EJPMR, 2026, 13(7), 575-582 **Review Article** **Impact Factor: 8.158**

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

ISSN (O): 2394-3211
ISSN (P): 3051-2573
Coden USA: EJPMAG

REVIEW ON THE FORMULATION AND EVALUATION OF ORO DISPERSIBLE TABLETS

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DOI: https://doi.org/10.5281/zenodo.21294754

How to cite this Article: B. Mugundhan*[1], D. Sudhan[2]. (2026). Review on The Formulation and Evaluation of Oro Dispersible Tablets. European Journal of Pharmaceutical and Medical Research, 13(7), 575-582.

Article Received on 19/06/2026 **Article Revised on 09/07/2026** **Article Published on 10/07/2026**

ABSTRACT

Advances in pharmaceutical technology have led to the development of innovative drug delivery systems aimed at improving therapeutic efficacy and patient compliance. Among oral dosage forms, tablets remain the most commonly prescribed and administered formulations due to their convenience, accurate dosing, and cost-effective production. However, difficulties in swallowing conventional tablets among pediatric, geriatric, and dysphasia patients have prompted the development of Orodispersible Tablets (OD's), which offer rapid disintegration and ease of administration without the need for water. Tablets are solid dosage forms containing one or more active pharmaceutical ingredients (API s), with or without suitable excipient, and are prepared by compression or moulding methods. Depending on the manufacturing process, tablets can be broadly classified into compressed tablets and mould-ed tablets. Compressed tablets may be further categorized into directly compressible tablets, chew-able tablets, tablet triturates, and other specialized forms. In recent years, Orodispersible Tablets(ODTs) have gained significant attention as an advanced oral drug delivery system. These tablets are designed to disintegrate rapidly in the mouth, usually within a few seconds, without the need for water. DTs offer several advantages, including improved patient compliance, ease of administration for pediatric, geriatric, and dysphasia patients, rapid onset of action, and enhanced convenience. Owing to these benefits, the formulation and evaluation of or orodispersible tablets have become an important area of pharmaceutical research and development.

KEYWORDS: Orodispersible tablets, Etoricoxib, Natural Superdisintergrant.

INTRODUCTION[1]

Etoricoxib is a selective cyclooxygenase-2 (COX-2) inhibitor belonging to the nonsteroidal anti-inflammatory drug (NSAID) class and is marketed under the brand name Arcoxia. It is commonly prescribed for the management of pain and inflammation associated with various musculoskeletal disorders, including osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, and acute gout. Etoricoxib is classified as a Biopharmaceutics Classification System (BCS) Class II drug, exhibiting high permeability but poor aqueous solubility. Its aqueous solubility is approximately 0.00328 mg/mL, which contributes to low and variable oral bioavailability. Poor solubility often limits the dissolution rate of the drug, thereby affecting its absorption and therapeutic efficacy. Consequently, improving the solubility and dissolution characteristics of Etoricoxib is essential for enhancing its bioavailability and achieving optimal clinical outcomes.

Orally disintegrating tablets (O DTs) represent a significant advancement in oral drug delivery technology. These dosage forms are commonly known by various names, including fast-disintegrating tablets, fast-dissolving tablets, rapid-melt tablets, and quick-dissolve tablets. Despite the differences in terminology, all these formulations are designed to achieve rapid disintegration in the oral cavity without the need for water.

O DTs are solid pharmaceutical preparations formulated to break down quickly upon contact with saliva, producing a suspension or solution that can be swallowed easily. This characteristic makes them particularly suitable for patients who have difficulty

swallowing conventional tablets, such as pediatric, geriatric, and bedridden individuals. Following disintegration, the drug is released and becomes available for absorption, primarily through the gastrointestinal tract.

The United States Food and Drug Administration (US FDA) defines an orally disintegrating tablet as a solid dosage form containing active pharmaceutical ingredients that disintegrates rapidly, usually within a few seconds, when placed on the tongue. To provide regulatory guidance for the development of such formulations, the FDA issued the *Guidance for Industry: Orally Disintegrating Tablets* in 2008. According to this guidance, O DTs should generally exhibit an in vitro disintegration time of 30 seconds or less. In addition, the tablet weight is typically recommended not to exceed 500 mg. However, factors such as tablet dimensions, composition, and ingredient solubility are also important considerations that influence product performance, patient acceptability, and regulatory approval.

Due to their rapid disintegration, ease of administration, and improved patient compliance, orally disintegrating tablets have become an attractive alternative to conventional oral dosage forms and continue to gain widespread acceptance in modern pharmaceutical therapy.

The effectiveness of oro dispersal tablets is largely attributed to the inclusion of superintendents, which promote rapid tablet disintegration upon contact with saliva. As a result, the drug is released quickly and becomes available for absorption, leading to a faster onset of therapeutic effect. In addition, absorption through the oral cavity may partially avoid hepatic first-pass metabolism, thereby enhancing the bio-availability of certain drugs.

The growing interest in oro dispersal tablets is due to their numerous therapeutic and patient-related advantages. These formulations provide rapid drug action, improved bio-availability, enhanced patient compliance, and greater convenience of administration without the need for water. Furthermore, they are capable of incorporating relatively high doses of active pharmaceutical ingredients, making them a suitable and effective alternative to conventional oral dosage forms.

Recent advances in pharmaceutical technology have led to the development of several innovative methods for formulating orodispersible tablets. These techniques focus on improving key characteristics such as rapid disintegration, effective taste masking, pleasant mouthfeel, sugar-free composition, and manufacturing convenience. Commonly used approaches include direct compression, molding, extrusion, sublimation, spray drying, cotton candy processing, lyophilization, thin-film technology, and ionization.

Most of these methods enhance tablet porosity or utilize super disintegrates to achieve rapid tablet disintegration. The formulated ODs are subsequently evaluated for parameters such as hardness, variability, drug stability, mouthfeel, disintegration time, dissolution behavior, taste, drug absorption, and bio-availability to ensure optimal product performance and patient compliance.

Oro dispersible tablets ODTs[2]

Orodispersible tablets (ODs), also termed orally disintegrating tablets, are solid oral dosage forms engineered to disintegrate within the oral cavity without water — within less than 1 minute by USP standards, or under 3 minutes as defined by the European Pharmacopoeia — leaving a easily swallow-able residue. Their primary clinical rationale is addressing dysphagia, which disproportionately affects pediatric and geriatric populations, making conventional tablets impractical or unsafe. This review examines the ideal physiochemical characteristics, formulation advantages and limitations, manufacturing technologies, standardized evaluation parameters, and emerging research directions that define the current and future landscape of ODT development.

The oral route remains the most widely accepted route of drug administration owing to its non-invasive nature, patient compliance, and ease of self-medication. Orodispersible tablets (ODTs) are solid dosage forms engineered to disintegrate within the oral cavity in under one minute upon contact with saliva, leaving a soft, easily swallow-able residue — eliminating the need for water intake. Rapid disintegration is primarily achieved through the incorporation of super disintegrates, which absorb moisture and swell rapidly, facilitating prompt tablet breakdown. ODTs are particularly advantageous for pediatric and geriatric populations, where dysphagia and poor compliance with conventional tablets are persistent clinical concerns. Beyond convenience, ODT technology has demonstrated utility in enhancing the bio-availability of poorly soluble drugs through improved mucous contact and faster dissolution onset. Established manufacturing technologies include direct compression, freeze-drying (lyophilization), sublimation, mass extrusion, and the cotton candy process — each offering distinct advantages in porosity, disintegration speed, and scalability. Since disintegration occurs entirely within the oral cavity, taste masking is a critical formulation parameter. Standard evaluation of ODs encompasses hardness, friabilityy, wetting time, disintegration time, and in vitro dissolution profiling.

ADVANTAGES OF ODT[3]

1.ODT can be administer to the patients who cannot swallow tablets/cap., such as the elderly, stroke victims, bedridden patients, patients with esophageal problems & patients who refuse to swallow such as pediatric, geriatric & psychiatric patients and thus improves patient compliance.

2.ODT is most convenient for disabled, bedridden patients, travelers and busy people, who do not always have access to water.
3.Suitable during traveling where water may not be available.
4.Cost effective.
5. Good chemical stability as conventional oral solid dosage form.
6. No chewing needed.
7.Rapid onset of action.

DISADVANTAGES OF ODTS[3]

1.ODT is hygroscopic in nature so must be keep in dry place.
2. Some time it possesses mouth feeling.
3. It is also shows the fragile, effervescence granules property.
4. ODT requires special packaging for properly stabilization & safety of stable product.

MECHANISM[4]

ODTs achieve rapid disintegration through a combination of physicochemical mechanisms that collectively facilitate fast breakdown of the tablet matrix within the oral cavity:

Capillary Action: Saliva rapidly penetrates the porous tablet matrix through capillary forces, initiating wetting and triggering the disintegration cascade from within the compact.

Swelling: Superdisintegrants and hydrophilic excipients incorporated into the formulation absorb moisture rapidly and swell, generating sufficient internal mechanical stress to rupture interparticulate bonds and fragment the tablet matrix into fine, easily swallowable particles.

Chemical Reaction (Gas Evolution): Effervescent excipient systems — comprising an acid source such as citric or tartaric acid and an alkaline carbonate — react upon contact with saliva to liberate carbon dioxide gas, creating localized pressure that physically disrupts the tablet structure and accelerates disintegration.

Together, these mechanisms ensure that water-soluble excipients and appropriate disintegrants work synergistically to produce rapid tablet breakdown, yielding a solution or fine suspension of the drug that can be swallowed effortlessly without the need for water.

MARKETED FORMULATION

- EZACT (Sun Pharmaceutical Industries Ltd).
- ETOSHINE (Sun Pharmaceutical Industries Ltd).
- NUCOXIA (Zydus Cadila)
- BRUTAFLAM (Mankind Pharma Ltd).
- Etody (Abbott)

PROPERTIES

- The tablet must present as an elegant, finished product with a distinct identity — free from chips, cracks, discoloration, and contamination.
- It must possess sufficient mechanical strength to endure the physical stresses of manufacturing, packaging, transportation, and dispensing without compromise.
- Its physical attributes must remain stable throughout its intended shelf life, resisting any change in appearance, form, or structure over time.
- Drug release must be predictable and reproducible, ensuring consistent bioavailability upon administration.
- Chemical integrity of the active pharmaceutical ingredient(s) must be maintained across the product's shelf life, preventing degradation or alteration that could compromise therapeutic efficacy.

INGREDIENTS

Tablet Excipients and Their Examples

In addition to the active ingredient(s), tablets contain several inert materials termed **additives** or **excipients**, each serving a specific functional role in the formulation.

S.No.	Category	Examples
1	**Diluents**	Calcium Phosphate; Carboxymethylcellulose Calcium; Cellulose; Dextrin; Lactose; Microcrystalline Cellulose; Pregelatinized Starch; Sorbitol; Starch
2	**Binders**	Acacia; Alginic Acid; Carboxymethylcellulose; Cellulose; Dextrin; Gelatin; Liquid Glucose; Magnesium Aluminum Silicate; Maltodextrin; Methylcellulose; Povidone; Sodium Alginate; Starch; Zein
3	**Lubricants**	Calcium Stearate; Glyceryl Palmitostearate; Magnesium Oxide; Poloxamer; Polyvinyl Alcohol; Sodium Benzoate; Sodium Lauryl Sulfate; Sodium Stearyl Fumarate; Stearic Acid; Talc; Zinc Stearate
4	**Glidants**	Colloidal Silicon Dioxide; Magnesium Trisilicate; Cellulose; Starch; Talc; Tribasic Calcium Phosphate
5	**Anti-adherents**	Corn Starch; Metallic Stearates; Talc
6	**Disintegrants**	Alginic Acid; Carboxymethylcellulose Sodium; Colloidal Silicon Dioxide; Croscarmellose Sodium; Crospovidone; Polacrilin Potassium; Povidone
7	**Coloring Agents**	FD&C Dyes; D&C Dyes; Lake Pigments
8	**Flavoring Agents**	Ethyl Maltol; Ethyl Vanillin; Menthol; Vanillin
9	**Absorbents**	Kaolin; Magnesium Aluminum Silicate; Tricalcium Phosphate

1. Diluents
Diluents are inert fillers incorporated into tablet formulations when the active ingredient alone is insufficient to produce a tablet of adequate size and weight. Beyond bulk provision, they enhance cohesiveness of the powder mass and facilitate direct compression manufacturing.

2. Binders
Binders impart cohesive strength to powder blends, enabling the formation of firm, compressible granules or compacts suitable for direct compression tableting.

3. Lubricants
Lubricants serve a threefold mechanical purpose — preventing tablet material from adhering to punch and die surfaces, reducing interparticulate friction during compression, and improving the flow rate of granulations prior to tablet formation.

4. Glidants
Glidants enhance the flowability of granules or bulk powders by minimizing frictional forces between particles, thereby ensuring uniform die-fill during compression.

5. Anti-adherents
Anti-adherents are incorporated to prevent the tablet mass from sticking to the punch faces and die walls during the compression cycle, reducing picking and sticking defects.

6. Disintegrants
Disintegrants are added to promote rapid breakdown of the tablet upon contact with aqueous fluids in the gastrointestinal tract, facilitating drug release and subsequent absorption.

7. Coloring Agents
Colors and dyes are employed in tablet formulations for three distinct purposes:

- **(A)** Masking the unappealing appearance of off-colored drugs
- **(B)** Enabling product identification and differentiation
- **(C)** Enhancing the overall aesthetic appeal of the finished dosage form

8. Flavoring Agents
Flavoring agents are particularly essential in chewable tablet formulations to improve palatability. Flavoring oils are preferably incorporated in a dry, particulate form — typically as spray-dried beadlets — to ensure uniform distribution and stability.

9. Absorbents
Absorbents are included in tablet formulations when the product contains incomplete.

Characteristic of an Ideal Orodispersible Tablet[5]

1. The manufacturing method should be cost-effective and economically feasible.
2. The formulation should not require water for oral administration and must disintegrate upon contact with saliva.
3. The tablet should dissolve, disperse, or disintegrate within one minute.
4. T he ODT should provide a pleasant and acceptable mouthfeel, along with effective taste masking of the incorporated drug.
5. The tablet should possess adequate mechanical strength, with sufficient hardness and low friability to withstand handling and transportation.
6. The formulation should leave little to no residue in the mouth after administration.

VARIOUS TECHNIQUES USED IN PREPARATION OF ORODISPERSIBLE TABLETS[6]

2.1 Conventional Technology

2.1.1 Freeze Drying

Freeze drying, also known as lyophilization, is one of the most widely used techniques for the preparation of orally disintegrating tablets (ODTs). This method produces a highly porous dosage form that rapidly disintegrates or dissolves upon contact with saliva in the oral cavity. During the process, the formulation is frozen below its eutectic point, followed by a drying step to remove the bound moisture to the desired level.

Lyophilization imparts a glossy amorphous structure to both the drug and the bulking agents, thereby enhancing the dissolution rate and improving drug release. However, freeze drying is an expensive manufacturing technique because it requires specialized equipment and extensive processing. Although the method offers excellent disintegration properties, the resulting tablets often possess low mechanical strength and may exhibit poor stability under conditions of high temperature and humidity.

ADVANTAGES

1.Provides faster dissolution compared to most conventional solid dosage forms.
2.Produces highly porous tablets with rapid disintegration characteristics.

DISADVANTAGES

1. High Cost Of Equipments.
2. Lack Of Physical Resistance in Blister Packs.

2.1.2. SUBLIMATION

Sublimation is a technique used in the preparation of orally disintegrating tablets (ODTs) to create a highly porous tablet structure. In this method, volatile and chemically inert substances such as urea, urethane, naphthalene, camphor, menthol, and ammonium bicarbonate are incorporated into the tablet formulation and compressed into tablets. These volatile materials are

subsequently removed through sublimation, leaving behind a network of pores within the tablet matrix. The porous structure enhances saliva penetration, resulting in rapid tablet disintegration and dissolution in the oral cavity.

This method enables the production of mouth-dissolving tablets with both high porosity and adequate mechanical strength.

ADVANTAGES

1. Tablets disintegrate rapidly, typically within 10–20 seconds.
2. Provides sufficient mechanical strength while maintaining fast dissolution characteristics.

2.1.3. MOLDING

Molding is a commonly employed technique for manufacturing quick-disintegrating tablets. In this process, the drug is dispersed within a matrix either as discrete particles or microparticles. Molded tablets are generally less compact than conventional compressed tablets and possess a porous structure that facilitates rapid disintegration and dissolution.

The dispersion matrix usually contains water-soluble sugars, which improve the palatability of the tablets and enhance patient acceptance. However, molded tablets often exhibit poor mechanical strength, making them susceptible to breakage and erosion during handling and removal from blister packs. To improve tablet strength, excipients such as sucrose, acacia, or polyvinyl pyrrolidone (PVP) may be incorporated into the formulation.

ADVANTAGES

1. Rapid disintegration due to the porous tablet structure.
2. Improved taste and mouthfeel owing to the presence of water-soluble sugars.

DISADVANTAGES

1. Low mechanical strength compared to compressed tablets.
2. Prone to erosion and breakage during hamddling and production.

2.1.4 Spray Drying

Spray drying is a technique used to prepare highly porous orally disintegrating tablets. In this method, an aqueous solution containing a support matrix and other formulation components is spray-dried to produce a fine, porous powder. The resulting powder is then blended with the active pharmaceutical ingredient and compressed into tablets.

The high porosity of the spray-dried matrix allows for extremely rapid tablet disintegration, often within 20 seconds. Despite its effectiveness in achieving fast dissolution, the technique is associated with high production costs, lengthy processing times, and the formation of tablets with relatively poor mechanical strength.

ADVANTAGE: Rapid disntegration of tablets

2.1.5 Mass Extrusion

Mass extrusion is a formulation technique in which a blend of the active drug and excipients is softened using a solvent system, typically consisting of water-soluble polyethylene glycol and methanol. The softened mass is then extruded through an extruder or syringe to produce a cylindrical structure. This extrudate is subsequently cut into uniform segments using heated blades to form tablets.

An additional advantage of this technique is its application in taste masking. The dried extruded material can be used to coat granules of bitter-tasting drugs, thereby improving palatability and patient compliance.

2.2.1 Zydis Technology

Zydis technology is a patented freeze-drying (lyophilization) technique used for the development of orally disintegrating tablets (ODTs). In this system, the drug is either dissolved or physically entrapped within a rapidly disintegrating matrix composed of suitable carrier materials. Upon administration, the freeze-dried tablet disintegrates almost instantaneously in the oral cavity without the need for water, thereby enhancing patient convenience and compliance.

The formulation of the Zydis matrix involves the incorporation of specialized excipients to achieve multiple functional objectives. Polymers such as gelatin, dextran, and alginates are utilized to provide mechanical strength and resilience during handling and packaging. These polymers contribute to the formation of a glossy, amorphous matrix structure that enhances tablet integrity. Additionally, saccharides such as mannitol and sorbitol are incorporated to impart a highly crystalline structure, thereby improving the tablet's hardness, elegance, and overall aesthetic appearance.Water plays a critical role during the manufacturing process,it facilitates the formation of a highly porous structure upon freeze-drying. This porous network enables rapid penetration of saliva into the tablet matrix, resulting in extremely fast disintegration and dissolution characteristics.

2.2.2 Flashtab Technology

Flashtab technology is a patented approach developed by Prographarm Laboratories for the production of orally disintegrating tablets (ODTs). This technology involves the preparation of rapidly disintegrating tablets containing the active pharmaceutical ingredient in the form of coated microcrystals or microgranules. These drug-loaded particles are produced using conventional techniques such as coacervation, extrusion–spheronization, pan coating, and microencapsulation.

The prepared microcrystals or microgranules are subsequently incorporated into a blend of excipients, which is processed through either wet or dry granulation. The resulting granules are then compressed into tablets using standard tableting equipment and conventional manufacturing procedures.

Tablets produced using Flashtab technology exhibit adequate mechanical strength while maintaining rapid disintegration characteristics, typically disintegrating within one minute after administration. The use of conventional pharmaceutical processing techniques makes this technology both practical and suitable for large-scale industrial production.

Nanocrystal-Based Freeze-Dried ODT Technology

Rapid disintegration of the tablet matrix is essential for achieving optimal pharmacokinetic performance in orally disintegrating tablet (ODT) formulations. In this technology, orally administered nanoparticles, typically smaller than 2 μm, are incorporated into a rapidly disintegrating tablet matrix. Product differentiation is achieved through the integration of proprietary and patented technological components that enhance both formulation performance and patient acceptability.

The manufacturing process is designed to be cost-effective and employs conventional, scalable unit operations suitable for large-scale production. The resulting dosage forms exhibit excellent physical stability and durability, allowing the use of standard packaging systems such as bottles and blister packs. Furthermore, the technology accommodates a wide range of drug loads, with active pharmaceutical ingredient (API) concentrations of up to 200 mg per unit.

The formulation utilizes conventional pharmacopeial excipients, ensuring regulatory acceptance and safety. Drug nanocrystal colloidal dispersions are combined with water-soluble ingredients classified as Generally Recognized as Safe (GRAS), filled into blister cavities, and subsequently subjected to lyophilization. The freeze-drying process produces robust wafer-like structures that dissolve rapidly in small volumes of water within seconds.

An additional advantage of this approach is its suitability for handling potent or hazardous compounds. Since the process eliminates conventional operations such as granulation, blending, and tableting, the generation of aerosolized powders is minimized, thereby reducing the risk of operator exposure. Moreover, the freeze-drying method is particularly beneficial when only limited quantities of drug substance are available, as manufacturing losses are minimal, enabling efficient conversion of scarce materials into ODT dosage forms.

2.2.4 Wowtab Technology

Wowtab technology is a patented orally disintegrating tablet (ODT) platform developed by Yamanouchi Pharmaceutical Co. and has been extensively utilized in the Japanese pharmaceutical market. The term "WOW" stands for “Without Water,” reflecting the tablet's ability to disintegrate rapidly in the oral cavity without the need for water.

This technology employs a combination of sugar and sugar-like excipients, such as mannitol, to achieve both rapid disintegration and sufficient mechanical strength. Specifically, the formulation incorporates low-moldability saccharides, which possess rapid dissolution characteristics, along with high-moldability saccharides that provide excellent binding properties. The synergistic combination of these two types of saccharides results in tablets with adequate hardness while maintaining a fast dissolution rate.

Compared with other ODT technologies, such as Zydis and OraSolv, Wowtab formulations exhibit greater environmental stability due to their enhanced mechanical strength. This improved hardness facilitates packaging in conventional containers, including bottles and blister packs, without compromising tablet integrity.

In addition, the technology incorporates effective taste-masking agents and utilizes the patented SMOOTHMELT® mechanism to enhance mouthfeel and patient acceptability. Tablets manufactured using Wowtab technology typically exhibit rapid dissolution, with disintegration occurring within approximately 15 seconds after administration.

2.2.5 DuraSolv Technology

DuraSolv technology is the second-generation orally disintegrating tablet (ODT) platform developed by Cima Labs. Unlike the earlier OraSolv technology, DuraSolv employs higher compression forces during tablet manufacturing, resulting in tablets with superior mechanical strength and durability. The technology utilizes conventional tableting equipment, enabling efficient large-scale production and cost-effective manufacturing. Tablets produced using this approach exhibit low friability (typically less than 2%) and sufficient rigidity for handling, packaging, and transportation.

Due to their enhanced mechanical properties, DuraSolv tablets can be packaged using conventional pharmaceutical packaging systems, including blister packs, pouches, and vials. The improved robustness of the tablets also facilitates faster manufacturing rates compared to some other ODT technologies.

Despite these advantages, DuraSolv technology has certain limitations. The high compression pressures employed during tablet formation make it less suitable for formulations containing large doses of active pharmaceutical ingredients (APIs). Excessive compression may compromise the integrity of taste-masking coatings surrounding drug particles, leading to

coating fracture and subsequent exposure of bitter-tasting drugs in the oral cavity. Consequently, DuraSolv technology is most appropriate for formulations containing relatively low doses of active compounds, where effective taste masking and rapid disintegration can be maintained without compromising tablet quality.

Orodis Technology

Orodis® is a compressed orally disintegrating tablet (ODT) technology designed to produce tablets that rapidly disintegrate in the oral cavity, typically within 15–30 seconds. This technology offers several advantages over conventional ODT manufacturing approaches.

A key feature of Orodis® technology is the production of tablets with high mechanical strength, making them less fragile and easier to handle during manufacturing, packaging, transportation, and administration. Unlike some freeze-dried ODT formulations, Orodis® tablets do not require specialized packaging and can be conveniently packed in standard push-through blister packs.

In addition, tablets manufactured using this technology provide a smooth and pleasant mouthfeel, thereby enhancing patient acceptability. The incorporation of effective taste-masking agents and flavoring materials further improves palatability, ensuring a more favorable patient experience. Another important advantage is that all excipients and materials employed in the formulation comply with the standards specified by the United States Pharmacopeia (USP) and the European Pharmacopoeia (EP), supporting product quality, safety, and regulatory compliance.

EVALUATION FOR ODTS TABLETS[7]

1) THICKNESS

Tablet thickness is an important quality attribute that influences the uniform appearance of tablets and ensures accurate counting during packaging. Some filling equipment uses the uniform thickness of tablets as a counting mechanism. The thickness of the tablets was measured using a Vernier caliper.

2) WEIGHT VARIATION

A number of 20 tablets were selected randomly from the lot and weighed individually to check for weight variation.

3) FRIABILITY

Efforts to reduce the disintegration time of orally disintegrating tablets (ODTs) often result in increased friability compared with conventional tablets. Certain ODT formulations, such as Zydis, are particularly fragile. Friability is an important parameter used to evaluate the mechanical strength of tablets. Tablets with high friability are more likely to break or crumble during packaging, transportation, and handling. Friability was determined using a Roche friabilator. A pre-weighed sample of tablets was placed in the friabilator, which consists of a plastic chamber rotating at 25 rpm. During each revolution, the tablets were allowed to fall from a height of approximately 6 inches. The test was carried out for 4 minutes. After completion of the test, the tablets were dedusted and reweighed.

4) HARDNESS

Tablet hardness is measured with hardness testers like Monsanto. A tablet is placed in the hardness tester and load required to crush the tablet is measured. The hardness of ODTs is generally kept lower than conventional tablets as increased hardness delays the disintegration of the tablet. The force is measured in kg and the hardness of about 3-5 kg/cm2 is considered to be satisfactory for uncoated tablets.

5) WATER ABSORPTION RATIO

A small piece of tissue paper, folded twice, was placed in a Petri dish containing 6 mL of distilled water. A tablet was carefully placed on the tissue paper, and the time required for complete wetting of the tablet was recorded as the wetting time. After complete wetting, the tablet was removed and reweighed to determine the amount of water absorbed.

The water absorption ratio (R) was calculated using the following equation:

[R = \frac{100 \times (W_a - W_b)}{W_b}]

Where,

- (W_b) = Weight of the tablet before water absorption
- (W_a) = Weight of the tablet after water absorption

UNIFORMITY OD DISPERSION

Keep the Two tablets in 100ml water and stir gently for 2 minutes. The dispersion is passed through 22 meshes. The tablets will consider passing the test if no residue remained on the screen.

WETTING TIME

Five circular tissue papers, each with a diameter of 10 cm, were placed in a 10 cm diameter Petri dish. Approximately 10 mL of water containing eosin, a water-soluble dye, was added to the Petri dish. A tablet was carefully placed on the surface of the tissue paper, and the time required for the water to reach the upper surface of the tablet was recorded as the wetting time.

DISINTEGRATION TIME

According to the European Pharmacopoeia, orally disintegrating tablets (ODTs) should disintegrate within 3 minutes without leaving any residue on the test screen. However, accurately evaluating the disintegration time of ODTs using the conventional disintegration test is challenging, as it employs 900 mL of distilled water, which does not simulate the physiological conditions of the oral cavity where only a few milliliters of saliva are present. Consequently, the disintegration time obtained by the conventional method may not accurately reflect the actual in vivo performance of ODTs.To address this limitation, several modified methods have been

developed to better simulate the conditions in the human mouth. One such method utilizes a charge-coupled device (CCD) camera or a texture analyzer to determine the disintegration time. Another method employs a modified disintegration test apparatus consisting of a wire basket (3 cm in height and 2 cm in diameter) with a mesh size of #10, positioned above a beaker containing 900 mL of simulated saliva. The basket is adjusted so that it contains only 6 mL of the medium. The assembly is maintained at 37 ± 0.5°C using a heater and is stirred at 25 rpm with a magnetic stirrer. The time required for complete tablet disintegration is recorded.A simpler alternative method involves placing a tablet in a measuring cylinder containing 6 mL of simulated saliva without shaking or stirring. The time required for complete disintegration is then recorded as the in vitro disintegration time.

DISSOLUTION TEST

The dissolution method for oral disintegrating tablets is the same as that of conventional tablets. USP 2 paddle apparatus is most suitable and common choice for dissolution test of oral disintegrating tablets, where the paddle speed is 50 rpm is used. The USP 1 (basket) apparatus may have certain application for such tablets but is used less frequently due to specific physical properties of tablets.

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