness: Finding a balance between formulating and producing ODTs with the intended characteristics, all while keeping costs reasonable, is a delicate endeavor. The technology chosen for crafting ODT must align with the overall pricing of the end product. Approaches like Zydis and Orasolv, which necessitate specialized techniques and packaging, notably elevate the expenses involved.[15]

3. RATIONALE FOR DEVELOPING ORALLY DISINTEGRATING TABLETS

ODTs are really useful in making medicines for specific reasons and to meet special patient requirements. They are especially good for older people who have problems like difficulty swallowing or shaky hands. Some important reasons for making ODTs are:

Patient Convenience and Compliance: ODTs are intended to dissolve fast in the mouth without the use of water, making them extremely useful for patients**.** especially those who have trouble swallowing conventional tablets or have limited presence of water. This ease of administration can improve patient compliance with medication regimens.[16]

Pediatric and Geriatric Populations: Children and elderly patients often have difficulty swallowing tablets or capsules. ODTs provide a viable alternative for these populations, ensuring that they receive accurate dosages without the discomfort associated with swallowing larger or multiple tablets.

a) Children who are Swallowing impairment comfortably because they're Nervous System and core muscles have not fully grown.
b) Patients traveling with travel sickness and loose stools who do not have the presence of water.

c) Patients who have had continuous vomiting sensations for an extended period of time are difficult to swallow.
d) Patients who are mentally challenged bedridden or psychiatric patients.[17]

4. CHOOSING DRUG CANDIDATES FOR FORMULATION OF ODTs

The selection of drug candidates for ODT involves a comprehensive evaluation process to ensure the successful development of this specialized dosage form. Key considerations include the characteristics of the target patient population, such as pediatric or geriatric patients, who may benefit from the convenience and ease of administration offered by ODTs. [18]

Additionally, the therapeutic category plays a crucial role; drugs requiring rapid onset of action, short half-lives, or prone to first-pass metabolism are prime candidates. Solubility and permeability are important factors, ensuring efficient dissolution and absorption through the oral mucosa. The taste and palatability of the drug candidate are vital, particularly since ODTs are consumed without water.[19]Compatibility with excipients, stability throughout manufacturing and storage, and potential for improved bioavailability further influence candidate selection. Regulatory standards, manufacturability feasibility, and commercial viability, in terms of market demand and competition, are also pivotal factors.

By meticulously considering these elements, pharmaceutical companies can identify drug candidates suitable for ODT formulation that align with therapeutic objectives, patient needs, and market opportunities.[20]

5. SUPER DISINTEGRANTS

One crucial element that contributes to the success of ODTs is the use of super disintegrants. These specialized excipients play a pivotal role in achieving rapid disintegration and dissolution of the tablet, ensuring efficient drug absorption and a pleasant patient experience. Super disintegrants are substances added to pharmaceutical preparations to facilitate the breakdown of tablets or capsules into lower particles upon contact with water or saliva. In the context of ODTs, super disintegrants are essential because they enable the tablet to disintegrate quickly in the buccal cavity, often in just a few seconds, without any extra water required.[21]

Mechanism of super disintegrants

The mechanism of super disintegrants involves a combination of swelling, wicking, and capillary action, all of which contribute to the efficient breakdown of tablets upon contact with moisture.

Swelling Mechanism: Super disintegrants are typically hydrophilic in nature, meaning they have a strong affinity for water. When an ODT containing a super disintegrant interacts with saliva or water in the oral cavity, the hydrophilic particles within the tablet begin to absorb moisture. This absorption causes the super disintegrant particles to swell significantly, creating internal pressure within the tablet matrix. As a result, the tablet structure weakens, and cracks and fissures develop, ultimately leading to the disintegration of the tablet into smaller fragments.[22]

Capillary Action: Capillary action refers to the ability of liquids to move through small spaces due to the cohesive forces between the liquid molecules. In the context of super disintegrants, the swollen particles create capillary pathways within the tablet. These capillaries draw in saliva or water, which further promotes the infiltration of moisture into the tablet matrix.[23]The combination of capillary attraction and swelling amplifies the disintegration process by facilitating the movement of liquid throughout the tablet.

Wicking Effect: The wicking effect is a phenomenon where the liquid is drawn into narrow spaces or crevices. In ODTs containing super disintegrants, the swollen particles create microchannels and crevices within the tablet. When moisture is introduced, it is drawn into these tiny spaces due to the wicking effect. This action further accelerates the disintegration of the tablet as the moisture permeates the tablet matrix, breaking down the bonds between the particles.[24]

6. APPROACHES IN THE FORMULATION OF ODTS

Several methods are employed in the formulation of ODTs, each designed to achieve quick disintegration and dissolution of the tablet in the oral cavity. Some of these methods include:

a) Freeze drying:

The Freeze-Drying Method also known as cryodesiccation, represents an advanced technique for formulating ODTs, especially beneficial for drugs sensitive to heat. In this approach, the medication is embedded within a Hydrophilic matrix and subsequently cryodesiccated to yield an exceptionally permeable structure. Upon placing lyophilized tablets in the mouth, they dissolve rapidly in under 5 seconds due to the swift saliva

of infiltration into the pores. The lyophilization procedure typically involves three key stages. freezing the substance below its eutectic freezing point, followed by primary drying to decrease the moisture content to around 4% w/w of the moisture-free output and finally, Secondary moisture removal to achieve the desired final volume by decreasing bound moisture.[25]

b) Aerosol drying:

Aerosol drying offers a rapid and cost-effective method for eliminating liquids and producing exceedingly porous, minute powders that dissolve rapidly. Within the process of spray drying, the swift evaporation of the processing solvent can lead to the creation of exceptionally porous, fine powder. This technique finds application in the creation of fast-dissolving tablets. To accomplish this, a particulate support matrix is employed. This matrix is generated by subjecting a water-based formulation including the stabilizing matrix and additional ingredients to spray drying, resulting in a finely powdered, highly porous structure. [26]Subsequently, active ingredients are introduced, followed by tablet compression. The supportive agents encompass both hydrolyzed and non-hydrolyzed gelatins, Mannitol is used as a bulking agent, the glycolate of sodium starch or croscarmellose sodium is used as a disintegration agent and an acidic or alkaline material is used as a preservative (such as bicarbonate of soda) to enhance the breakdown and dissolving properties.

c) Molding:

Molding is a common manufacturing method for orally disintegrating tablets (ODTs). In molding, the tablet is formed by compressing a wet mixture of active pharmaceutical ingredients (API), excipients, and a solvent. The solvent is then evaporated, leaving behind a solid tablet. Compression molding is the most common type of molding process for ODTs. In compression molding, the wet mixture is compressed into a mold under high pressure. The solvent is then evaporated, leaving behind a solid tablet.[27]

d) Sublimation:

Sublimation is a manufacturing process for orally disintegrating tablets (ODTs) that involves converting the active pharmaceutical ingredient (API) and excipients into a sublimable form, such as a powder or a thin film. The sublimable form is then placed in a vacuum chamber, where it is heated to a temperature at which the API and excipients sublime or vaporize without melting. The vapor then condenses on a cold surface, forming a solid tablet. To achieve rapid disintegration in the mouth, ODTs are formulated with super disintegrants, which are excipients that facilitate the quick breakup of the tablet when exposed to saliva.[28] The disintegration process involves the tablet absorbing saliva and softening, followed by the swelling and rapid dispersion of the tablet into fine particles, which can be easily swallowed without the need for water.

e) Direct compression:

Direct tablet formation is a simple, low-cost method for producing strong tablets with adequate disintegration qualities. It also delivers improved active medicinal ingredient stability, rapid dissolving, simple validation, and reduced microbiological contamination. Furthermore, ODTs produced using direct compression have a substantially larger drug-loading capacity, and their ultimate mass quickly exceeds that of conventional formulation procedures. Direct compression tablets, on the other hand, have significantly stronger durability but take much prolonged to disintegrate.[29] The primary idea of direct tableting is to combine Tablet disintegration agents or effervescence inducers, with water-soluble substances. Super disintegrants at optimal doses are frequently utilized to promote quick disintegration of ODTs as well as a pleasant mouth feel.

7. SIGNIFICANT PATENTED TECHNOLOGIES IN ODTS ZYDIS:

Zydis Technology, developed by R.P. Scherer (now Catalent Pharma Solutions), is a pioneering innovation in ODTs. Through a freeze-drying process, it creates porous tablets that rapidly dissolve upon contact with moisture in the mouth, allowing quick absorption through the oral mucosa. This technology addresses the challenges of swallowing traditional tablets, enhances medication adherence, and offers a patient-friendly experience.[30] It has revolutionized drug delivery by providing a convenient, water-free option for administering medications, making it especially valuable in situations where access to liquids is limited. Zydis Technology embodies a fusion of science and patient-centric design, reshaping the pharmaceutical landscape and setting new standards for drug delivery innovation.

Limitation:

1. In most cases, the quantity of medicine that can be assimilated must be ≤ 400 mg for insoluble pharmaceuticals and ≤ 60 mg for soluble drugs.
2. The particle size of the insoluble medicines must be between 50 and 200μm, to avoid sedimentation during processing.[31]

Orosolv:
Orosolv Technology, also known as "Orally Soluble Technology," is a proprietary platform for developing orally disintegrating tablets (ODTs). ODTs formulated using Orosolv Technology are designed to dissolve or break down fast in the mouth and do not require water, making them convenient and easy to administer.[32]

1. Rapid Disintegration: Orosolv ODTs are formulated with specific excipients and super disintegrants that facilitate quick disintegration upon contact with saliva. This feature allows the tablet to break down rapidly, usually within seconds, into small particles or a smooth paste, enabling easy swallowing and fast drug absorption.

2. Improved Patient Compliance: ODTs developed using Orosolv Technology are particularly useful for patients who have struggled to swallow conventional pills or soft gels. They offer a patient-friendly alternative that can improve compliance, especially for pediatric and geriatric populations.[33]

Durasolv:
Durasolv technology is a patented platform used for the development of orally disintegrating tablets (ODTs). It was originally developed by CIMA Labs Inc., which was later acquired by Cephalon Inc. (now a part of Teva Pharmaceuticals). Durasolv technology is designed to create ODTs with specific attributes and benefits for enhanced patient compliance and convenience. The versatility of Durasolv technology is adaptable to a wide range of drug compounds, allowing for the development of ODTs in various therapeutic categories. The stability of Durasolv ODTs is formulated to maintain their stability during storage, ensuring a reasonable shelf life.[34]

Wowtab:
WOWTAB (With Out Water) technology, developed by Yamanouchi Pharma Technologies, focuses on producing tablets that dissolve rapidly without the need for water. It offers versatile dosing options and improved patient compliance. It represents a revolutionary advancement in medication administration by introducing tablets that dissolve rapidly without requiring water. This innovation transforms the way medications are taken, enhancing patient convenience and accessibility.[35]This innovation combines super disintegrants and effervescence to facilitate swift tablet disintegration upon contact with saliva, overcoming challenges of swallowing and water availability. WowTab not only offers a user-friendly alternative for patients but also addresses taste-masking concerns, improving palatability. Beyond its rapid disintegration, WowTab allows for precise dosing and customizable release profiles, empowering pharmaceutical manufacturers to tailor tablets to specific therapeutic needs. This technology redefines oral drug delivery by enhancing patient compliance, broadening treatment possibilities, and elevating the medication experience. As pharmaceutical innovation progresses, WowTab stands as a testament to inventive approaches that shape the future of drug delivery and patient well-being.[36]

Flashdose:
FlashDose Technology, developed by CIMA Labs, introduces a unique method for formulating ODTs by compressing drug-coated beads into a rapidly dissolving tablet. This innovative approach combines controlled drug release from the beads with the quick disintegration characteristic of ODTs. It offers precise dosing, customizable release profiles, and potential applications in simplifying dosing regimens and enhancing treatment outcomes. FlashDose represents a versatile and sophisticated advancement in pharmaceutical drug delivery, marrying precision with rapid disintegration to expand the possibilities of ODT technology.[37]

Flashtab:
FlashTab technology is a method for manufacturing orally disintegrating tablets (ODTs) that use a combination of wet and dry granulation. The first step is to granulate the excipients, which are typically a swellable agent, a super disintegrant, and a taste-masking agent. The granulated excipients are then blended with the API, and the mixture is compressed into tablets.[38]

8. EVALUATION OF ODTS

The evaluation of ODTs involves a multifaceted process that includes assessing various aspects of these pharmaceutical dosage forms to ensure their quality, effectiveness, and suitability for patient use. Here are some of the essential parameters considered during the evaluation of ODTs.[39]

a) Tablet thickness:
Measurement of tablet thickness is an important aspect of evaluating ODTs. the evaluation of tablet thickness in ODTs is crucial for ensuring rapid disintegration, proper drug delivery, patient comfort, and overall product quality. It impacts various aspects of ODT performance, including drug release, dosing accuracy, manufacturing, packaging, and patient acceptability, all of which

contribute to the successful development and commercialization of ODTs.[40]

b) Weight variation:

It refers to the assessment of the uniformity of mass among individual tablets within a batch. Weight variation is a critical quality attribute that has significant implications for the safety, efficacy, and consistency of ODTs. It impacts dosing accuracy, patient safety, regulatory compliance, dissolution characteristics, manufacturing control, and overall product quality. Ensuring minimal weight variation contributes to the effective and safe use of ODTs by patients.[41]

Average weight of the tablet	% Deviation
80 mg or less	± 10
More than 80 mg or but less than 250 mg	± 7.5
250 mg or more	± 5

c) Friability:

It refers to the susceptibility of tablets to undergo abrasion or damage during handling, transportation, and packaging. Friability testing involves subjecting a sample of tablets to mechanical stress in a tumbling apparatus and then measuring the percentage of weight loss. It assesses tablet durability, dosing uniformity, patient safety, regulatory compliance, dissolution behavior, manufacturing consistency, and overall product quality. Ensuring acceptable friability levels is essential to produce reliable and robust ODTs that deliver accurate dosages and maintain their integrity throughout their lifecycle.[42]

% Friability = (W1 - W2) / W1 × 100

Where,

- W1 is the initial weight of the tablets
- W2 is the weight of the tablets after tumbling

d) Hardness (crushing strength):

Monsanto hardness testers are used to assess the hardness of tablets. The amount of force necessary to crush a tablet is measured when it is placed in the hardness tester. ODTs are often kept less firm than ordinary tablets since more hardness prevents the tablet from disintegrating as quickly. For uncoated tablets, a hardness of between 3 and 5 kg/cm2 is seen to be adequate when measuring force in kilograms.[43]

e) Uniformity of dispersion:

Uniformity of dispersion is a measure of how evenly the active pharmaceutical ingredient (API) is distributed throughout an orally disintegrating tablet (ODT). It is an important quality control parameter for ODTs, as it can affect the drug release profile and the patient's ability to receive the correct dose of the drug.[44]

Uniformity of dispersion (%) = [(Highest concentration - Lowest concentration) / Average concentration] × 100

f) Water absorption ratio:

The water absorption ratio (WAR) of an orally disintegrating tablet (ODT) is a measure of how much water the tablet absorbs when placed in a solution. It is an important quality control parameter for ODTs, as it can affect the disintegration time and drug release profile of the tablets.[45]

WAR (%) = (Wet Weight - Dry Weight) / Dry Weigh× 100

g) Wetting time:

Wetting time is a key parameter in the evaluation of ODTs. It refers to the time taken for a tablet to absorb a specified amount of liquid and disintegrate upon contact with saliva or other relevant fluids. This measurement provides valuable insights into the disintegration behaviour and effectiveness of ODTs.[46] As the primary phase of an ODT's breakdown involves moisture absorption and tablet wetting, the assessment of wetting time emerges as a pivotal determinant. Moreover, it facilitates exploration into the influence of diverse excipients on the disintegration process, further enriching our understanding of ODT behaviour.[47]

h) Disintegration time:

The disintegration time of oral dispersible tablets (ODTs) is a crucial parameter that measures how quickly the tablet breaks down into microparticles or dissolves in the oral cavity after administration. ODTs are designed to rapidly disintegrate without the need for water, providing a convenient and easy method of drug administration.[48] Even with modest volumes of water, it might be challenging to gauge the disintegration rate. Furthermore, human saliva only contains a few ml compared to the 900 ml used in the typical test, which uses distilled water instead. Therefore, it appears that the disintegration rate determined by a standard test does not accurately represent the breakdown rate in the oral cavity.[49]Many fresh approaches have been put out to solve these issues. One of these methods uses a Charge Couple Device (CCD) camera or texture analyzer to determine the disintegration time of tablets. Another technique makes use of a modified DT device. here, a beaker filled with 900 ml of simulated saliva is put atop a wire basket with a mesh size of #10 and dimensions of 3 cm in height by 2 cm in diameter. Only 6 cc of the liquid is in the basket because of how it is positioned in the liquid. A magnetic stirrer

and a heater are used to sustain the assembly and keep the temperature at 37°C. At 25 rpm, DT is detected. Take 6 ml of simulated saliva and put it in a graduated cylinder. Place the cylinder in a testing chamber.[50]

i) In vivo disintegration time:

The in vivo disintegration time of orally disintegrating tablets (ODTs) refers to the time it takes for the tablet to completely disintegrate and dissolve in the oral cavity of a living subject, typically a human patient. It is a critical parameter in assessing the performance and effectiveness of ODTs in real-life conditions.[51]

j) Dissolution test:

A dissolution test is a method used in pharmaceutical testing to measure how quickly a solid dosage form releases its active pharmaceutical ingredients (APIs) in a liquid medium. This test simulates the process that occurs in the body when the dosage form dissolves in the stomach or intestine, making the API available for absorption into the bloodstream. The results of a dissolution test provide crucial information about the drug's release profile, which helps ensure its effectiveness and consistency in different formulations and batches.[52]In the context of ODTs, a dissolution test measures how rapidly the tablet's active ingredients dissolve in a liquid, typically simulating the conditions of the mouth and stomach. This test mimics the process that occurs when an ODT is placed in the mouth, allowing it to disintegrate and release its active substances for absorption through the oral mucosa. The results of a dissolution test for ODT offer insights into their effectiveness, how quickly they deliver the medication and their consistency across different batches or formulations.[53]

9. FUTURE ASPECTS

The future of ODTs is positioned for a transformative evolution, driven by the convergence of cutting-edge pharmaceutical science and patient-centric healthcare. Anticipated developments hold the potential to reshape treatment paradigms and elevate the patient experience. Personalized medicine emerges as a guiding light, with ODTs tailored to individual patients, offering customized dosages and combining multiple medications for optimal therapeutic regimens. Novel drug delivery technologies, such as nanotechnology and microencapsulation, promise precise release and targeted efficacy, minimizing side effects. ODTs could evolve into versatile platforms for administering combination therapies, accommodating biologics and peptides, and even integrating electronic sensors for real-time monitoring. Advancements in taste-masking and sustainable formulations further enhance patient acceptability and environmental considerations. As ODTs embrace 3D printing, long-acting formulations, and telehealth integration, they bridge innovation with accessibility, offering global populations enhanced drug delivery solutions. Geriatric and pediatric formulations, regenerative therapies, and interventions for neurological and behavioural conditions underscore ODTs' expansive potential. In this impending landscape, ODTs are on the brink of not only delivering medications but also reshaping healthcare delivery, enriching patient care, and improving health outcomes through patient-centric design and next-generation pharmaceutical possibilities.

CONCLUSION

In conclusion, ODTs have emerged as a significant advancement in drug delivery technology, offering a range of benefits over traditional solid oral dosage forms. ODTs excel in enhancing patient compliance, ensuring rapid drug action, and providing the flexibility of administration without the need for water. Their unique characteristics make them a promising option for various patient groups and situations, from busy lifestyles to medical conditions that hinder swallowing. The continuous exploration of novel formulations, innovative technologies, and optimized manufacturing processes will further contribute to the expansion of ODTs' application across a wide spectrum of therapeutic areas.

In essence, the development and utilization of Orally Dispersible Tablets represent a significant stride toward improving patient outcomes and experiences in the realm of drug administration. As research and development in this field progress, ODTs hold the promise of becoming a prominent player in modern healthcare, revolutionizing the way medicines are taken and contributing to enhanced patient well-being.

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