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ORODISPERSIBLE TABLETS: AN OVERVIEW OF FORMULATION APPROACHES, SUPERDISINTEGRANTS AND RECENT DEVELOPMENTS

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ABSTRACT

Orodispersible tablets (ODTs) have emerged as an effective oral drug delivery system designed to overcome swallowing difficulties associated with conventional tablets and capsules. They rapidly disintegrate in the oral cavity without the need for water, improving patient compliance, particularly among paediatric, geriatric, and dysphagic patients. The performance of ODTs is strongly influenced by formulation components, especially the type and concentration of superdisintegrants, as well as the manufacturing technique employed. This review highlights the ideal properties, drug selection criteria, advantages, limitations, formulation challenges, and mechanisms of drug release associated with ODTs. Emphasis is placed on superdisintegrants, including synthetic, natural, and co-processed materials, along with their mechanisms of action. Various preparation techniques such as direct compression, lyophilization, sublimation, spray drying, and nanonization are discussed. Recent studies demonstrate significant improvements in disintegration time, dissolution rate, and bioavailability, indicating the growing potential of ODTs as a patient-friendly dosage form.

KEYWORDS: Orodispersible tablets; Superdisintegrants; Direct compression; Drug release; Patient compliance.

INTRODUCTION

Tablets and hard gelatin capsules remain the most commonly used oral drug delivery systems. However, many patient groups—such as paediatric and geriatric patients, as well as individuals who are mentally challenged, uncooperative, nauseated, or on restricted fluid intake—often experience difficulty in swallowing these conventional dosage forms. To overcome these limitations, orodispersible tablets (ODTs) have been developed. When an ODT is placed in the oral cavity, saliva rapidly enters the porous structure of the tablet, leading to quick disintegration and allowing the drug to be swallowed easily without the need for water.[1]

Orodispersible tablets (ODTs) release the medicament in the oral cavity, allowing absorption through the oral mucosa and throughout different regions of the gastrointestinal tract, including the pre-gastric region (oral cavity, pharynx, and oesophagus), gastric region (stomach), and post-gastric region (small and large intestine). ODTs are also known by various terms such as orally disintegrating tablets, mouth-dissolving tablets, fast-dissolving tablets, rapid-dissolving tablets, quick-disintegrating tablets, and fast-disintegrating tablets.[2] The performance of orally disintegrating tablets (ODTs) is strongly influenced by the manufacturing technology employed. Their rapid disintegration is mainly due to the fast penetration of saliva or water into the tablet matrix, leading to the formation of a porous structure and subsequent tablet breakup. Therefore, the fundamental strategies for developing ODTs involve enhancing the porosity of the tablet matrix, incorporating suitable disintegrating agents, and using highly water-soluble excipients in the formulation.[3]

Ideal Properties of Orodispersible Tablets (ODTs)[4]

- Orodispersible tablets should not require water for administration and must rapidly disintegrate or dissolve in the oral cavity within a few seconds.
- They should be capable of accommodating a high drug load.
- ODTs should provide a smooth and pleasant mouthfeel to enhance patient acceptability.
- The formulation should be compatible with taste-masking agents and other pharmaceutical excipients.
- Especially for poorly soluble and hydrophobic drugs, ODTs should improve bioavailability through rapid disintegration and dissolution.

Drug Selection Criteria for Orodispersible Tablets[5]

- The drug should be capable of saturating the oral mucosa.

- It should possess sufficient ability to diffuse and partition into the epithelial lining of the upper gastrointestinal tract.
- Drugs belonging to Biopharmaceutics Classification System (BCS) Class II are considered suitable candidates for ODT formulation.
- The drug should remain at least partially non-ionized at the pH of the oral cavity.
- An ideal drug candidate should have a molecular weight below 500 Daltons.
- ODTs are more suitable for low-dose drugs, typically less than 50 mg.
- The drug should exhibit adequate stability in saliva as well as in aqueous media.
- Drugs with poor oral bioavailability are good candidates for formulation as ODTs.
- Drugs with a short biological half-life requiring frequent dosing are generally unsuitable for ODT formulation.
- Drugs with an extremely bitter taste or unpleasant Odor are not ideal candidates for ODTs.

Advantages of Orodispersible Dosage Form[6]

- Orodispersible formulations are easy to administer to patients who experience difficulty in swallowing conventional tablets, including geriatric, paediatric, mentally ill, disabled, and uncooperative patients.
- These dosage forms do not require water for swallowing, improving convenience.
- They ensure accurate dosing when compared with liquid formulations.
- Rapid disintegration followed by quick dissolution leads to faster absorption and an early onset of therapeutic action.
- Drug bioavailability is enhanced as a portion of the drug may be absorbed through the oral cavity, pharynx, and esophagus as saliva is swallowed.
- Orodispersible dosage forms offer advantages over liquid formulations in terms of ease of administration, handling, storage, and transportation.
- Reduction in first-pass hepatic metabolism results in improved bioavailability, allowing lower doses and minimizing adverse effect.
- Orodispersible systems may also be designed to accommodate sustained or controlled release active pharmaceutical ingredients.
- Allow high drug loading.

Disadvantages of Orodispersible Tablets[4]

- ODTs are not suitable when an immediate and intensive therapeutic intervention is required.
- In certain cases, these formulations may necessitate more frequent dosing.
- There is a possibility of dose dumping, particularly in improperly designed formulations.
- Precise dose adjustment may be limited with this dosage form.
- To ensure product stability and patient safety, ODTs often require specialized packaging.
- These tablets generally possess low mechanical strength, making them fragile and requiring careful handling.
- If not appropriately formulated, ODTs may produce an unpleasant taste or a gritty sensation in the oral cavity.

CHALLENGES IN THE FORMULATION OF ODT[7]

Mechanical Strength and Disintegration Time

ODTs are required to disintegrate rapidly in the oral cavity. However, they are often composed of porous or soft-molded matrices or compressed at low compression forces, which makes the tablets brittle and difficult to handle. Achieving an optimal balance between mechanical strength and rapid disintegration remains a major challenge. Only a limited number of technologies, such as Wowtab and those developed by CIMA Laboratories, are capable of producing sufficiently rigid and robust ODTs suitable for packaging in multidose containers.

Taste Masking and Mouth Feel

Since most pharmaceutical drugs possess an unpleasant or bitter taste, effective taste masking is crucial to ensure patient compliance and acceptability. This challenge is particularly significant for ODTs, as the drug dissolves directly in the oral cavity. Masking the taste of bitter drugs selected for ODT formulations is therefore difficult for formulation scientists. Additionally, large particles should not remain after disintegration; instead, ODTs should break down into very fine particles to provide a smooth and pleasant mouth feel.

Size of Tablet

Tablet size plays a critical role in patient convenience and ease of administration. Studies have reported that the optimal tablet size for swallowing is approximately 7–8 mm, whereas tablets larger than 8 mm are easier to handle. Consequently, designing an ODT that balances ease of handling with patient comfort during administration remains challenging.

Amount of Drug

The applicability of ODT technology is limited by the amount of drug that can be incorporated into a single unit dose. Ideally, the tablet mass should not exceed 500 mg; however, achieving this limit is difficult, especially for drugs requiring higher doses.

Hygroscopicity

ODTs are often hygroscopic in nature and may lose their physical integrity when exposed to standard temperature and humidity conditions. Therefore, protection from moisture is essential, and specialized packaging is required to maintain product stability.

Packaging Design

Appropriate packaging design is crucial and should be optimized from the initial stages of product development to protect ODTs from environmental factors, particularly moisture and humidity.

MECHANISM OF DRUG RELEASE[3]

The overall drug release mechanism of orally disintegrating tablets (ODTs) is based on their ability to rapidly disperse or disintegrate in the oral cavity, typically within three minutes, as specified by the European Pharmacopoeia. The development of ODTs primarily involves the incorporation of super disintegrants such as sodium starch glycolate (Primojel®, Explotab®), croscarmellose sodium, and polyvinylpyrrolidone (Polyplasdone®), which promote fast tablet disintegration upon contact with saliva. This rapid disintegration facilitates immediate drug release into the saliva. For certain drugs, bioavailability may be enhanced due to absorption through the oral mucosa or pregastric absorption of the drug dispersed in saliva before reaching the stomach. Consequently, the fraction of drug subjected to hepatic first-pass metabolism is reduced.

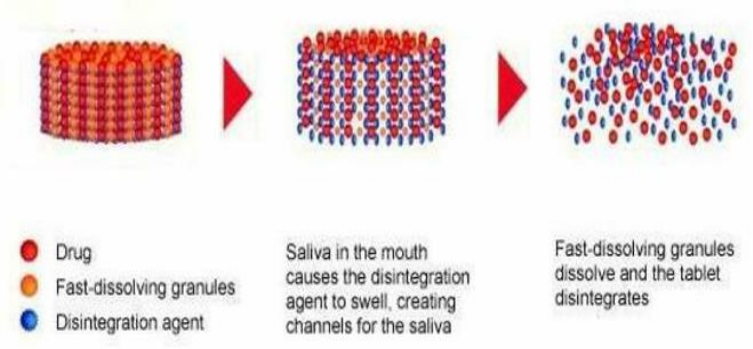


Figure No. 1: Conceptual Diagram of Disintegration and Dissolution.

EXCIPIENT USED IN PREPARATION OF ODTs[11]

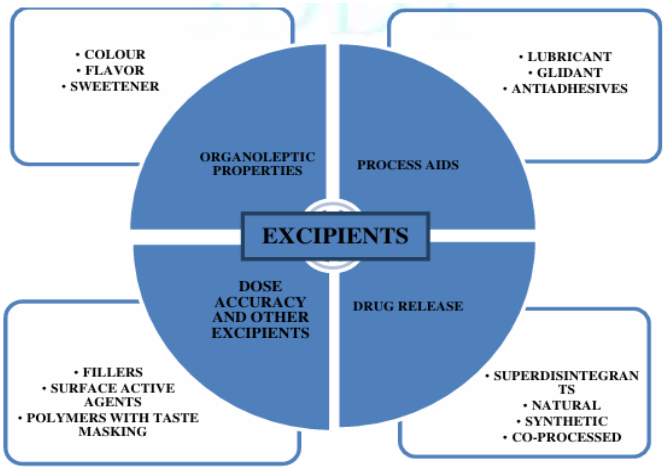


Figure No. 2: Classification of excipients used in orodispersible tablets.

SUPERDISINTEGRANTS[8]

Super-disintegrants are substances capable of producing more rapid disintegration than conventional disintegrants used in tablets and capsules. When incorporated into a tablet or capsule formulation, they promote the breakup of the dosage form into smaller particles, thereby enhancing the rate of dissolution. Super-disintegrants are generally available in granular form and are used at low concentrations, typically ranging from 1–10% of the total weight of the unit dosage form.

In recent years, considerable research efforts have focused on identifying disintegrating agents that combine safety with high efficacy, enabling rapid tablet disintegration even at high crushing strengths exceeding 3.5 kg. Evaluation parameters such as disintegration time in the oral cavity and wetting time, which is influenced by surface free energy, have demonstrated that materials possessing a high polar component of surface free energy exhibit faster wetting behaviour. Disintegrating agents that meet these criteria are commonly referred to as super-disintegrants.

Advantages of Superdisintegrants[9]

- Exhibit excellent wetting properties, resulting in rapid tablet disintegration
- Disintegrate without forming lumps or aggregates.
- Show good compatibility with most commonly used drugs and excipients.
- Do not adhere to punches and dies during compression.
- Effective even at low concentrations.
- Have minimal impact on tablet compressibility and flow characteristics.

- Demonstrate greater efficiency when incorporated intragranularly.
- Some superdisintegrants are anionic in nature and may exhibit slight in-vitro binding with cationic drugs.
- Environmentally friendly due to their biodegradable nature.

Disadvantages of Superdisintegrants[9]

- Relatively expensive compared to conventional disintegrants.
- Processing can be time-consuming, and the materials may be fragile.
- Highly sensitive to moisture and tend to be hygroscopic.

Types of superdisintegrants[10,12]

Superdisintegrants can be classified on the basis of their source of origin

a) Synthetic superdisintegrants
b) Natural superdisintegrants
c) co-processed superdisintegrants.

a) Synthetic Superdisintegrants: Synthetic superdisintegrants are widely used in tablet formulations to enhance the rate of tablet disintegration. They accelerate the breakup of the tablet, thereby improving drug dissolution and solubility. Commonly employed synthetic superdisintegrants include crospovidone (cross-linked polyvinylpyrrolidone), croscarmellose sodium (cross-linked cellulose), sodium starch glycolate, soy polysaccharides (Emcosoy®), chitin, and chitosan.

b) Natural Superdisintegrants: Natural superdisintegrants are derived from biological sources and are commonly incorporated into tablet formulations to promote rapid disintegration. They are often used to overcome certain limitations associated with synthetic superdisintegrants. Examples of widely used natural superdisintegrants include Plantago ovata husk, Ocimum tenuiflorum, Aloe vera mucilage, Hibiscus rosa-sinensis, Lepidium sativum, Mangifera indica pectin, guar gum, and related materials.

c) Co-processed Superdisintegrants: To meet the demands of advanced tablet manufacturing, novel and improved superdisintegrants have been developed through co-processing techniques. These co-processed excipient blends are designed to deliver optimized performance and desirable formulation characteristics. Examples include Ludipress®, Starlac®, StarCap® 1500, Ran-Explo-C®, Ran-Explo-S®, and Ludiflash®.

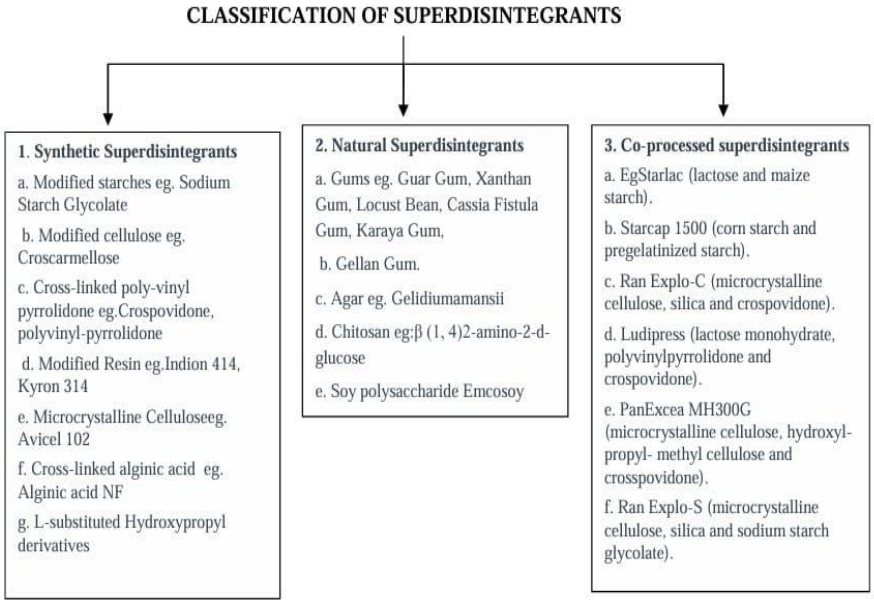


Figure 3: Disintegration mechanism of superdisintegrant materials.

Selection of Superdisintegrants[11]

Since superdisintegrants are used as excipients in tablet formulations, they must satisfy several requirements in addition to their swelling ability. Therefore, the essential characteristics of tablet disintegrants should be well defined. An ideal disintegrant should possess the following properties.

1. Low solubility in water.
2. Minimal or no gel formation after hydration.
3. High hydration and water uptake capacity.
4. Good flowability and moulding properties to support uniform tablet manufacturing.
5. No tendency to interact or form complexes with the active drug.
6. Pleasant mouth feel, particularly in fast dissolving or orally disintegrating tablets.

Mechanism of Action of Superdisintegrants[11,12]

There are five major mechanisms for tablet disintegration as follows

1. Swelling
2. Porosity and Capillary Action (Wicking)
3. Deformation
4. Particle Repulsive Forces
5. Enzymatic reaction

1. Swelling: Swelling is considered one of the most commonly accepted mechanisms of tablet disintegration. When disintegrating agents come into contact with water, they absorb it and swell, thereby overcoming the adhesive forces of other formulation components such as binders. The swelling ability of these agents (for example, starch) generates internal stress within the tablet matrix, leading to its breakup into smaller fragments. The process is shown in Figure 4.

E.g. Sodium Starch Glycolate

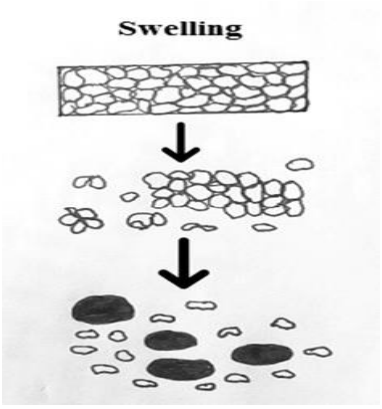
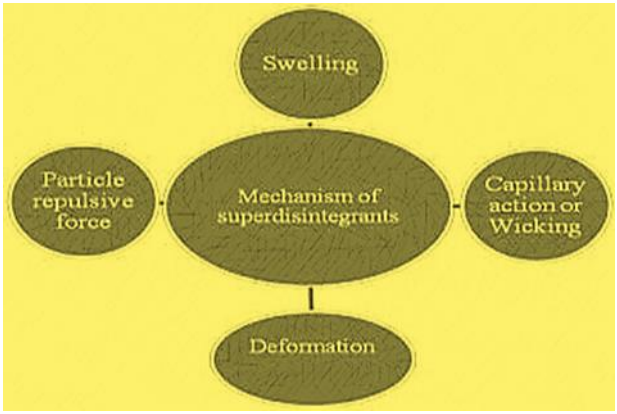


Figure No. 4: Mechanism of disintegration by Swelling.

2. Porosity and Capillary Action (Wicking): Some highly effective disintegrants do not exhibit swelling upon contact with water. Instead, they promote tablet disintegration through the mechanisms of porosity and capillary action. The inherent porosity of the tablet provides channels that allow rapid penetration of fluid into the matrix. Disintegrant particles with low compactness and compressibility further enhance this porosity, creating pathways within the tablet. Through capillary action, liquid is drawn into these channels, weakening the inter-particulate bonds and ultimately causing the tablet to disintegrate. The mechanism is depicted in Figure 5.

E.g. Crosscararmellose



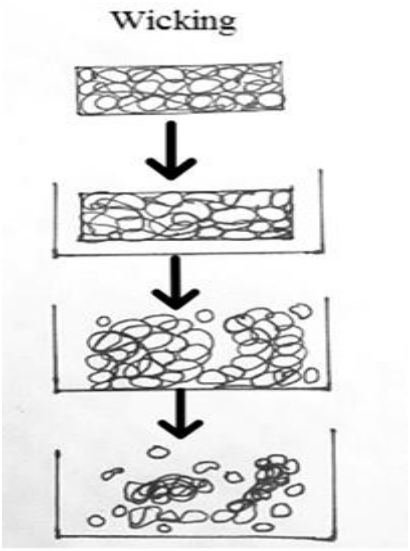


Figure 5: Mechanism of disintegration by Wicking.

3. Deformation: During tablet compression, disintegrant particles undergo deformation. Upon exposure to water or an aqueous medium, these distorted particles recover their original shape. This recovery leads to an increase in particle size, generating internal stress within the tablet matrix and resulting in tablet disintegration. This mechanism is particularly significant for disintegrants that exhibit minimal or no swelling behavior. The mechanism is expressed in Figure 6 E.g. Crosspovidone.

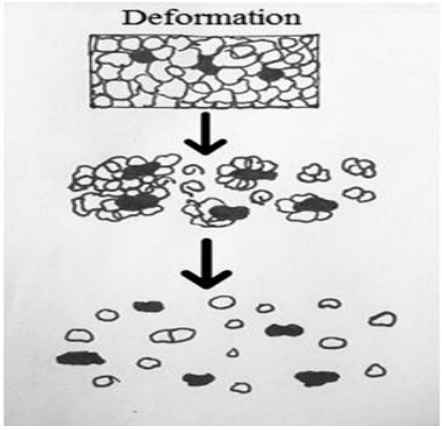


Figure 6: Mechanism of disintegration by Deformation.

4. Particle Repulsive Forces: Particle repulsive forces represent an important mechanism of tablet disintegration, particularly in formulations containing non-swelling disintegrants. According to Guyot-Hermann's particle–particle repulsion theory, water enters the tablet through hydrophilic pores, generating significant hydrostatic pressure within the matrix. This pressure weakens the hydrogen bonding between particles, leading to tablet breakup. The

presence of water enables the development of electrical repulsive forces between particles, which act as the primary driving force for tablet disintegration.The process is shown in Figure 7.

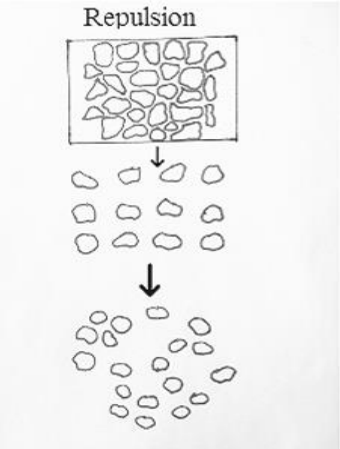


Figure 7: Mechanism of disintegration by Repulsion.

5. Enzymatic Reaction: Enzymes present in the body can contribute to tablet disintegration by reducing the binding strength of binders within the formulation. As fluid is absorbed, swelling pressure within the tablet matrix increases and is directed outward. This rise in internal pressure may cause the tablet to split, or the rapid uptake of water can result in a significant expansion of granules, ultimately leading to tablet disintegrate.

TECHNIQUES USED IN PREPARARTION OF ODTs[13]

1. Direct compression method
2. Freeze-drying or lyophilization
3. Molding Method
4. Sublimation
5. Spray drying
6. Mass extrusion
7. Cotton candy process
8. Nanonization.

1. Direct compression method

Direct compression is one of the simplest and most economical methods for tablet preparation. It involves the use of conventional tablet compression machines and commonly available excipients, requiring only a limited number of processing steps. Microcrystalline

cellulose (MCC) and low-substituted hydroxypropyl cellulose (HPC) are frequently employed in the manufacture of rapidly disintegrating tablets. Fast disintegration may also be achieved by incorporating effervescent agents into the formulation, which produce carbon dioxide upon contact with moisture and can additionally aid in taste masking. However, a major limitation of effervescent formulations is their hygroscopic nature, making them prone to absorbing moisture from the atmosphere. In some cases, superdisintegrants are added in optimal amounts to enhance oral dispersibility and provide a pleasant mouthfeel. Commonly used superdisintegrants include sodium starch glycolate, crospovidone, alginic acid, calcium silicate, and croscarmellose sodium, which promote rapid tablet disintegration through water absorption and swelling. Overall, direct compression is a cost-effective technique and closely resembles conventional tablet manufacturing, although the use of higher concentrations of disintegrants may sometimes lead to reduced tablet hardness.

2. Freeze Drying (Lyophilization)

Drying, also known as lyophilization, is a pharmaceutical technique used to dry heat-sensitive drugs and biological products at low temperatures by applying a vacuum, which removes water through sublimation. In this process, the drug is dissolved or dispersed in an aqueous carrier solution, filled into preformed blister packs, and subjected to nitrogen flushing to induce freezing. The frozen product is then placed in a refrigerated environment to complete the drying process. Lyophilized formulations are characterized by high porosity and a large specific surface area, allowing rapid dissolution in the oral cavity and enhanced drug bioavailability. However, this technique has several limitations, including high production costs, a time-intensive process, and the fragile nature of the resulting dosage form, which makes conventional packaging unsuitable and raises stability concerns under stress conditions.

3. Molding Method

In the molding technique, tablets are formulated using hydrophilic excipients to enhance drug dissolution. The powder blend is moistened with a hydroalcoholic solvent and then molded into the desired dosage form by compression. After molding, the solvent is allowed to evaporate. Taste masking of the drug can be achieved by spray congealing a molten mixture containing hydrogenated cottonseed oil, sodium carbonate, lecithin, polyethylene glycol, and the active pharmaceutical ingredient onto a lactose-based tablet triturate. Tablets prepared by

the molding method are highly porous, as solvent removal during drying leaves behind a porous structure, which facilitates rapid dissolution of the tablet in the oral cavity.

4. Sublimation

The sublimation technique enhances rapid tablet disintegration and dissolution by creating a highly porous matrix. This is achieved by incorporating volatile inert solids such as urea, camphor, ammonium carbonate, ammonium bicarbonate, and hexamethylenetetramine into the formulation. These substances are blended with other excipients and compressed into tablets. Subsequently, the volatile components are removed by applying reduced pressure and mild heating, leaving behind a porous tablet structure. Tablets prepared by the sublimation method are characterized by their high porosity, which promotes fast disintegration. In some cases, organic solvents such as cyclohexane and benzene may be employed in this process.

5. Spray-Drying

In the spray-drying technique, formulation components are combined using hydrolyzed and non-hydrolyzed gelatin as matrix-forming agents, mannitol as a bulking agent, and disintegrants such as sodium starch glycolate or croscarmellose sodium. To further enhance tablet disintegration and dissolution, acidic substances (e.g., citric acid) and/or alkaline agents (e.g., sodium bicarbonate) may be incorporated. Dosage forms prepared by the spray-drying method are characterized by extremely rapid dissolution, typically occurring within 20 seconds upon contact with an aqueous medium.

6. Mass-Extrusion

In the mass-extrusion method, the blended ingredients are softened using a water-soluble agent such as polyethylene glycol, with methanol serving as the solvent. The softened mass is then pushed through an extruder to form thin cylindrical rods, which are subsequently sliced with a heated blade to produce small tablet units. Tablets prepared by this technique are particularly useful for masking the bitter taste of drugs, as the process creates small granules that can enhance oral bioavailability.

7. Cotton Candy Process

In the cotton candy process, a polysaccharide matrix is produced through the combined effects of rapid melting and spinning. The resulting candy-floss–like structure is subsequently recrystallized, milled, and blended with the active pharmaceutical ingredient along with suitable excipients. This mixture is then compressed to obtain fast-dissolving tablets. Dosage

forms prepared by this method are capable of accommodating a high drug load while also exhibiting good mechanical strength.

8. Nanonization

Nanonization is a technique that reduces drug particle size to the nanometer range using wet grinding methods. The resulting nanocrystals are stabilized to prevent agglomeration by physically adsorbing them onto the surface of inert carrier materials. This approach is particularly suitable for poorly water-soluble drugs with low bioavailability. Additionally, nanonization is a cost-effective process, produces stress-resistant dosage forms, and allows incorporation of a wide range of drug doses, including high-dose formulations (≥ 200 mg).

CHARACTERISATION AND EVALUATION PARAMETERS[3,14]

❖ **Pre- compression parameters**

Bulk Density: Bulk density refers to the mass of soil per unit volume. Soils exhibiting bulk density values greater than 1.6 g/cm³ generally hinder root penetration and growth. Bulk density rises as soil compaction increases and typically becomes higher with increasing soil depth.

$$\text{Bulk density} = \frac{\text{mass}}{\text{unsettled apparent volume}}$$

Tapped density: Tapped density refers to the higher bulk density achieved after a powder sample is mechanically tapped. It is determined by repeatedly tapping a graduated measuring cylinder or vessel that contains the powder until a constant volume is obtained.

$$\text{Tapped density} = \frac{\text{mass}}{\text{final tapped volume}}$$

Compressibility index: It indicates powder flow properties. It is expressed in percentage and it is given as

$$\text{I} = \frac{\text{Tapped density} - \text{bulk density}}{\text{tapped density}} X100$$

Relationship between % compressibility and flowability

%Compressibility	Flow ability
5-10	Excellent
12-16	Good
18-21	Fair Passable
23-25	Poor

33-38	Very Poor
<40	Very Very Poor

Angle of repose: It was calculated by using funnel method powder blend was poured on vertically placed funnel until cone of maximum height was formed.

$$\text{Tan}\,\theta = \frac{\text{Height of cone (h)}}{\text{Radius of the conel (r)}}$$

Where **θ** = Angle of repose

Angle of Repose	Type of flow
>20	Excellent
20-30	Good
30-34	Passable
>34	Very Poor

Hausner's ratio: Hausner's ratio is a parameter used to assess the flow properties of a powder or granular material.

$$\text{Hausner ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

❖ **Post Compression parameters**

Hardness / Crushing strength: Tablet hardness is evaluated using standard hardness testers such as the Monsanto hardness tester. For orodispersible tablets, hardness is maintained at the lower end of the acceptable range to facilitate rapid disintegration in the oral cavity.

Friability: Maintaining friability within acceptable limits is challenging because most preparation methods for orodispersible tablets tend to increase friability. Generally, an acceptable friability range of 0.1%–0.9% is maintained. Friability is commonly measured using a Roche friabilator.

Wetting time: Wetting time reflects the internal structure of the tablet and the hydrophilic nature of the excipients used. It is associated with the contact angle of the dosage form. A shorter wetting time indicates faster tablet disintegration. Wetting time is determined using five circular tissue papers, each 10 cm in diameter, placed in a 10 cm diameter Petri dish. Ten millilitres of a water-soluble dye solution, such as eosin, is added to the Petri dish. A tablet is gently placed on the surface of the tissue paper, and the time taken for the liquid to reach the upper surface of the tablet is recorded as the wetting time. For the determination of the water absorption ratio, the tablet is weighed before placement in the Petri dish (Wb). After wetting,

the tablet is removed and reweighed (Wa). The water absorption ratio (R) is calculated using the following equation: R = 100 (Wa − Wb) / Wb.

Thickness: The thickness of tablets is measured with a calibrated dial calliper by randomly selecting five tablets from each batch. Acceptable thickness variation should not exceed ±5% of the standard value.

Weight variation test: Twenty tablets are randomly selected and weighed individually as well as collectively using an electronic balance to determine the mean tablet weight. Each tablet weight is recorded, and the standard deviation is calculated for each batch. The average weight of a single tablet is obtained from the total collective weight.

$$\text{Weight variation} = \frac{\text{Individual wt} - \text{Average wt.}}{\text{Average Wt.}} \text{X100}$$

Disintegration test: One tablet is placed into each tube of the disintegration apparatus, and a disc is added to each tube. The assembly is then immersed in a beaker containing buffer and the apparatus is operated for 3 minutes. Water maintained at a temperature of 26°C is used as the disintegration medium.

Uniformity of dispersion: This test is applicable only to dispersible tablets. One tablet is placed in 100 mL of water and gently stirred until complete dispersion occurs. The resulting dispersion should be smooth and capable of passing through a sieve with a nominal mesh aperture of 710 µm (sieve No. 22).

Drug content uniformity: The percentage drug content uniformity is determined using a spectrophotometric method.

***In-vitro* dissolution study:** In-vitro dissolution testing is performed using the USP XXIII tablet dissolution apparatus (paddle method). The study is carried out in 900 mL of phosphate buffer (pH 6.8) at a rotation speed of 100 rpm for 20 minutes, with the temperature maintained at 37°C. One tablet from each formulation is used for the study. At predetermined time intervals, 1 mL samples are withdrawn from the dissolution medium and appropriately diluted to obtain a concentration of 10 µg/mL. The withdrawn volume is replaced with an equal amount of fresh dissolution medium to maintain sink conditions. The absorbance of the samples is measured using a UV spectrophotometer.

Scanning Electron Microscopy (SEM): Scanning electron microscopy is employed to evaluate particle size distribution, surface morphology, structural characteristics of fractured or sectioned surfaces. SEM is widely used to obtain three-dimensional surface images based on secondary electron emission. Examination of the surface of polymeric drug delivery systems using SEM provides valuable information regarding the porosity and microstructural features of the formulation.

Stability study: Stability testing is conducted to assess changes in the quality of a drug substance or drug product over time under the influence of environmental factors such as temperature, humidity, and light. These studies help to establish recommended storage conditions and determine the shelf life of the product. According to ICH guidelines, the duration and storage conditions for stability studies are specified as follows:

Long-term testing: 25 ± 2°C / 75% RH ± 5% for 6 months

Accelerated testing: 40 ± 2°C / 75% RH ± 5% for 6 months

Table No. 01: RECENT STUDIES REPORTED.[15-33]

SI. NO	AUTHOR	METHOD	EXCIPIENTS	OBSERVATION
1	Shirsekar *et al.*,(2024**)**	Direct compression method.	Isabgol, Crospovidone, Sodium Starch Glycolate	The study Empagliflozin orodispersible tablets prepared by direct compression using natural superdisintegrants exhibited rapid disintegration, acceptable tablet properties, and improved patient compliance with immediate onset of action.
2	Alburyhi *et al*., (2023)	Wet granulation method	Sodium Starch Glycolate, Croscarmellose Sodium, Avicel PH101, Crospovidone, Aerosil	The study Famotidine ODTs formulated with superdisintegrants showed rapid disintegration and enhanced dissolution, with F4 and F6 being

				best (DT 23.97 s & 10 s; drug release 106.48% & 92.82% in 5 min) for quick onset and improved bioavailability without water.
3	Panda *et al.*, (2019)	Direct compression method	Cajan seed polysaccharide, sodium starch glycolate.	The drug-excipient interactions were characterized by Fourier transform infrared studies. The Optimized formulation F5 containing 15% polysaccharide showed wetting time of 118.7 seconds with 105.3 seconds of disintegration time and 95.61% dissolved in 3 min.
4	Sheeba *et al.*, (2020)	Direct compression method	Sodium starch glycolate, Crospovidone, Gellan gum.	FTIR studies showed that no any chemical interaction between drugs and excipients. The in vitro drug release study revealed that formulation F9 combination of both crospovidone and karya gum was the most successful formulation and disintegrate time within 13 seconds and drug release within 10 min. The drug release from the best formulations followed first-

				order kinetics, which is concentration-dependent. Short terms stability studies of the tablet for three months showed non-significant drug loss.
5	Kumar *et al.*, (2022)	Direct compression method	Sodium starch glycolate , Ac-Di-Sol.	The study Meclizine HCl solid dispersion ODTs prepared by direct compression using natural/synthetic superdisintegrants showed good flow and tablet properties with dispersion <90 s, and optimized formulation (FMODs3) achieved 99.99% drug release in 30 min following first-order kinetics
6	Lakshmi *et al.*, *(*2017)	Direct compression method	Ipomoea batatas starch, Amorphophallus campanulatus starch, crosspovidone.	Levocetirizine ODTs prepared with starch citrate–modified natural starch (5–10%), especially with crospovidone ± Ludiflash, showed rapid disintegration and high drug release, making it a promising superdisintegrant for direct compression.
7	Sindhu *et al.*, (2022)	Direct compression method	Crospovidone, Guar gum	The results were announced that tablet containing 15% crospovidone (F3) showed short

				disintegration time (12) with maximum drug release (99.2%) in 15 min. DSC and FTIR results showed no evidence of interaction between the drug and superdisintegrants.
8	Dasari *et al.*, (2024)	Direct compression method	Croscarmellose sodium.	The optimized formulation demonstrated a disintegration time of 46.25±0.85 sec and a dissolution rate of 100.50±2.50. Compendial tests remained stable without any significant fluctuations after the stability study. Also, the taste of the drug was pleasant after taste
9	Prashanthievangelin *et al.*, (2020)	Direct compression method	Starch citrate, Sodium Starch glycolate, Croscarmellose sodium.	The study Atenolol ODTs prepared by direct compression using a combination of croscarmellose sodium and crospovidone (F5) showed fastest disintegration and highest drug release, achieving effective fast-dissolving tablets with improved patient compliance.
10	Rani *et al.*, (2022)	Direct compression method	Calcium complexed tamarind gum.	The Modified calcium-complexed tamarind seed

				gum (F5) showed superior superdisintegrant activity with faster disintegration (37±2 s) than marketed croscarmellose sodium (48±2 s), making it promising for future fast-dissintegrating tablet formulations.
11	Albburyhi *et al.*, (2024)	Direct compression method	Croscarmellose Sodium, Crospovidone.	The optimized formulation F10 showed the fastest disintegration and highest drug release, confirming it as the best performing Domperidone ODT.
12	Prajapati *et al.*, (2015)	Spray drying method	Crosspovidone, Kyron T314, Ac-Di-Sol, Sodium Starch glycolate	The study Polymer-based spray-dried dispersion significantly improved the solubility and dissolution of Cilnidipine, and formulation F9 with Kyron T-314 showed rapid release, short-term stability, and suitability as an effective orodispersible tablet.
13	Dhobale *et al.*, (2024)	Direct compression method	Crospovidone, Sodium Starch glycolate.	The study Formulation S7 showed the best performance with fastest disintegration (16

				sec) and highest drug release (102.89% in 5 min), making it the optimal ODT of ticagrelor for improved bioavailability.
14	Neupane *et al.*, (2023)	Direct compression method	Mango Peel Pectin, Dehydrated Banana Powder, Gellan Gum	The optimized formulation F6 containing banana powder showed a better drug release profile of 98.94 % at the end of 12 minutes with the disintegration time of 21 seconds.
15	Sahoo *et al.*, (2016)	Wet granulation method	Agar	The study Granisetron HCl ODTs were successfully formulated by wet granulation using Plantago ovata, with F4 showing best drug release and dispersion time and confirmed drug–excipient compatibility, improving patient compliance and rapid onset.
16	Patel *et al.*, (2022)	Direct compression method	β-cyclodextrin, Hibiscus Rosa-Senesis Mucilage.	The study Etoricoxib ODTs prepared by direct compression using Hibiscus rosa-sinensis mucilage and β-cyclodextrin inclusion complex showed improved dissolution, with optimized F5 giving fast disintegration (30±1.25 s) and

				highest drug release (95.84±2.08% in 30 min) and good stability.
17	Throat *et al.*, (2017)	Direct compression method	Croscarmellose sodium, Ispaghula husk, Sodium starch glycolate.	The study Ondansetron fast disintegrating tablets prepared by direct compression with 6% sodium starch glycolate (O1) showed best performance with least disintegration time (24 s) and maximum drug release (98.1% within 30 min).
18	Swain *et al.*, (2015)	Direct compression method	Crospovidone, Crosscarmellose, sodium, Sodium carboxy methyl cellulose.	Ibuprofen ODTs formulated with crospovidone (optimized F3) showed faster orodispersion, improved drug release with good stability, indicating feasible large-scale production and enhanced bioavailability**.**
19	Naik *et al.*, (2016)	Direct compression method	Sodium starch glycolate, Croscarmellose sodium.	OLZ ODTs were successfully prepared by co-processed super disintegrants and evaluated. From the results, it could be concluded that the formulation F8 and F9 showed maximum drug release within short period of

				time i.e. 2 min, hence there is a lot of scope for in-vivo studies.
20	Darade *et al.*, (2017)	sublimation method	Camphor, Menthol, Thymol.	Sublimation improved tablet porosity, significantly reduced disintegration time, and maintained acceptable hardness and friability, with formulation F3 showing optimal performance.

APPLICATION OF ORAL DISPERSIBLE TABLET

Orally dispersible tablets (ODTs) have some very practical, patient-friendly applications.

- **Pediatric patients** – easy to administer for children who have difficulty swallowing conventional tablets.
- **Geriatric patients –** ideal for elderly patients with dysphagia or reduced saliva production.
- **Psychiatric and bedridden patients –** improves compliance where swallowing is problematic.
- **Patients with nausea or vomiting –** tablets disintegrate quickly without the need for water.
- **Emergency and rapid-action therapy –** provides faster onset of action due to rapid disintegration and absorption.
- **Improved patient compliance** – pleasant taste and ease of administration enhance acceptance.
- **Travel and convenience** – can be taken anytime, anywhere, without water.

CONCLUSION

Orodispersible tablets represent a promising and patient-centric oral dosage form offering rapid disintegration, improved bioavailability, and enhanced therapeutic onset. The selection of suitable superdisintegrants and manufacturing techniques plays a critical role in achieving optimal tablet performance. Recent research highlights the effectiveness of both natural and

synthetic superdisintegrants in producing robust ODTs with excellent dissolution characteristics. Despite challenges related to mechanical strength, taste masking, and moisture sensitivity, advancements in formulation technologies continue to expand the applicability of ODTs. Overall, ODTs hold significant potential for improving drug therapy outcomes and patient adherence.

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