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# DISPERSIBLE AND ORODISPERSIBLE TABLETS DELIVERY SYSTEMS FOR ANTIBACTERIALS DEVELOPMENT

**Mahmoud Mahyoob Alburyhi[1]*, Maged Alwan Noman[1], Abdalwali Ahmed Saif[1] and Abdu Faisal Alemad[2]**

[1]Professor Dr. of Pharmaceutics and Industrial Pharmacy, Department of Pharmaceutics and Industrial Pharmacy, Faculty of Pharmacy, Sana'a University, Sana'a, Yemen.

[2]B.SC, Department of Pharmaceutics and Industrial Pharmacy, Faculty of Pharmacy, Sana'a University, Sana'a, Yemen.

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***Corresponding Author**
**Dr. Mahmoud Mahyoob Alburyhi**
Professor Dr. of Pharmaceutics and Industrial Pharmacy, Department of Pharmaceutics and Industrial Pharmacy, Faculty of Pharmacy, Sana'a University, Sana'a, Yemen.

## ABSTRACT

The most common and preferable route of drug administration is through the oral route. Novel oral drug delivery systems aim to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for ease of administration and to achieve better patient compliance. Orodispersible tablets (ODTs) are among these systems, the concept of Orodispersible tablets is to disperse the tablets within seconds in the mouth in the presence of saliva with no need for water, and without any difficulty of swallowing, due to the presence of superdisintegrants in their formulation. Solid dose forms known as Orodispersible tablets (ODTs) dissolve in the mouth in less than1min, allowing for water less swallowing. Orodispersible tablets results in rapid dissolving and, thus, a rapid start of action. Pediatrics, the elderly, psychotic, dysphagic, bedridden, comatose, young patients with under developed neurological and muscular systems, patients with hand tremors, and patients who travel frequentlyare among the particular populations for which Orodispersible tablets ODTs are an appropriate dosage form. It offers reduced packing size, precise dosing, superior stability, and convenience of manufacture. Since water is not needed during transportation, self-administration is feasible. Orodispersible tablets ODTs are a cost- effective way to distribute medications. When a medicine is absorbed from the buccal cavity, Orodispersible tablets ODTs are a crucial drug delivery method. For the creation of

Orodispersible tablets ODTs, a variety of scientific methods have been used, including as molding, direct compression, spray drying, sublimation, and freeze drying. Orodispersible tablets ODTs are becoming more readily accessible as over-the-counter medications for the treatment of a wide range of illnesses. The objectives of this article are reviewing dispersible tablets and Orodispersible tablets ODTs benefits, drawbacks, formulation difficulties, manufacturing processes, patented technologies, commercial formulations, and evaluation testing.

**KEYWORDS:** Orodispersible tablets, Dispersible tablets, Superdisintegrants, Evaluation methods, Development.

## INTRODUCTION

The basic aim behind development of any drug delivery system (DDS) is to achieve a safe and effective therapy for the human being.[1] Oral administration is the most desirable approach for delivery of pharmaceuticals in different dosage forms like capsules, tablets, syrups, suspension, and solution because of greater flexibility in design of formulations. It is a highly recommended route due to ease of manufacturing because it does not require sterile conditions, it is cost-effective due to no special packaging requirements, and there is patient compliance in addition to greater surface area provided by mucosal lining enhancing adsorption and absorption, but there are some hurdles of hepatic first-pass metabolism, less aqueous solubility and reduced dissolution rate, drug degradation at acid gastric environment, and by gastric enzymes prohibiting the administration of certain classes of drugs especially peptides and proteins. So, achieving greater solubility, stability, and higher oral bioavailability of many drugs became challenging for pharmaceutical researchers.[2] Oral solid dosage forms are administered for attaining a local therapeutic effect in the mouth, throat, digestive tract or for a systemic effect in the body after oral or gastrointestinal absorption. For preparing oral solid dosage forms, active ingredients and suitable excipients can be milled, dried, encapsulated, blended, granulated or tableted. Various oral solid dosage forms such as tablets, capsules, lozenges, powders and granules etc.[3] Dispersible tablets are defined as uncoated or film-coated tablets intended to be dispersed in water prior to administration, which provides homogeneous dispersion. Usually, a dispersible tablet is dispersed in water and the subsequent dispersion is given to the patient. Dispersible tablets are a substitute to conventional a formulation with precise dosing.[4] Orodispersible tablets (ODTs), also referred to as orally disintegrating or fast-disintegrating tablets, are uncoated

tablets intended to be placed in the mouth where they disperse rapidly before being swallowed.[5]

**Oral administration dosage forms[6,7]**

**Liquid dosage forms** e.g. syrup, solution, suspension, emulsion.

**Solid dosage forms**

- **Tablets:** They are defined as compressed powder forms and there many types such as:
  - Standard Tablets: Basic form, often coated for protection.
  - Enteric-Coated Tablets: Designed to dissolve in the intestine, not the stomach.
  - Sustained-Release Tablets: Release medication over time.
  - Controlled-Release (CR): Release the drug at a predetermined rate, maintaining therapeutic levels over time.
  - Dispersible tablets are oral dosage forms designed to dissolve in water before administration, making them easier to swallow, especially for children and elderly patients. They dissolve quickly, improving drug absorption and providing a flexible dosing option. Commonly used for medications like paracetamol and antibiotics, these tablets enhance patient compliance while ensuring stability and palatability.
  - Orally Disintegrating Tablets (ODTs): they are defined as tablets Designed to dissolve quickly in the mouth without the need for water, enhancing convenience for patients who have difficulty swallowing. There are commonly used for pediatric and geriatric populations.
  - Effervescent Tablets are defined as tablets contain acids and bases that react with water to produce carbon dioxide, creating a fizzing effect when dissolved. It can enhance solubility and palatability, often used for vitamins and antacids.
  - Multilayer Tablets are defined as tablet of multiple layers that may contain different drugs or different release profiles. For example: Tablets that combine immediate and extended release of two separate active ingredients.
- **Capsules:** They are defined as gelatin shells containing powdered or liquid medication and they are classified into:
  - Hard Capsules: Typically contain dry powders.
  - Soft Capsules: Usually contain liquid formulations.
- **Powders** are defined as dry, powdered forms that need to be mixed with a liquid before administration. E.g. Antibiotic powders for reconstitution.

- **Granules** are small, free-flowing particles used in pharmaceutical formulations, typically composed of active ingredients and excipients. They are larger than powders, which improves their flowability and handling during manufacturing. Granules can enhance the dissolution rate of medications and can be formulated for immediate or controlled release. Commonly used in oral medications, they can be compressed into tablets, filled into capsules, or mixed with liquids for administration, making them a versatile option in drug delivery systems.

**Tablet dosage form**

Tablets are one of the most common and versatile forms of oral dosage medication, designed to deliver precise doses of active ingredients in a solid form. They are typically composed of a mixture of the active pharmaceutical ingredient (API) and various excipients that aid in the manufacturing process, enhance stability, and improve patient acceptance. Tablets can be classified into several categories, including standard tablets, coated tablets, and specialized formulations such as sustained-release or orally disintegrating tablets. The manufacturing process often involves compression of powdered ingredients, which can be tailored to achieve desired release characteristics—such as immediate or controlled release—allowing for flexibility in treatment regimens. Additionally, the tablet form can be easily mass-produced, making it cost-effective and widely accessible. Tablets are also designed to withstand various environmental conditions, ensuring stability and efficacy over their shelf life. Overall, their convenience, dosage accuracy, and adaptability make tablets a preferred choice for both patients and healthcare providers in the management of various health conditions.

**Dispersible tablets dosage form**[1],[4],[8-10]

Dispersible tablets are a unique form of oral dosage designed to dissolve or disperse in water before administration, making them easier to ingest, especially for individuals who have difficulty swallowing, such as children and the elderly. These tablets are formulated with excipients that facilitate rapid dissolution, typically dissolving within minutes when mixed with a small amount of water. The primary advantages of dispersible tablets include improved bioavailability, as the active ingredients can be absorbed more quickly once dissolved, and the flexibility of dosing, allowing for adjustments based on individual patient needs. Commonly used for medications such as analgesics, antibiotics, and antipyretics, dispersible tablets often feature taste-masking agents to enhance palatability. Their

convenience and effectiveness make them an important option in pharmaceutical formulations, promoting better medication adherence and patient compliance.

**Oral Disintegrating Tablets (ODTs)[11-15]**

Oral disintegrating tablets (ODTs) are a specialized form of medication designed to dissolve rapidly in the mouth without the need for water, providing a convenient and effective way to administer drugs. These tablets are formulated with superdisintegrants that facilitate quick disintegration upon contact with saliva, typically dissolving within seconds to minutes. ODTs are particularly beneficial for individuals who have difficulty swallowing traditional tablets, such as children, the elderly, or patients with certain medical conditions. They can enhance patient compliance by eliminating the need for water and improving the overall experience of taking medication. ODTs are often used for a variety of medications, including analgesics, antihistamines, and antiemetics, and they can be formulated to include flavoring agents to improve taste. The rapid onset of action associated with ODTs can also lead to quicker therapeutic effects, making them a valuable option in many treatment regimens. Overall, oral disintegrating tablets combine convenience, ease of use, and effective drug delivery, making them a popular choice in modern pharmacotherapy.

**Ideal Characteristics of Dispersible Tablets[8],[11],[15-16]**

Dispersible tablets possess several ideal characteristics that enhance their effectiveness and usability. Here are the key attributes:

1. Rapid disintegration
- Should dissolve quickly in water, typically within a few minutes, to facilitate easy ingestion.
2. Taste masking
- Must have a pleasant flavor or taste-masking agents to improve palatability, especially for pediatric formulations.
3. Stable formulation
- Should maintain chemical stability of the active ingredients over its shelf life, resisting degradation from moisture and light.
4. Appropriate particle size
- Granules should be of suitable size to ensure uniform dispersion and quick dissolution in water.
5. Good flowability

- The formulation should allow for consistent manufacturing processes, ensuring uniformity in weight and dosage.

6. Easy handling

- The tablets should be easy to handle and package, minimizing the risk of breakage or damage.

7. Non-Hygroscopic

- Should ideally be non-hygroscopic to prevent moisture absorption, which could affect stability and performance.

8. Flexible dosing

- Formulations should allow for easy dose adjustments, facilitating personalized treatment options.

9. Compatibility

- Should be compatible with a wide range of active pharmaceutical ingredients and excipients to ensure effective formulation.

These characteristics contribute to the overall effectiveness, safety, and patient acceptance of dispersible tablets, making them a valuable option in pharmaceutical formulations.

**Special features of dispersible tablets**[4],[15],[17-19]

Dispersible tablets possess several special features that enhance their usability and effectiveness as an oral dosage form. One of the most notable characteristics is their ability to dissolve or disperse rapidly in water, making them particularly suitable for patients who have difficulty swallowing, such as children and the elderly. This rapid disintegration is facilitated by the inclusion of superdisintegrants that promote quick breakdown upon contact with liquid. Additionally, dispersible tablets are often flavored to improve palatability, which further encourages adherence to medication regimens. They can also provide improved bioavailability since the active ingredients are more readily available for absorption once dissolved. The formulation allows for flexible dosing, enabling healthcare providers to adjust the amount of medication based on individual patient needs. Overall, the combination of these features makes dispersible tablets a valuable option in modern pharmacotherapy.

**Advantages of dispersible tablets**[1],[20-22]

Dispersible tablets offer several advantages that make them a preferred choice in pharmaceutical formulations. Here are the key benefits:

1. Ease of administration: Dispersible tablets dissolve in water, making them easier to swallow for patients who have difficulty with traditional tablets, such as children and the elderly.
2. Rapid dissolution: They typically dissolve quickly, often within minutes, allowing for faster onset of action and improved bioavailability of the active ingredients.
3. Improved palatability: Many dispersible tablets are flavored or sweetened, enhancing their taste and encouraging adherence, especially in pediatric patients.
4. Flexible dosing: They can be easily adjusted in dosage by varying the amount of water used for dispersion, allowing for tailored treatment plans based on individual patient needs.
5. Enhanced bioavailability: The rapid dissolution of the active ingredients in water can lead to improved absorption in the gastrointestinal tract, potentially increasing the therapeutic effect.
6. Convenient for travel: Dispersible tablets do not require water for swallowing, making them convenient for use outside the home or in situations where water may not be readily available.
7. Stability: They can be formulated to provide stability and protection to sensitive active ingredients, ensuring they remain effective over their shelf life.
8. Reduced risk of choking: by providing a liquid form upon dispersion, they minimize the risk of choking, which is particularly important for vulnerable populations.

Overall, dispersible tablets combine convenience, effectiveness, and patient-friendly characteristics, making them a valuable option in modern medicine.

**Disadvantages of dispersible tablets**[1],[17],[22-24]

- Stability issues: Dispersible tablets can be more susceptible to moisture absorption, which may affect the stability and shelf life of the active ingredients.
- Taste masking challenges: Formulating dispersible tablets to mask the unpleasant taste of certain active ingredients can be difficult, potentially impacting patient acceptance.
- Complex manufacturing process: The production of dispersible tablets may require specialized equipment and techniques, increasing manufacturing complexity and costs.
- Limited formulation options: Not all active ingredients are suitable for use in dispersible tablet formulations, which can limit their application in certain therapeutic areas.
- Dosing accuracy: The dosage may vary if the tablet is not fully dissolved or if the powder is not evenly distributed in the liquid, leading to potential dosing inaccuracies.

- Potential for caking: If stored improperly, dispersible tablets may cake or clump together, making them difficult to use.
- Shorter stability compared to traditional tablets: because they are designed to disintegrate in liquid, their stability may be shorter than that of conventional tablets.

**Recommendations for using dispersible tablets**[1],[25,26]

1. Dispensing guidelines, amount: Use a small volume of liquid (5 to 10 ml) such as clean water or milk for dispersion.
2. Dispersing Process, stirring: Gently stir the liquid to help the tablet disperse completely before swallowing.
3. Maximize medication intake, rinsing: To ensure you receive the full dose, rinse the container with a bit more water or milk after swallowing and consume the rinse.
4. Handle with Care, fragility: be cautious when handling dispersible tablets, as they are more fragile than regular tablets and can break easily.
5. Immediate use required, stability: use the tablets immediately after removing them from their blister packaging, as their stability outside the packaging cannot be guaranteed

**Mechanism of drug release**[4],[25],[27]

The mechanism of drug release from dispersible tablets involves several interconnected processes. Initially, upon contact with liquid, the tablets undergo disintegration facilitated by disintegrants, which promote rapid swelling and fragmentation. This is followed by the dissolution of the released drug particles into the surrounding medium, where the rate of dissolution is influenced by the drug's solubility, particle size, and the viscosity of the liquid. Once dissolved, the drug molecules diffuse through the medium, governed by concentration gradients and temperature. Additionally, the hydration of excipients can further enhance disintegration and dissolution. Factors such as formulation composition, pH, ionic strength, and particle size play critical roles in determining the overall release profile, making it essential to carefully design dispersible tablets for optimal therapeutic efficacy.

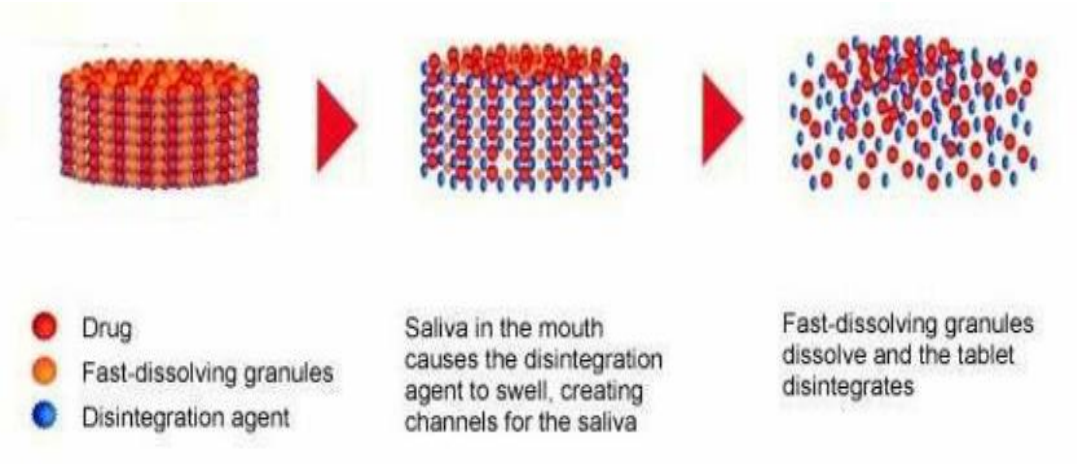


**Fig. 1: Conceptual Diagram of Disintegration and Dissolution.**

**Basic components of dispersible tablets**[1],[28-31]

1. Active Pharmaceutical Ingredient (API)

- The therapeutic agent responsible for the intended effect.
- Example: cefixime in antibiotic dispersible tablets.

2. Excipients: the excipients that may be used in formulation of dispersible tablets are summarized in Table 1.

**Table 1: List of Excipients Used in the Formulation of Dispersible and Orodispersible Tablets.**

| Excipient | Function | Example |
|---|---|---|
| Superdisintegrants | Facilitate the breakdown of the tablet in water. | Sodium starch glycolate, crospovidone, croscarmellose Na |
| Binders | Help hold the tablet together | Gelatin, glucose, lactose, MC, EC, HPMC, HPC starch, Povidone, copovidone, Sodium alginate, CMC, Acacia, |
| Diluents (Fillers) | Provide bulk to the tablet | Lactose, Spray dried lactose, MCC, Mannitol, Sorbitol, Dibasic calcium phosphate. |
| Flavoring agents | Improve taste for better patient compliance | Artificial or natural flavors |
| Sweeteners | Produce a palatable dosage form | Aspartame, sucralose, or natural sweeteners like stevia |
| Colorants | Improve the aesthetic appeal of the tablets. | Artificial colorants or natural colorants derived from plants |

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| Lubricants | essential for reducing friction during the tablet compression process. They help prevent sticking to the punches and dies, ensuring smooth ejection of tablets. | Insoluble- Steric acid, Magnesium stearate, Talc, Paraffin, Soluble- SLS, Sodium benzoate, PEG. |
| Glidants | Glidants improve the flow properties of the powder mixture during the manufacturing process. They reduce interparticle friction, which helps in achieving uniformity in tablet weight and content. | Colloidal Silicon dioxide, Corn starch, Talc etc. |

**Challenges in formulation of rapid dispersible tablets**[4],[32,33]

- Disintegration time: Achieving a fast disintegration time is critical for patient compliance. Balancing the use of disintegrants without compromising tablet integrity can be challenging.
- Taste masking: Many active pharmaceutical ingredients (APIs) have an unpleasant taste. Effective taste masking without affecting the tablet's disintegration and dissolution can be difficult.
- Stability of the active ingredient: Some APIs are sensitive to moisture, light, or temperature. Ensuring stability throughout the shelf life while maintaining efficacy poses a significant challenge.
- Manufacturing process: The choice of manufacturing method (e.g., direct compression vs. wet granulation) can affect the final product's quality. Each method has its own set of challenges regarding consistency and scalability.
- Excipient interaction: Compatibility between the API and excipients is crucial. Incompatible excipients can lead to reduced efficacy, stability issues, or changes in bioavailability.
- Moisture sensitivity: Rapid dispersible tablets must be formulated to withstand humidity and moisture, which can lead to caking or degradation of the product.
- Mechanical properties: Ensuring the tablets have adequate hardness, friability, and tensile strength while remaining sufficiently porous for rapid dispersion is a balancing act.
- Cost of ingredients: high-quality excipients and APIs can increase production costs. Finding a cost-effective formulation without compromising quality is a challenge.

- Regulatory compliance: meeting regulatory standards for manufacturing, stability testing, and labeling can be complex, especially for new formulations.

Technologies used to manufacture rapid dispersible tablets are summarized in Table 2.

**Table 2: Technologies Used to Manufacture Dispersible and Orodispersible Tablets.**

| | **Conventional Techniques** | | |
|---|---|---|---|
| **Sr. No** | **Method** | **Definition** | **Ref** |
| 1 | Direct Compression | Direct compression is a traightforward method where the active armaceutical ingredient (API) and excipients are mixed and compressed into tablets without additional processing. This technique is cost-effective and preserves the stability of heat-sensitive ingredients, making it a popular choice for formulating rapid dissolving tablets. | [29],[34] |
| 2 | Wet Granulation | Wet granulation involves mixing the API and excipients with a liquid binder to form granules, which are then dried and compressed into tablets. This method improves the flow properties of the powder blend and allows for better content uniformity, making it suitable for a wide range of formulations | [35] |
| 3 | Melt Granulation | In melt granulation, a binder is melted and mixed with the powder blend to form granules, which are then cooled and compressed into tablets. This technique can enhance the solubility of poorly soluble drugs and reduces the need for solvents, facilitating a more efficient manufacturing process. | [36] |
| 4 | Sublimation | The sublimation technique is utilized in the preparation of dispersible tablets (DTs) by incorporating sublimable excipients (such as camphor or menthol) in the formulation. After compressing the mixture into tablets, the sublimable agents are vaporized through heat or vacuum treatment, creating a porous structure. This enhances the tablets' ability to disintegrate and dissolve rapidly in water, improving the onset of action and overall patient compliance, particularly for those who have difficulty swallowing traditional tablets. | [37] |
| 5 | Lyophilization (Freeze-Drying) | Lyophilization involves freezing the formulation and reducing the surrounding pressure to allow for the sublimation of frozen water. This results in a highly porous structure that dissolves rapidly in water, making it an effective method for formulating heat-sensitive drugs. | [38] |
| 6 | Spray Drying | Spray drying involves dissolving the API in a | [39] |

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| | | solvent, which is then sprayed into a hot chamber where the solvent evaporates, leaving fine particles. This method produces uniform and fine particles that can be compressed into tablets, enhancing the solubility of poorly soluble drugs. | |
| 7 | Cotton Candy Process | The cotton candy process is a novel method for producing rapidly dissolving tablets, named for its resemblance to the fluffy texture of cotton candy. This technique utilizes a rotating mechanism to create a matrix of saccharides or polysaccharides through instant melting and spinning, resulting in a floss-like crystalline structure. The matrix is then moderately recrystallized to enhance its flow and compressibility. Active pharmaceutical ingredients are blended into this candy floss matrix, which is subsequently ground and compressed into tablets. This method allows for the incorporation of high drug doses while providing improved mechanical strength. However, the high processing temperatures involved may limit its application for heat-sensitive compounds. | [40] |
| 8 | Tablet Molding Method | The tablet molding method involves wetting, dispersing, or dissolving the drug in a solvent to create a mixture that is then molded into tablets using a lower compression pressure than conventional methods. This process allows the solvent to evaporate at room temperature, resulting in a highly porous structure as the molded tablets are air-dried. The reduced compressive strength compared to traditional tablets enhances disintegration and dissolution rates. To further optimize the dissolution, the powder mixture can be sieved through a very fine screen before molding, ensuring a uniform particle size and improved solubility of the final product. | [41] |
| B | Novel Technologies | | |
| 1 | Zydis Technology | R.P. Scherer's patented Zydis technology revolutionized the pharmaceutical industry by introducing the first commercially available fast-dissolving tablet. This innovative technology offers a convenient and rapid drug delivery system, particularly beneficial for individuals with swallowing difficulties or those seeking discreet administration. Zydis tablets are produced through lyophilization or freeze-drying, resulting in a lightweight and delicate formulation that requires special packaging. | [42],[43] |

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| | | These tablets dissolve rapidly upon contact with saliva, eliminating the need for water. To enhance patient experience, Zydis formulations incorporate flavors and sweeteners to mask unpleasant tastes and utilize techniques like micro-encapsulation and ion exchange complexation to reduce bitterness. | |
| 2 | Advatab | Advatab tablets are designed to dissolve rapidly within 30 seconds. They are manufactured using polymer-coated drug particles evenly dispersed in a low-moisture, ultra-thin matrix. This unique formulation ensures quick disintegration and pleasant taste. Adva Tab tablets are produced using a patented lubrication system that applies lubricant only to the tablet's surface, resulting in strong, durable tablets suitable for both bottle and blister packaging | [4],[44] |
| 3 | Frosta Technology | Akina patented a technology known as Frosta, which involves compressing highly plastic granules at low pressure to create fast-dissolving tablets. These granules consist of three key components: a plastic material (malt dextrin and corn syrup solids), a water penetration enhancer (Mannogem EZ Spray), and a wet binder (sucrose, polyvinylpyrrolidone, and hydroxypropyl methylcellulose). Each component contributes to the tablet's rapid disintegration and enhanced strength. | [45] |
| 4 | Oraquick | K.V. Pharmaceuticals patented a microsphere technology known as micro-mask. This technology enhances the taste and performance of oral medications. By encapsulating the drug in microparticles, it improves the oral sensation, mechanical strength, and disintegration speed of the tablets. This process also allows for the creation of Oraquick rapid dispersible tablets, which use a patented taste-masking technology. The lower production temperature of Oraquick makes it suitable for heat-sensitive drugs compared to other similar technologies. | [46] |
| 5 | Pharmaburst Technology | SPI Pharma, based in New Castle, patented a technology called Pharmaburst ODT. This technology uses a patented disintegrating agent, Mannitol, combined with traditional tablet manufacturing aids to create orally disintegrating tablets (ODTs) that dissolve within 30-40 seconds. The process involves dry mixing of drugs, lubricants, and flavoring agents, followed by tablet compression. | [47] |
| 6 | Nano Crystal | Elan's patented NanoCrystal technology, also | [48] |

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| | Technology | known as Nanomelt, enhances the performance and properties of drugs. By significantly reducing particle size through a patented wet grinding technique, this technology increases the surface area of the drug particles. This increased surface area leads to faster dissolution rates, improving drug absorption and efficacy. NanoCrystal particles, typically less than 1000 nanometers in diameter, provide a more efficient and predictable way to enhance drug delivery | |
| 7 | Wow Tab Technology | Yamanouchi Pharmaceutical Co. patented the Wow tab technology, which enables tablets to dissolve rapidly without water. This technology utilizes a blend of high and low moldable saccharides to create tablets with suitable hardness and disintegration properties. Active ingredients can constitute up to 50% of the tablet weight. Wow tab tablets dissolve within 13 seconds or less and can be packaged in vials or blisters. | [49] |
| 8 | Flash Dose Technology | Fuisz Corporation patented the Flash Dose technology, which utilizes a self-powered, cut-shaped matrix resembling dental floss. This technology involves a unique spinning process to create a crystalline sugar structure, similar to cotton candy, into which the active drug is incorporated. The resulting tablets have a high surface area, allowing for rapid disintegration and dissolution upon contact with the tongue. By adjusting manufacturing conditions, the characteristics of the product, including the use of small saccharide spheres as drug carriers, can be customized. | [50] |
| 9 | Flashtab technology | Prographarm Laboratories patented the Flashtab technology, which involves granulating excipients using either dry or wet methods before compressing them into tablets. These tablets incorporate both disintegrating and swelling agents. Disintegrating agents like carboxymethyl cellulose (CMC) or cross-linked polyvinylpyrrolidone (PVP) and swelling agents such as starch, modified starch, and various cellulose derivatives are used to ensure rapid disintegration within one minute. Despite their quick disintegration, these tablets maintain adequate physical strength. | [51] |
| 10 | Durasolv Technology | Durasolv, a second-generation rapid-dissolving tablet technology developed by CIMA Lab, is an improvement on Orasolv. Durasolv tablets are significantly stronger due to higher compaction | [52] |

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| | | pressures during manufacturing. This added strength allows for more efficient and cost-effective production. Durasolv tablets can be packaged in traditional blister packs or glass vials. However, the high compaction pressures limit the maximum dose of active ingredient that can be incorporated into Durasolv tablets. | |
| 11 | Orasolv Technology | CIMA Lab introduced a direct compression technique that produces tablets with low compressive strength, leading to faster oral dissolution. Orasolv, a type of effervescent tablet, quickly dissolves in the mouth. The effervescent disintegrating agents mask the taste of the drug and disperse it in saliva. The effervescent mixture typically constitutes 18-27% of the tablet weight. Due to their soft and fragile nature, Orasolv tablets require special packaging. | [53] |

**Evaluation of dispersible tablets[53-56]**

**Physical tests**

1. **Hardness**

Measures the mechanical strength of the tablet to ensure the tablet can withstand handling and packaging.

2. **Friability**

Evaluates the tablets resistance to chipping or breaking during handling and shipping to ensure the tablets integrity.

3. **Weight variation**

Determines the uniformity of tablet weight to ensure consistent drug dosage.

4. **Thickness**

Measures the tablet thickness to impact the tablet's appearance and disintegration time.

5. **Disintegration time**

Measures the time taken for the tablet to disintegrate into smaller particles in a specified medium to ensure rapid drug release.

6. **Dispersion time**

Measures the time taken for the disintegrated particles to disperse completely in the specified medium to ensure rapid drug dissolution.

**Chemical tests**

**1. Drug content uniformity**

Assesses the uniformity of drug content in individual tablets to ensure consistent drug dosage.

**2. Related substances**

Identifies and quantifies impurities in the drug substance and the final product to ensure product quality and safety.

**In vitro dissolution studies**

- **Dissolution Rate and Extent**

Measures the rate and extent of drug release from the tablet to Predict drug absorption and bioavailability.

**Stability studies**

- **Accelerated and Long-Term Stability**

Evaluates the stability of the tablet under various conditions (temperature, humidity, light) to ensure product quality and shelf life.

In reviewing different previous studies of formulation Dispersible and Orodispersible tablets are summarized in Table 3.

**Table 3: Available Studies of Selective Formulation Dispersible and Orodispersible Tablets.**

| Drug (s) | Dosage Form | Title | Ref. No. |
|---|---|---|---|
| Cefpodoxime Proxetil and Roxithromycin | DTs | HME-assisted formulation of taste-masked dispersible tablets of cefpodoxime proxetil and roxithromycin | [57] |
| Cefpodoxime Proxetil | DTs | Development of Taste-Masked Oral Dispersible Tablets of Cefpodoxime Proxetil | [58] |
| Cefdinir | ODTs | Formulation and Evaluation of pH-Modulated Amorphous Solid Dispersion-Based Orodispersible Tablets of Cefdinir | [59] |
| Lamotrigine | ODTs | Formulation of Immediate Release Lamotrigine Tablets and Bioequivalence Study. | [60] |
| Fluconazole | ODTs | Preparation and advanced characterization of highly drug-loaded, 3D printed orodispersible tablets containing fluconazole | [61] |
| Moxifloxacin | ODTs | A hybrid framework of artificial intelligence-based neural network model | [62] |

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|---|---|---|---|
| | | (ANN) and central composite design (CCD) in quality by design formulation development of orodispersible moxifloxacin tablets: Physicochemical evaluation, compaction analysis, and its in-silico PBPK modeling | |
| Artemether-Lumefantrine and Amoxicillin Trihydrate | DTs | Evaluation of Oro-dispersible tablets (Artemether- Lumefantrine and Amoxicillin trihydrate) used for some common childhood diseases (Malaria and pheumonia) | [63] |
| Amoxicilin and Clavulanic Acid | ODTs | A Comprehensive Review on Amoxicilin and Clavulanic Acid as Potential Antibacterial Agent. | [64] |
| Cefixime | ODTs | Formulation and evaluation of orodispersible tablet of cefixime trihydrate by using fenugreek mucilage as a superdisintegrant. | [65] |
| Cefpodoxime Proxetil | DTs | Formulation and characterization of dispersible tablets of cefpodoxime proxetil: A cephalosporin antibiotic | [66] |
| Third Generation Cephalosporins | | Design of flexible dispersible tablet with high drug loading using quality by Design: Proof of concept study using third generation cephalosporins model drug | [67] |
| Triclosan | DTs | Formulation and evaluation of Triclosan dispersible tablets for oral hygiene | [68] |
| Co-Trimoxazole | ODTs | Formulation, in vitro characterization and optimization of taste-masked orally disintegrating co-trimoxazole tablet by direct compression | [69] |
| Roxithromycin | FDNFM | Fast dissolving nanofiber mat for the local antimicrobial application of roxithromycin in oral cavity | [70] |
| Cefpodoxime Proxetil | FDTs | Cefpodoxime proxetil fast dissolving tablets: comparative study | [71] |
| Isoniazid, Pyrazinamide, and Rifampicin | DTs | Design and optimization of a child-friendly dispersible tablet containing isoniazid, pyrazinamide, and rifampicin for treating tuberculosis in pediatrics | [72] |
| Cefixime Trihydrate | ODF | Development and characterization of orodispersible film containing cefixime trihydrate | [73] |
| Gemifloxacin Mesylate | ODTs | Formulation and Evaluation of Orally Disintegrating Taste masked Gemifloxacin Mesylate Tablet | [74] |
| Roxithromycin | ODTs | Orodispersible tablet Based on amorphous surface solid dispersions of Roxithromycin | [27] |
| Cefuroxime Axetil | DTs | Design and optimization of pediatric | [75] |

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| | | Cefuroxime axetil dispersible tablet Containing ion-exchange resin | |
| Metronidazole | ODTs | Design and characterization of taste masked metronidazole microcapsules and its utilization in the formulation of orodispersible tablets | [76] |
| Cefdinir | FDTs | Formulation and Evaluation of Fast Dissolving Tablets of Cefdinir by Employing Solid Dispersion | [77] |
| Azithromycin | DTs | Formulation and biopharmaceutical evaluation of bitter taste masking microparticles containing azithromycin loaded in dispersible tablets | [78] |
| Cefpodoxime | DTs | Design and Development of Taste Masked Cefpodoxime Dispersible Tablets | [79] |
| Cefuroxime Axetil | FDTs | Formulation development of fast dispersible tablet of Cefuroxime axetil | [80] |
| | DTs | Formulation and evaluation of Sultamicillin dispersible tablets | [81] |
| Moxifloxacin.HCL | FDTs | Formulation Development and Evaluation of Moxifloxacin.HCL Fast Dissolving Tablets | [82] |
| Amoxycillin Trihydrate | DTs | Preparation and evaluation of taste masked dispersible tablets of Amoxycillin trihydrate by using polyelectrolyte complex technique | [83] |
| Roxithromycin | DTs | Spray-Dried Microspheres of Roxithromycin for Formulating into Dispersible Tablets Using Central Composite Design | [84] |
| Co-Amoxiclav | DTs | Formulation and Evaluation of Co-Amoxiclav 228 and 312 mg Dispersible Tablets | [85] |
| Cefixime | DTs | Preparation and Evaluation of Cefixime Dispersible Tablets Using CoProcessed Excipients | [86] |
| Clindamycin Hydrochloride | ODTs | Development and optimization of taste-masked orally disintegrating tablets (ODTs) of clindamycin hydrochloride | [87] |
| Cefadroxil | DTs | Disintegrants combination: Development and optimization of a cefadroxil fast disintegrating tablet | [88] |
| Roxithromycin | ODTs | Formulation and Evaluation of Microspheres Based Oro Dispersible Tablets of Roxithromycin | [89] |
| Cefixime | DTs | Formulation Development and Evaluation of Cefixime Dispersible Tablets | [90] |
| Cefuroxime Axetil | DTs | Formulation Development and Evaluation of Taste Masked Cefuroxime Axetil | [91] |

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| | | Dispersible Tablets by Inclusion Complexation with B-Cyclodextrin Method | |
| Cephalexin Monohydrate | DTs | Formulation and Development of Taste Masked Dispersible Tablet of Cephalexin Monohydrate Using Ion Exchange Fibers and Resins | [92] |
| Clindamycin Hydrochloride | ODTs | Development and optimization of tasted-masked orally disintegrating tablets (ODTs of clindamycin hydrochloride) | [93] |
| Amoxycillin and Clavulanic Acid | | Development of Stable Formulation and Evaluation of Combination of Amoxycillin and Clavulanic Acid | [94] |
| Cefpodoxime | DTs | Formulation And Evaluation Of Dispersible Tablets Of Cefpodoxime Proxetil | [95] |
| Cefpodoxime Proxetil | DTs | Formulation Development and Evaluation of the Dispersible Tablet of Cefpodoxime Proxetil | [96] |
| Cefixime | RDTs | Formulation, Characterization and Evaluation of Taste-Masked Rapid Disintegrating Tablet of Cefixime by Ion Exchange Resin Technique | [97] |
| Ciprofloxacin | FDTs | Effect of superdisintegrants on formulation of taste masked fast disintegrating Ciprofloxacin tablets | [98] |
| Macrolide | MDTs | Formulation and Evaluation of Mouth Dissolving Tablets Containing a Macrolide Antibiotic | [99] |
| Ampicilin and Cloxacillin | DTs | Formulation and Characterization of Tasteless Dispersible Tablet Containing Ampicilin and Cloxacillin | [100] |
| Cephalexin | MDTs | Design and Development of Mouth Dissolving Tablet of Cephalexin | [101] |
| Macrolide | FDTs | Formulation and Evaluation of Taste Masked Fast Dissolving Tablets and Dry Suspension of Some Macrolide Antibiotics by Various Techniques | [102] |
| Fluoroquinolone | ODTs | Formulation and Evaluation of Orodispersible Tablets of Fluoroquinolone Derivative | [103] |
| Gemifloxacin | FDTs | Development and Evaluation of Fast Dissolving Tablets Containing Gemifloxacin | [104] |
| Amoxycillin Sodium plus Cloxacillin Sodium | DTs | Formulation, Evaluation and Validation of Dispersible tablet of Amoxycillin Sodium plus Cloxacillin Sodium | [105] |
| Roxithromycin | | Impact of pharmaceutical dosage form on stability and dissolution of roxithromycin | [106] |

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| Ornidazole | ODTs | Formulation and Evaluation of Orodispersible Tablet of Ornidazole | [107] |
| Atifloxacin Sesquihydrate | RDTs | Formulation, Characterization and Evaluation of Rapid Disintegrating Tablet of Atifloxacin Sesquihydrate by ion exchange resin technique | [108] |
| Amoxycillin Trihydrate | | Effect of Dispersants on the Dissolution of Amoxycillin Trihydrate From Capsule Formulations | [109] |
| Artemisia Arborescence Extract | ODTs | Formulation and Evaluation of Antibacterial Orodispersible Tablets of Artemisia Arborescence Extract Herbal Product. | [110] |
| Ciprofloxacin | Tablets | Recent Innovations of Delivery Systems for Antimicrobial Susceptibility Study of Ciprofloxacin Biodegradable Formulations for Post-Operative Infection Prophylaxis. | [111] |
| Ceftriaxone | Tablets | Recent Innovations of Delivery Systems for Antimicrobial Susceptibility Study of Ceftriaxone Biodegradable Formulations for Post-Operative Infection Prophylaxis. | [112] |
| Amoxicillin Trihydrate and Clavulanic Acid | Oral Suspension | Stability Study of Six Brands of Amoxicillin Trihydrate and Clavulanic Acid Oral Suspension Present in Yemen Markets. | [113] |
| Ceftriaxone and Ciprofloxacin | Tablets | Preformulation Study of Ceftriaxone and Ciprofloxacin for Lipid Based Drug Delivery Systems. | [114] |

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| **DTs** | Dispersible tablets |
| **ODTs** | Oro-dispersible tablets |
| **RDTs** | Rapid dispersible tablets |
| **MDTs** | Mouth disintegrating tablets |
| **FDTs** | Fast disintegrating tablets |
| **NFOS** | Nanofibrous oral strip |
| **ODF** | Oro-disintegrating film |
| **FDNF** | Fast dissolving nanofiber mat |

## CONCLUSION

Orodispersible drug-delivery system server major benefit over the conventional dosage forms because the drug dispersible rapidly and dissolve in saliva without the use of water. Orodispersible tablets ODTs technologies is to optimize the porosity structure of the tablet matrix in order to ensure rapid Orodispersible tablets in the buccal cavity, as well as acceptable taste-masking qualities and enough mechanical strength. Future difficulties for

many Orodispersible tablets ODTs makers include improved mechanical strength, taste-masking potential, packaging variety, and cost reduction through the use of conventional machinery. Orodispersible tablets are therefore more widely accepted due to patient demand and the availability of different technologies. The methods and tools discussed in this article illustrate how current advancements in formulation and processing technology contribute to the endeavor to create dispersible tablets and Orodispersible tablets that dissolve in the mouth.

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