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Original Article

A Contemporary Approach to The Medicate Conveyane Through Orodispersible Tablets

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ABSTRACT

The development of dosage forms that are easy to manufacture and administer, as well as rapid release and increased bioavailability, have led to new drug delivery systems. To achieve the desired result, drugs must be delivered to the site of action at a speed and concentration that maximizes therapeutic benefits and minimizes side effects. The most popular and efficient way of drug administration is oral. Recently, many medicinal products have been released in the market. The use of lyophilizers and oral tablets or films have expanded treatment options. Both children and adults can benefit from advantages such as ease of operation and ease of use. This study focuses on oral tablets, a new approach in drug delivery systems that is increasingly gaining attention in the manufacturing industry. Due to the highly disintegrating ingredients in the formulation, an orally disintegrating tablet dissolves in the mouth in about a minute with saliva without the need to drink water. This study focuses on currently available technologies and advances in orodispersible tablet formulation. In addition to traditional manufacturing methods, this review presents some new technologies such as freeze-drying, direct compression, slab casting, shrinking and quick-melting film, and their advantages and disadvantages. their weakness. Many researchers have developed breakout boards using proprietary technologies such as Zydis, wow tab, flash tab, Oroquick and Orosolv. It applies to hardness, brittleness, wet time, moisture absorption, Disintegration, dissolution testing and other solids dosage forms measurements.

Keywords: Orodispersible tablets, Fast dissolving films, Orodispersible Technologies, Fast Dissolving Tablets.

INTRODUCTION

The drug must be administered at a speed and concentration that maximizes the effect of the drug and minimizes side effects to achieve the desired result. To develop an acceptable dosage form, a thorough examination of the physicochemical principles governing the formulation of a given drug must be performed. The oral method of drug administration is the most common and recommended method of drug delivery in solid and liquid form[(1)]. Dissolving Tablets (ODT) are solid dosage units that are placed in the mouth and allowed to disperse/dissolve in saliva and then removed without liquid. Difficulty swallowing (dysphasia) can be seen in all age groups, especially the elderly, and can also be felt when taking traditional pills and capsules. Orodispersible tablets are also called orally disintegrating tablets, disintegrating tablets, fast-acting tablets, fast-acting tablets, fast-acting tablets. This condition is associated with a variety of serious illnesses, including stroke, Parkinson's disease, AIDS and other neurological diseases such as cerebral palsy[(2)]. ODT is easy to administer because no water is needed to dissolve the tablets, making it suitable for elderly patients, children and ambulatory patients. ODTs have been investigated for their ability to increase the bioavailability of poorly-soluble drugs by changing the way the drug is eliminated, and improving patient compliance. However, due to the rapid breakdown of ODT, strong absorption into the taste receptors and the need for sweet taste become an important part of the patient's life. Therefore, masking the taste of harmful active substances is a major obstacle to overcome in the production of ODT products[(3)]. In summary, oral administration of bitter active compounds through ODT formulation may result in greater patient compliance, better efficacy and better therapeutic effect. Commercially available

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ODT is produced using a variety of methods such as lyophilization, casting, freeze-drying, freezing, high-speed films, and direct compression. Both lyophilization and dissolution techniques result in the ODT being degraded within 30 seconds despite low physical activity and very weak absorption. On the other hand, boards made by direct compression are very fragile but will break quickly. Recently, new preparation methods for orodispersible tablets, such as WOW tab technology, flash tab method, Zydus and orosoly methods, have been developed as barrier technology for ODT. Current investment research highlights the trends and benefits. Medicines included in ODT; and evaluation of oral fracture sites[4].

Orodispersible tablets (ODTs): Orally disintegrating tablets (ODTs) are a new dosage form that disintegrates rapidly in the mouth (1-3 minutes) and is not chewable after oral administration and requires no liquid. The best time to break the floor is measured in less than one minute. Most decay times range from 5 to 30 seconds and you'll be ready for the count. Direct compression, solid dispersion, lyophilization, or conventional casting. ODTs are detected by the addition of supersolvents such as cross-linked cellulose. Carboxymethylcellulose, sodium starch glycolate, polyvinylpyrrolidone, which provides rapid breakdown in water or salivary secretions. The bioavailability of drugs increases due to oral and gastric absorption before the stomach and reduces the first cycle in the gastrointestinal tract[5].

Advantage of Orodispersible Tablets (ODTS) [6]

- Improved stability.
- Appropriate for controlled/sustained Offers moved forward compliance and comfort to patients and prescribers.
- It makes strides understanding adherence and decreases the advancement of resistance within the case of antimicrobials.
- Rearranges the coordinations of acquirement and dissemination.
- For Quick sedate conveyance, ODTs are considered to be favored dose frame.
- The medicate is discharged rapidly from this measurement frame and gets break up in GIT tract without getting into the stomach, expanded bioavailability can be accomplished.
- ODTs are exceptionally helpful for regulating to different classes of patients from crippled, travelers and busy individuals, who don't continuously have get to to water.
- A few drugs are retained from the pharynx and esophagus as the spit passes down into the stomach; in such cases, the bioavailability of drugs is expanded.
- No water required.
- No chewing needs.
- Superior taste.
- Discharge actives.
- High drug loading.

Disadvantage of Orodispersible Tablets (ODTS) [4]

- Immediate pharmacologic intervention is not possible
- Sometimes more doses are needed
- Dose can be reduced
- Less risk for dose adjustment
- For stabilization accuracy and safety of the product, ODT to Must have special packaging.
- Usually insufficient engine capacity. Therefore, it should be handled with care
- If it is not properly formulated, it may leave an aftertaste and a gritty/gritty taste in the mouth.

Limitations of Orodispersible Tablets (ODTs) [7]

- In many cases, the solvent solutions used to make ODTs can introduce a moisture content that can be problematic. If these tablets are not made properly, they can cause a bad taste or roughness in the mouth.
- A separate package may be required for prescription and over-the-counter medications. Precautions should be taken during use immediately after removal from the package.
- Drug sensitive, ODTs may not be suitable as film coatings.

Selection of the ODTs drug candidates [8]

Several factors should be considered when selecting drugs for delivery as ODT dosage forms:

- Drugs with different pharmacokinetic profiles compared to the same dose. For example, selegiline, apomorphine, buspirone, etc.
- Drugs that produce large amounts of toxic metabolites through hepatic and gastric metabolism and drugs that have a high fraction of absorption in the oral cavity and organs. Pre-abdominal gastrointestinal tract
- Drugs can be secreted and partitioned into the epithelium of the upper gastrointestinal tract (log P > 1 or better > 2). and those capable of penetrating

the oral mucosal tissue are considered suitable for ODT production.

- Patients taking anticholinergic drugs regularly may not be good candidates for these drugs.
- Patients with Sjøgren's Syndrome or dry mouth due to low saliva production may not be suitable for ODT production.
- Drugs that have a short half-life and require multiple doses, are too bitter, have an unacceptable taste that cannot be masked, or require sustained release are not recommended for ODT production.

CHALLENGES IN THE FORMULATION OF ODTs [9-12]

- **Mechanical efficiency and disintegration time:** ODTs are designed to achieve a break-in time of less than one minute. While working, maintaining engine power is a big challenge. Many ODTs are fragile, and their protective surfaces may break during packaging, shipping, or patient handling. It is very common for an increase in engine power to lengthen the deceleration time. Therefore, there is a good trade-off between these two relevant parameters.
- **Retaining the bitterness of various medicines:** A tablet that dissolves in the mouth can significantly affect patient acceptance and acceptance of the dosage form. Therefore, the taste of bitter medicines should be masked so that the taste of the medicine is not felt in the oral cavity.
- **Water solubility:** Water-soluble drugs present many manufacturing challenges because they form a eutectic mixture, resulting in the collapse of the freezing point and the formation of a crystalline solid, due to the loss of the supporting structure. during the downstream process. In some cases, such collapse can be prevented by the use of matrix forming agents such as mannitol, which can be activated and hardened in an amorphous composite.
- **Size of tablets:** The ease of consumption of tablets is contingent upon their size. It has been reported that the most easily swallowed size of tablet is between 7-8 mm, whereas the most easily handled size is one larger than 8 mm. Hence, it is challenging to find a tablet size that is convenient for administration and manageable for handling.
- **Quantity of medication:** It is a restricting factor in the utilization of technologies for Orally Disintegrating Tablets (ODTs). The amount of drug that can be included in each unit dose is limited. According to the United States Pharmacopeia (USP), it is generally recommended that the weight of orally disintegrating tablet (ODT) should not exceed 500 mg. For the lyophilized dosage form, the drug dose should be less than 400 mg for insoluble drugs and less than 60 mg for soluble drugs. This parameter poses a particular challenge when developing fast-dissolving oral films or wafers.
- **Hygroscopicity:** Several dosage forms that disintegrate orally are hygroscopic, meaning they cannot maintain their physical integrity under normal temperature and humidity conditions. Accordingly, they require protection from humidity, necessitating specialized packaging for products.
- **Mouthfeel:** ODTs should not break down into larger particles in the oral cavity. The particles produced after the decomposition of ODTs must be very small. In addition, the addition of flavoring and warming agents such as menthol improves the mouthfeel.
- **Good packaging design:** To protect ODTs from moisture and other environmental hazards, packaging design should be considered early in development.

Table 1 Summary of recent research on ODTs

Researcher Name & Year	Title	Drug Name	Method of Preparation	Publication
Mahmoud Mahyoob Alburyhi et. al. (2024)	Formulation and evaluation of domperidone Orodispersible tablets	Domperidone	Direct compression method	WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES
Mahmoud Mahyoob Alburyhi et. al. (2024)	Formulation and evaluation of Rivaroxaban Orodispersible tablets	Rivaroxaban	Direct compression method	WORLD JOURNAL OF PHARMACY AND

				PHARMACEUTICAL SCIENCES
Mahmoud Mahyoob Alburyhi et. al. (2023)	Formulation and evaluation of Diclofenac orodispersible tablets	Diclofenac	Direct compression method	EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH
Amitkumar M. Lokade et. al. (2021)	Formulation and Evaluation of Orodispersible Tablet for Anti-Asthamatic Drug	Salbutamol	direct compression method	Journal of Pharmaceutical Research International
Robert-Alexandru Vlad et. al. (2022)	Development and Evaluation of Cannabidiol Orodispersible Tablets Using a 2^3 -Factorial Design	Cannabidiol	direct compression method	Pharmaceutics
B.Venkateswara Reddy* and K. Navaneetha (2015)	Formulation and evaluation of Orodispersible tablets of candesartan	Candesartan	Direct compression technique	The Pharma Innovation Journal
Mangesh Machhindranath Satpute and Nagesh Shivaji Tour (2013)	Formulation and in vitro evaluation of fast dissolving tablets of metoprolol tartrate	metoprolol tartrate	Direct compression	Brazilian Journal of Pharmaceutical Sciences
Vijay Sharma and Himansu Chopra (2012)	Formulation and evaluation of taste masked orodispersible tablet of levocetirizine dihydrochloride	Levocetirizine dihydrochloride	Direct compression	Iranian Journal of Pharmaceutical Research
Harshal Pawar, et. al. (2014)	Development and evaluation of orodispersible tablets using a natural polysaccharide isolated from Cassia tora seeds	Cassia tora	direct compression method	Integrative Medicine Research
Ranjit Prasad Swain et. al. (2015)	Formulation, in vitro Characterization and Stability Studies of Fast Dispersing Tablets of Diclofenac Sodium	Diclofenac Sodium	direct compression method	Journal of Applied Pharmaceutical Science
K. Vinod Kumar et. al. (2015)	Mouth Dissolving Tablets of Meclizine Hydrochloride by using Super Disintegrants Formulation and In-Vitro Evaluation	Meclizine Hydrochloride	Direct-Compression	International Journal of Chemistry and Pharmaceutical Sciences
P. Panzade et. al. (2015)	Formulation Design and Optimization of Orodispersible Tablets of Quetiapine Fumarate by Sublimation Method	Quetiapine Fumarate	sublimation method	Indian Journal of Pharmaceutical Sciences

Pinkal Prajapati et. al. (2014)	Formulation development and evaluation of fast dissolving Tablets of Cyproheptadine Hydrochloride	Cyproheptadine Hydrochloride	Direct compression method	International journal of pharmaceutical sciences
B. P. PATEL et. al. (2010)	Formulation and Evaluation of Mouth Dissolving Tablets of Cinnarizine	Cinnarizine	effervescent, superdisintegrant addition and sublimation technique by direct compression method	Indian Journal of Pharmaceutical Sciences
T. Ayyappan et. al. (2014)	Formulation design, optimization & in vitro evaluation of novel orodissolving tablets of Efavirenz for HIV infections	Efavirenz	direct compression method.	Bangladesh Journal of Scientific and Industrial Research
Radke R.S. et. al. (2009)	Formulation and evaluation of orodispersible Tablets of Baclofen	Baclofen	Direct compresion method	International Journal of ChemTech Research
Krutika K. Sawant et. al. (2008)	Formulation and Evaluation of Oro Dispersible Tablets of Ondansetron Hydrochloride by Direct Compression using Superdisintegrants	Ondansetron Hydrochloride	Direct compression	International Journal of Pharmaceutical Sciences and Nanotechnology
Metker Vishal et. al. (2011)	Formulation And Evaluation of Orodispersible Tablets of Lornoxicam	Lornoxicam	Sublimation Method	International Journal of Drug Development & Research

MECHANISM OF TABLET DISINTEGRATION (13, 14)

The major mechanisms for tablet disintegration are as follows:

- Swelling
- Porosity and capillary action (Wicking)
- Deformation
- Due to disintegrating particle/particle repulsive forces
- Enzymatic reaction·
- Chemical reaction (acid-base reaction).

➢ **Swelling:** Swelling is considered to be a mechanism by which specific disintegrating agents, such as starch, facilitate the disintegration process. When exposed to water, the swelling of certain ingredients in a tablet leads to the breakdown of the tablet as the adhesive properties of these ingredients are diminished. Examples of such ingredients include Sodium starch glycolate and Plantago Ovata.

➢ **Porosity and capillary action (Wicking):** Tablet porosity facilitates the ingress of fluid into tablets by providing pathways for penetration. The disintegrant particles, with low cohesiveness and compressibility, serve to enhance porosity and create pathways within the tablet. Liquid is drawn up or "wicked" into these pathways through capillary action, which results in the rupture of the interparticulate bonds, causing the tablet to break apart. Examples of common disintegrants used in pharmaceutical formulations include Crospovidone and Croscarmellose.

➢ **Deformation:** Starch grains are commonly perceived to possess an "elastic" nature, wherein grains that are subject to deformation under

pressure will revert to their original shape once the pressure is alleviated. However, due to the compression forces encountered during tableting, it is widely believed that these grains become deformed in a more permanent manner and are referred to as being "energy rich". This energy is subsequently released upon contact with water. In essence, the capacity of starch to swell is greater in starch grains classified as "energy rich" compared to those that have not been subjected to deformation under pressure.

- **Due to disintegrating particle/particle repulsive forces:** Another mechanism of disintegration attempts to explain the swelling of tablets made with "non-swellable" disintegrants. Guyot-Hermann has proposed a particle repulsion theory based on the observation that non-swelling particles also cause disintegration of tablets. The phenomenon of disintegration occurs due to the electric repulsive forces between particles. Water is essential for this process to take place. Researchers have determined that repulsion is subordinate to wicking.
- **Enzymatic reaction:** Enzymes found within the human body also serve as disintegrants. These enzymes lack the binding action of a binder and aid in disintegration. Due to swelling, the pressure is exerted in the outer direction that causes the tablet to burst, or the accelerated absorption of water leads to an enormous increase in the volume of granules to promote disintegration.
- **Chemical reaction (acid-base reaction):** The tablet is rapidly disintegrated through the release of CO_2 internally when immersed in water, caused by the chemical reaction between tartaric acid, citric acid (acids), and alkali metal carbonates or bicarbonates (bases) in the presence of water. The tablet disintegrates as a result of the generation of pressure within it. The enhancement of the dissolution of active pharmaceutical ingredients in water and taste masking effect is attributed to the liberation of CO_2 gas. As these disintegrants are highly sensitive to small changes in humidity level and temperature, strict control of the environment is required during the preparation of the tablets. The effervescent blend can either be added immediately prior to compression or in two separate fractions of the formulation.

TECHONOLOGIES FOR PREPARING ORODISPERSIBLE TABLETS [15-21]

The various technologies used for the production of orodispersible tablets are:

- Freeze-drying or lyophilization
- Tablet Molding
- Spray drying
- Sublimation
- Melt granulation
- Cotton candy process
- Mass extrusion
- Phase transition
- Nanonization
- Fast dissolving films
- Direct compression
- **LYOPHILIZATION OR FREEZE-DRYING:** The formation of a porous product in the freeze-drying process is used in the production of ODT. Lyophilization is a process that removes solvent from a frozen suspension or drug solution with structural additives. Freeze drying of materials and additives creates a glossy amorphous structure, resulting in a highly porous and transparent product. The tablet breaks down and dissolves quickly when placed on the tongue, and the freeze-dried unit immediately melts to release the drug. Many technologies related to the lyophilization process have been patented and discussed in this article. However, ODT produced by lyophilization has low mechanical strength and poor stability at high temperature and humidity. In addition to the aforementioned problems with expensive equipment, the use of freeze dryers is limited.
- **Tablet Molding:** The manufacturing process involves wetting, dissolving, or dispersing the drug in a solvent, then compressing the wet mixture into a tablet (compressing at a lower pressure than conventional tablet compression), and evaporating the solvent from a drug solution or suspension. at ambient pressure (no vacuum lyophilization). Air-molded panels are dried by air conditioning. Since the blasting force used is less than conventional plates, the metal plate results in a very porous structure that increases the speed of dissolution and elimination of the products. However, to improve the dissolution rate, the fruit powder mixture should be sieved using a fine sieve. It is often used together with

soluble substances (saccharides) to improve oral and tablet breakdown. However, the mechanical strength of metal plates is low and they tend to slip and break during handling.

- **Spray drying:** Spray drying is a process that can produce highly porous and fine powders. Spray drying is frequently used in the pharmaceutical industry to produce highly porous powders. Allen et al. the use of this process for the production of fast-melting plates has been discussed. The main purpose of drying is to obtain dry particles with the desired properties. Orally disintegrating tablets are composed of gelatin or non-hydrogenated gelatin as a matrix carrier, mannitol as a swelling agent, and sodium starch glycolate and croscarmellose sodium as disintegrating agents. Citric acid and sodium bicarbonate are used to improve dissolution. Finally, the formulation is dried in a spray dryer. ODTs prepared by this method are biodegradable.
- **Sublimation:** The slow dissolution of compacted pavement is a highly water-soluble substance due to the low porosity of the pavements. Insoluble solids that are easily absorbed (such as urea, ammonium carbonate, ammonium bicarbonate, hexamethylenetetramine, camphor, etc.) are added to the other tablet components and the mixture is pressed into the tablet. Values are removed by shrinkage, creating a porous structure. In addition, many solvents (eg, cyclohexane, benzene) can be used as pore forming agents. The boards made by this method will break in 10-20 seconds. Mannitol and camphor were used as tablet matrix and sublimating agent, respectively. Camphor was evaporated by degassing in vacuum at 80°C for 30 minutes to create pores in the tablets.
- **Melt granulation:** The melt granulation technique entails the efficient agglomeration of pharmaceutical powders using a meltable binder. Unlike traditional granulation, it does not require any water or organic solvents. In order to achieve this process, high shear mixers are employed. The product temperature is increased above the melting point of the binder through the use of a heating jacket or by the heat of friction created by the impeller blades. This method for preparing FDT with adequate mechanical strength entails utilizing a hydrophilic waxy binder known as Superpolystate©, specifically PEG-6-stearate. Superpolystate© is a waxy material with a melting point of 33-37°C and an HLB value of 9. The substance will serve not only as a binder to enhance the physical resistance of tablets, but also aid in their disintegration as it dissolves in the mouth and quickly solubilizes, without leaving any residues.
- **Cotton candy process:** This process is appropriately titled as it employs a distinctive spinning mechanism to create a floss-like crystalline structure, reminiscent of cotton candy. It is commonly referred to as the candy floss process. The process of creating cotton candy entails the formation of a matrix of polysaccharides or saccharides through the simultaneous actions of flash melting and spinning. The matrix is partially recrystallized in order to enhance its flow properties and compressibility. The candy floss matrix is milled and blended with active ingredients and excipients before being compressed into orally disintegrating tablets (ODT). This process can accommodate high doses of drug and offers improved mechanical strength. Nevertheless, the high process temperature restricts the application of this method.
- **Mass extrusion:** The process entails the softening of the active mixture by utilizing a solvent blend of water-soluble polyethylene glycol and methanol. The softened mass is then extruded or injected through an extruder or syringe to produce a cylindrical product, which is then cut into uniform segments using a heated blade to form tablets.
- **Phase transition:** A novel approach has been developed for the preparation of orally disintegrating tablets (ODTs) with adequate hardness, which utilizes the phase transition of sugar alcohol. This method offers significant potential for improving the quality and performance of ODTs in pharmaceutical applications. This technique involves the production of orally disintegrating tablets (ODTs) through the compression and subsequent heating of tablets containing two sugar alcohols, one with a high melting point and the other with a low melting point. The heating process improves the bonding between particles, resulting in increased

hardness of tablets that was previously lacking due to low compatibility.

- **Nanonization:** The recently developed Nanomelt technology entails diminishing the particle size of a drug to nanoscale dimensions through the utilization of a proprietary wet-milling technique. Orally disintegrating tablets (ODTs) are made up of stabilizers that are added to the nanocrystal samples and used as a base to prevent cellular aggregation through surface sorption on specific stabilizeers. This technique is particularly advantageous for poorly water-soluble drugs. Further, this technology offers faster disintegration and dissolution of nanoparticles which improves the absorption by increasing bioavailability. This technology also offers a cost-effective manufacturing process, standard packaging due to its exceptional durability, and a diverse range of dosage options (up to 200 mg of drug per unit).
- **Fast dissolving films:** It represents a novel advancement in oral dosage forms which offers a highly convenient method for consuming medications and supplements. In this methodology, a non-aqueous solution is prepared, comprising water-soluble film-forming polymers such as pullulan, carboxymethylcellulose, hydroxypropyl methylcellulose, hydroxy ethylcellulose, hydroxyl propylcellulose, polyvinyl pyrrolidone, polyvinyl alcohol, or sodium alginate, along with the drug and additional taste-masking components. These ingredients are then permitted to form a film following the evaporation of the solvent. In the event of administering a bitter drug, it is possible to incorporate resin adsorbate or coated microparticles of the drug into the film. This method can help mask the bitter taste of the drug and improve patient compliance with medication. When the film is placed in the mouth, it melts or dissolves quickly, releasing the drug in a solution or suspension form. The system is characterized by several key features, such as paper-thin films measuring less than 2x2 inches, a rapid dissolution time of just 5 seconds, immediate drug delivery, and a pleasant flavored aftertaste.
- **Direct compression:** Direct compression is considered the most straightforward and economical method for manufacturing orally disintegrating tablets (ODTs). This is because ODTs can be produced using standard tablet manufacturing and packaging equipment. Additionally, there is a wide range of tableting excipients available that have enhanced flow, compressibility, and disintegration properties. These excipients include tablet disintegrants, effervescent agents, and sugar-based substances.
- **Superdisintegrants:** In many ODT technologies based on direct compression, the addition of supersolvents can significantly affect the rate of dissolution and dissolution. The presence of other ingredients such as water-soluble and effervescent agents accelerates the cracking process.
- **Effervescent agents:** The development of CO_2 as a dissolution method is the basis of the patented Orasolv (OT) technology, and is often used to develop over-the-counter formulations. This product has small particles in it, which makes it look fluffy. Saliva activates the effervescent agent and the tablet dissolves.
- **Sugar based excipients:** This is another way to generate ODT by direct compression. The use of sugar-sugar additives, especially bulking agents such as dextrose, fructose, isomalt, lactitol, maltitol, maltose, mannitol, sorbitol, starch hydrolysis, polydextrose and xylitol, show high solubility and the taste of water, and this creates wealth. of hiding the taste. Mizumito et al have classified sugar-glucose additives into two types based on their solubility and dissolution rate.

- Type 1: The saccharides (lactose and mannitol) have a low form but a high rate of elimination.
- Type 2: Saccharides (maltose and maltylol) show high production and low dissolution rates.

EVALUATION OF ORODISPERSIBLE TABLETS [22-30]

Content uniformity: The evaluation for uniformity of content relies on assaying the individual content of drug substance(s) in several individual dosage units to ascertain if the individual content falls within the specified limit. The test for content uniformity is necessary for tablets containing less than 25 mg or less than 25% of the weight of one tablet. The quantity of active ingredient present in each of the 10 randomly selected dosage units is determined using the method described in the assay. The preparation is considered to be in accordance with the test standards if the

individual content falls within the range of 85-115% of the average content.

Hardness: The hardness of a tablet is determined by the force applied across the diameter of the tablet in order to break it. The tablet's resistance to chipping, abrasion, or breakage during storage, handling, and transformation prior to usage is determined by its hardness. The hardness of the tablet for each formulation was assessed utilizing the Monsanto Hardness tester. The hardness of orally disintegrating tablets (ODTs) is typically maintained at a lower level than that of conventional tablets because higher hardness levels can hinder the disintegration process of the tablet. The force is measured in kilograms, and a hardness of approximately 3-5 kg/cm^2 is considered satisfactory for uncoated tablets.

Uniformity of weight: The weight variation test entails the weighing of twenty tablets individually and the subsequent calculation of the average tablet weight. Afterwards, the individual tablet weights are compared to the average weight to determine any variation.

Table 2 Pharmacopeial Orodispersible Tablet Weight variation limits

Monograph	Average weight	Deviation (%)
IP/BP	<80 mg	10
	Between 80 and 250 mg	7.5
	>250 mg	5
USP	<130 mg	10
	Between 130 and 325 mg	7.5
	>325 mg	5

Friability test: Friability is defined as the reduction in weight of a tablet within a container resulting from the detachment of fine particles from its surface. The friability test is conducted in order to assess the tablet's ability to withstand abrasion during packaging, handling, and transport. The Roche friabilator is utilized to determine the friability of tablets. The Friabilator comprises a plastic chamber that rotates at a speed of 25 revolutions per minute, dropping the tablets from a height of 6 inches in each revolution. Pre-weighed samples of tablets were placed in the friabilator and subjected to 100 revolutions. Tablets were de-dusted using a soft muslin cloth and reweighed. The loss in tablet weight is considered as the measure of friability and is expressed as a percentage.

% Friability = Lossinweight*100/ Initial Weight

Thickness: The thickness and diameter of the tablets were determined using a Micrometer screw gauge. Five tablets from each type of formulation were utilized, and the average values were computed. The measurement is stated in millimeters.

Water absorption ratio: A single piece of tissue paper was folded twice and then placed within a small Petri dish, which contained 6 ml of water. A tablet was placed on the paper, and the time taken for complete wetting was determined. This action was completed by measuring the time needed for the tablet to become fully soaked with liquid. The tablet that had been moistened was subsequently measured. The water absorption ratio (R) was calculated using the following equation:

$R= 10*W_a/W_b$

Where,

Wb is the weight of the tablet before water absorption,

Wa is the weight of the tablet after water absorption.

Disintegration time: The experiment involved the testing of six tablets using the apparatus described in I.P.-1996. Distilled water at a temperature of 37°C ± 2°C was utilized as the disintegration media. The duration, in seconds, required for the complete disintegration of the tablet, leaving behind no discernible mass in the apparatus, was recorded.

Modified disintegration test: Numerous reports indicate that traditional disintegration testing apparatus may not accurately provide values for the disintegration test of orally disintegrating tablets (ODTs). The quantity of saliva present in the oral cavity is limited to less than 6 ml. Conversely, the traditional disintegration testing device uses a significant amount of water with rapid up and down movements in kinetics. The most straightforward approach to overcoming this issue is by taking 6 ml of phosphate buffer with a pH of 6.8 in a 25 ml measuring cylinder. The temperature was maintained at 37± 2°C. An Oral Disintegration Tablet (ODT) was inserted, and the time required for the complete disintegration of the tablet was duly recorded.

Wetting time: A piece of tissue paper measuring 12 cm × 10.75 cm and folded twice was carefully positioned in a small Petri dish with an inner diameter of 9 cm. The Petri dish contained 6 ml of pH 6.8 phosphate buffer solution. A tablet was then placed on

the tissue paper, and the duration required for complete wetting of the paper was recorded. Three tablets from each formulation were randomly selected, and the average wetting time was noted.

Dissolution test: It is imperative to conduct this test as it allows for the acquisition of the drug-release profile through evaluation. Both the USP dissolution test apparatus can be used. The dissolution rate of orodispersible tablets is highly rapid. Hence, the USP 2 Paddle-type apparatus is utilized for dissolution testing, operating at speeds of 50-100 revolutions per minute (r/min). The USP Type I basket apparatus is specifically designed for use with orodispersible tablets. However, it is important to note that tablet fragments or disintegrated tablet masses may become trapped on the inside top of the basket at the spindle. An inaccurate dissolution profile is obtained, where there is little to no effective stirring. Therefore, Type II is the preferred option because it offers a more consistent dissolution profile.

Moisture-uptake studies: It is imperative to thoroughly investigate the properties and characteristics of orodispersible tablets. This study is being conducted with the purpose of evaluating the stability of the tablets. Ten tablets were placed in the desiccators containing calcium chloride at a temperature of 37°C for a duration of 24 hours. The tablets were subsequently weighed and exposed to a relative humidity of 75% for a period of two weeks at room temperature. The necessary humidity levels were attained by maintaining a saturated sodium chloride solution at the base of the desiccators for a period of three days. One tablet was designated as the control without the addition of super disintegrant, which was kept aside for the purpose of evaluating the moisture uptake caused by the other excipients. Tablets are carefully weighed and the percentage increase in weight is then meticulously recorded.

Packaging: Special care must be taken in packaging during manufacturing and storage to protect the dosage of other fast-dissolving dosage forms. Quick-dispersing and/or dissolving oral delivery systems can be packaged using a variety of options. These options include a single pouch, a blister card with multiple units, a multiple unit dispenser, and a continuous roll dispenser. The choice of packaging depends on the specific application and marketing objectives.

FUTURE PROSPECTIVE FOR ORODISPERSIBLE TABLETS [31-33]

Future challenges for many manufacturers of orally disintegrating tablets (ODTs) include reducing costs through the utilization of conventional equipment, implementing versatile packaging solutions, enhancing mechanical strength, and improving taste-masking capabilities. These advancements are essential for meeting the demands of the market and ensuring the continued success of ODT products in the pharmaceutical industry. Oral Drug Tablets (ODTs) may be considered a viable option for delivering drugs, particularly protein and peptide-based therapeutics with limited bioavailability through traditional tablets. This is due to the rapid degradation of such products in the stomach. Furthermore, there is a scope to develop controlled release orally disintegrating tablets (ODTs) prepared using various drug carriers.

CONCLUSION: The popularity of orally disintegrating tablets (ODTs) has witnessed a significant surge in the past decade. Based on the literature surveyed, it may be concluded that Orodispersible tablets are particularly beneficial to the pediatric, geriatric, bedridden, and psychotic patients affected by dysphagia. The tablets undergo conversion into a suspension upon contact with the salivary fluid in the oral cavity, leading to a rapid onset of action with enhanced bioavailability. Additionally, they provide improved patient acceptance and offer greater safety in comparison to conventional oral dosage forms. Today, Orodispersible tablets are increasingly accessible as over-the-counter products for addressing allergies, colds, and flu symptoms. All of the information collected above regarding the ODT provides a more comprehensive, scientific-based understanding. With the ongoing research and development of innovative pharmaceutical excipients, it is anticipated that new technologies will emerge for the production of more advanced orodispersible tablets in the future.

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