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FAST-DISSOLVING TABLETS AS A NOVEL DRUG DELIVERY SYSTEM: FORMULATION STRATEGIES, OPTIMIZATION TECHNIQUES, AND CLINICAL IMPLICATIONS

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ABSTRACT: Fast-dissolving tablets (FDTs) have emerged as a patient-friendly oral drug delivery system designed to enhance medication adherence, particularly among pediatric, geriatric, and dysphagic populations who experience difficulty swallowing conventional solid dosage forms. It aims to critically summarize formulation strategies, optimization techniques, and clinical implications of fast-dissolving tablets as a novel drug delivery platform. It discusses key formulation components such as superdisintegrants, fillers, binders, sweeteners, and taste-masking agents, highlighting recent advances in co-processed excipients and functional polymers. Major manufacturing approaches, including direct compression, freeze-drying, sublimation, spray drying, solid dispersions, and nanotechnology-based methods, are examined with respect to their impact on tablet performance and scalability. Optimization strategies based on Quality by Design (QbD), Design of Experiments (DoE), and Process Analytical Technology (PAT) are emphasized as essential tools for robust product development and large-scale manufacturing. Clinically, FDTs offer advantages such as rapid onset of action, improved bioavailability for poorly soluble drugs, and ease of administration in emergency and outpatient settings. Despite challenges related to moisture sensitivity, taste masking, and manufacturing complexity, regulatory frameworks from major authorities ensure quality, safety, and consistency. Overall, fast-dissolving tablets represent a promising and continuously evolving drug delivery system. Ongoing innovations, including 3D printing and personalized dosage forms, further strengthen the potential of FDTs to meet the growing demand for patient-centric therapies.

INTRODUCTION:

Overview of Oral Drug Delivery Systems: Given its ease of use, affordability, non-invasiveness, and high patient compliance, oral medication delivery is still the most popular and extensively used method of drug administration. Because the oral route provides for variable dose design, simplicity of manufacture, and good formulation stability, it accounts for almost 50–60% of marketed formulations.

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Tablets, capsules, and liquids are examples of traditional oral dose forms that are mainly intended for systemic distribution through gastrointestinal absorption. To attain therapeutic concentration, these systems make use of physiological processes such hepatic metabolism, intestinal permeability, and stomach dissolution [1]. Oral absorption is further hampered by medications with poor permeability or low water solubility (such as BCS Class II and IV medications).

Oral drug delivery technologies, such as controlled-release systems, gastroretentive delivery, mucoadhesive systems, solid dispersions, nanosystems, and fast-dissolving drug delivery platforms, have advanced significantly as a result of these constraints. Fast-dissolving tablets (FDTs), which dissolve or disintegrate quickly in the oral

cavity without the need for water, are one example of a novel dosage form that has been developed as a result of the evolution of patient-centered medicine and the requirement of quicker onset of action and improved drug bioavailability [2].

Definition and Characteristics of Fast-Dissolving Tablets (FDTs): Fast-dissolving tablets (FDTs), sometimes referred to as mouth-dissolving tablets or orally disintegrating tablets (ODTs), are solid unit dosage forms that dissolve or disperse in the oral cavity in a matter of seconds, usually between 10 and 30 seconds, when they come into contact with saliva. ODTs are described as "a solid dosage form that contains medicinal substances and disintegrates rapidly, usually within a few seconds, when placed on the tongue" by the US Food and Drug Administration (FDA) [3].

Important features of FDTs consist of:

Quick Disintegration: The tablet structure breaks down right away in saliva without needing any outside fluid.

Minimal or no Requirement for Water: Facilitates administration at any time and location.

Acceptable Mouth Feel: This is possible with the help of superdisintegrants, sweeteners, flavors, and taste-masking agents.

Porous Structure: Makes it easier for water to get in and break down.

Low Tablet Hardness: Meticulously balanced to keep the tablet's mechanical integrity while allowing it to break down quickly.

Use of Specialized Excipients: This includes volatile ingredients, superdisintegrants (like Croscarmellose sodium, sodium starch glycolate, and crospovidone), and sublimation agents.

Better Bioavailability: This is especially true for drugs that go through a lot of first-pass metabolism, since they can be absorbed before they reach the stomach through the mouth and under the tongue [4].

Advantages and Limitations of FDTs:
Advantages:

- No need for water: This makes it possible to give the medicine when water isn't available, like when traveling, in an emergency, or when you have motion sickness.
- Rapid onset of action: The drug breaks down and dissolves quickly, which makes it work faster.
- Better bioavailability as it skips first-pass metabolism.
- Easy to make: Direct compression, freeze-drying, sublimation, and spray drying are some of the methods that make production easier.
- Possible taste masking: Makes it taste better, which makes patients more likely to accept it.
- Solid-state stability keeps microbes from getting into the product and makes it last longer [5].

Limitations:

- Humidity sensitivity: Because porous tablets absorb moisture quickly, they need special packaging.
- Taste-masking difficulties: A lot of APIs have bitter or disagreeable tastes that need to be covered up using sophisticated methods.
- Dose restrictions: Because the tablet size becomes too big to dissolve quickly, it is not appropriate for high-dose medications (>500 mg).
- Without the use of solubility-enhancing methods like solid dispersion, micellar incorporation, or Nano sizing, hydrophobic medications may exhibit sluggish dissolution.
- Compared to traditional tablets, methods like spray drying and freeze-drying (lyophilization) raise production costs [6].

Types of Fast-Dissolving Tablets (FDTs):
Lyophilized (Freeze-Dried) Tablets: These tablets are prepared using freeze-drying to obtain a highly porous structure, enabling extremely rapid disintegration in the oral cavity. They offer the fastest dissolution among FDTs but suffer from low mechanical strength, high manufacturing costs, and moisture sensitivity, necessitating specialized packaging and storage.

Molded Tablets: Molded FDTs are produced without compression, resulting in porous tablets with smooth texture and rapid disintegration. Although they provide good patient acceptability, their low hardness and fragility require careful handling and protective packaging.

Direct Compression FDTs: Direct compression is the most widely used and economical method for FDT production. The use of superdisintegrants and co-processed excipients enables rapid disintegration with adequate mechanical strength. This approach is preferred industrially due to its simplicity, scalability, and cost-effectiveness [7].

Sublimation-Based FDTs: In this method, volatile substances are removed after compression to create pores within the tablet matrix. Sublimation enhances disintegration while maintaining tablet hardness; however, it requires additional processing steps and controlled conditions.

Spray-Dried FDTs: Spray drying produces porous powders that disintegrate rapidly when compressed into tablets. This technique improves dissolution, taste masking, and mouthfeel, particularly for poorly soluble or heat-sensitive drugs.

Cotton-Candy (FlashDose) Technique: This technique uses spun amorphous sugars to create highly porous tablets with excellent mouthfeel and ultrafast disintegration. Its major limitation is moisture sensitivity, which can affect product stability.

Mass-Extrusion Technique: Mass extrusion involves forming drug–polymer matrices that are extruded and dried. It is especially useful for taste masking bitter drugs and offers good dose uniformity, though processing complexity may limit large-scale use.

Nanoparticle or Solid Dispersion-Based FDTs: These formulations incorporate nanoparticles or solid dispersions to enhance drug solubility and bioavailability. They are particularly beneficial for poorly water-soluble drugs but may involve complex formulation strategies.

Effervescent FDTs: Effervescent systems utilize acid–base reactions to generate gas, accelerating tablet disintegration and improving palatability. Moisture sensitivity remains a key formulation challenge.

Orally Disintegrating Mini-Tablets: Mini-tablets are small, multi-unit dosage forms offering flexible dosing, improved mechanical strength, and reduced choking risk. They are especially suitable for pediatric and geriatric patients [8].

Mechanism of Disintegration and Drug Release: Fast-dissolving tablets (FDTs) are designed to dissolve quickly in the mouth, mostly due to intricate interactions between saliva, oral physiology, and formulation ingredients. Optimizing FDT performance, increasing bioavailability, and guaranteeing consistent therapeutic results all depend on a comprehension of the mechanistic pathways of disintegration and drug release [9].

Physicochemical Processes Involve:

Wetting and Capillary Action (Wicking): Wicking is the point at which disintegration begins. Saliva enters the tablet through capillary pores after it is placed on the tongue. Internal breakdown results from the fluid's penetration weakening intermolecular bonds.

Swelling-Induced Disintegration: Super-disintegrants that have a high capacity for swelling can expand up to four to ten times their dry volume. Both the initial breakup and the subsequent dispersion of particles are influenced by swelling [10].

Crospovidone Strain Recovery: This non-swellable superdisintegrant uses a different process called strain recovery. Crospovidone particles undergo elastic deformation during compression; after saliva penetrates, the particles return to their original shape, causing internal stress that fractures the tablet.

Effervescence-Induced Mechanism: The production of CO_2 gas speeds up disintegration in formulations that use effervescent couples (citric acid + sodium bicarbonate). Effervescence creates mechanical agitation in the tablet matrix, creating breaks and channels that significantly shorten the disintegration time and increase water penetration.

Particle Size Lowering and Greater Surface Area: According to the Noyes-Whitney equation, disintegration increases the dissolution surface area by reducing the drug into small particles. Solid dispersion technology greatly speeds up the dissolution of drugs that are poorly soluble, like curcumin [11].

Role of Saliva and Oral Mucosa:

Physicochemical Properties of Saliva: The function of fast-dissolving tablets (FDTs) is fundamentally and complexly influenced by saliva. Saliva is the main medium that starts hydration and activates superdisintegrants as soon as an FDT is applied to the tongue [12]. Because superdisintegrants need moisture to swell, wick, or recover from compressed states, this hydration step is essential. Many of the weakly acidic or basic medications found in FDTs are dissolved by saliva's physiologically appropriate pH range of 6.0–7.4, which facilitates quicker drug release. Saliva also contains viscoelastic glycoproteins called mucins, which add to its lubricating qualities [13]. Even the lowest physiological flow rate of about 0.3 mL/min is usually adequate to hydrate and effectively disintegrate the majority of FDTs, despite individual differences in salivary secretion [14].

Saliva Viscosity and Surface Tension: Saliva's ability to permeate an FDT's porous matrix is greatly influenced by its viscosity and surface tension. Because saliva naturally has a low viscosity (usually between 1 and 2 cP), it can pass through tablet microchannels with ease [15]. Saliva's surface tension, which is roughly 70 mN/m, encourages effective capillary action in addition to viscosity. High surface tension makes it easier for saliva to travel upward through hydrophilic channels and pores made during tablet compression or by formulation methods like lyophilization, sublimation, or the addition of porous carriers [16].

Interaction with Oral Mucosa: When it comes to the drug release and absorption processes connected to FDTs, the oral mucosa is equally significant. Its abundant blood supply enables the quick systemic absorption of drug molecules that can pass through the mucosal layers. This is especially true for medications that have advantageous physicochemical characteristics like low molecular weight and high lipophilicity [17]. Pre-gastric absorption is an occurrence that partially avoids hepatic first-pass metabolism and allows for a quicker onset of action. The relationship between the disintegrated particles and the mucosal surface consequently has a vital role not merely in dissolution but additionally in the early stages of drug absorption [18].

Taste-Masking and Mouthfeel: Additionally, saliva affects the sensory aspects of FDTs, especially taste and mouthfeel, which are important for patient compliance. Saliva interacts with taste-masking ingredients in the formulation as the tablet breaks down [19]. These substances could be cyclodextrin complexes, ion-exchange resins, or coated granules that are intended to shield the medication from the tongue's taste receptors [20]. In order to maintain the quick action anticipated from FDTs while offering a smooth and pleasant mouthfeel, effective taste masking makes sure that the barriers implemented to conceal bitterness do not impede disintegration or dissolution [21].

Factors Affecting Disintegration and Dissolution:

Type of Superdisintegrants: Since, every material has a unique mechanism, the efficiency of disintegration is mostly dependent on the particular superdisintegrant added to the formulation[22]. Crospovidone exhibits strain recovery and facilitates quick water absorption through wicking, which causes the tablet structure to disintegrate rapidly [23]. Croscarmellose sodium allows for simultaneous expansion and fluid penetration by combining swelling with capillary action. These agents' concentration, particle size, degree of crosslinking, and compatibility with any additional excipients in the formulation all affect how well they work overall [24].

Concentration of Superdisintegrant: Tablet disintegration time is directly impacted by the quantity of superdisintegrant used. Increasing the concentration usually improves tablet breakup and speeds up water absorption [25]. In certain polymers, overuse can also cause a gelling effect that slows down disintegration. Finding the ideal concentration is therefore crucial to attaining both adequate mechanical strength and quick disintegration [26].

Hydrophilicity of Excipients: Hydrophilic excipients greatly aid in wetting and enable effective salivary penetration into the tablet matrix [27]. Materials like lactose, mannitol, and microcrystalline cellulose increase the formulation's overall hydrophilicity, facilitating quicker water absorption and dosage form breakdown. Their solubility and chemical makeup affect the drug's initial dissolution profile as well as its rate of disintegration [28].

Porosity and Pore Size Distribution: How easily saliva are able to enter the internal structure of a tablet depends on its porosity. Tablets that have greater porosity permit faster capillary action, permitting rapid fluid uptake. Greater salivary penetration is facilitated by larger pore sizes, which lead to more consistent and rapid disintegration. Since greater compression reduces pore volume and slows fluid ingress, these characteristics are primarily determined by the compression force used during tableting [29].

Solubility of the Active Pharmaceutical Ingredient: The drug's solubility properties have a significant impact on the rate of dissolution. Once the tablet has broken up, highly water-soluble medications dissolve easily, resulting in a quick onset of action.

To improve wettability and dissolution behavior, poorly soluble drugs need to be enhanced using techniques like solid dispersions, nanosizing, micellar carriers, or cyclodextrin complexation. The advantage of quick disintegration might not result in increased bioavailability without such adjustments [30].

Use of Co-processed Excipients: Co-processed excipients improve powder flow, compressibility, and disintegration efficiency all at once by offering several functions in a single integrated material. Commercial blends designed to minimize formulation complexity while guaranteeing consistent performance include Ludiflash®, Pharmaburst®, and Prosolv® ODT [31]. Their ideal particle composition and structure improve saliva absorption and encourage consistent tablet disintegration [32].

pH Microenvironment: Drug solubility and dissolution rate can be greatly impacted by the pH of the tablet microenvironment. The local pH can be adjusted with buffering agents to make weakly acidic or basic medications more soluble. In order to improve overall bioavailability and therapeutic onset, a favorable microenvironment must be created so that dissolution starts quickly, sometimes even before the drug enters the gastrointestinal tract [33].

pH of the Oral Cavity: Saliva's pH affects the drug's ionization and solubility, which in turn affects the dissolution process. While weakly basic drugs dissolve better in mildly acidic environments, weakly acidic drugs usually dissolve more easily in alkaline conditions. Therefore, according to the physicochemical nature of the active ingredient, individual differences in oral pH can change the initial dissolution profile, either accelerating or slowing drug release [34].

Saliva Temperature: Another factor influencing dissolution behavior is the oral cavity's temperature, which typically stays around 37°C. Higher temperatures improve drug solubility, decrease salivary viscosity, and increase molecular mobility and diffusion rates. Once the tablet starts to disintegrate, these effects work together to speed up the wetting and dissolution processes. The rate at which the dosage form disperses can be slightly impacted by even slight changes in oral temperature [35].

Variability in Saliva Composition: Individual differences in saliva composition can affect how well fast-dissolving tablets work. Saliva's ability to enter the tablet matrix and interact with disintegrants is influenced by variations in mucin concentration, electrolyte levels, and viscosity. While changes in viscosity affect the rate of capillary action, higher mucin content may change lubrication and wetting behavior. Individual differences in disintegration time and efficiency may result from this physiological variability [36].

Excipients Used in Fast-Dissolving Tablets: The effectiveness, stability, and patient acceptability of fast-dissolving tablets (FDTs) are significantly influenced by excipients. They affect important characteristics like mouthfeel, mechanical strength, taste masking, disintegration time, and general dissolution behavior.

Therefore, choosing and optimizing excipients is crucial to creating a successful FDT formulation that satisfies therapeutic and regulatory requirements.

TABLE 1: SUMMARY OF EXCIPIENTS USED IN FDT

Category	Examples	Key Functions	Short Description	Ref.
Superdisintegrants	Crospovidone, Croscarmellose Sodium, Sodium Starch Glycolate	Promote rapid tablet breakup	Crospovidone works by capillary wicking; croscarmellose uses swelling + wicking; SSG causes fast swelling to generate internal pressure.	37
Fillers / Bulking Agents	Mannitol, Lactose, MCC, Dextrose	Improve weight, texture, mouthfeel	Mannitol gives cooling taste; MCC enhances porosity and disintegration; lactose and dextrose improve palatability and compressibility.	38
Binders	PVP, HPMC, Maltodextrin	Provide cohesiveness	Water-soluble binders maintain tablet strength without delaying disintegration.	39
Lubricants	Magnesium Stearate, Sodium Stearyl Fumarate	Reduce friction during compression	Used in small amounts; hydrophobic lubricants can slow wetting, so hydrophilic alternatives are preferred.	40
Sweeteners & Flavors	Aspartame, Sucralose, Saccharin; Mint, Orange, Strawberry	Enhance taste and patient acceptability	Improve palatability; used especially for bitter APIs.	41
Taste-Masking Agents	Polymeric coatings, Ion-exchange resins, Cyclodextrins	Mask bitterness	Coat or bind bitter drugs, or trap molecules to reduce unpleasant taste without affecting disintegration.	42
Novel / Co-Processed Excipients	Ludiflash®, Pharmaburst®, Prosolv® ODT, F-Melt®	Improve flow, compressibility, disintegration	Engineered blends offering rapid wetting, good mechanical strength, and consistency for industrial production.	43

Formulation Strategies: Several formulation strategies have been developed to achieve rapid tablet disintegration while maintaining acceptable mechanical strength and drug stability. The selection of a suitable method depends on drug properties, scalability, and cost considerations. Direct compression is the most widely used approach due to its simplicity, low cost, and suitability for large-scale manufacturing. The incorporation of superdisintegrants enables rapid disintegration, and the absence of heat or solvents makes this method ideal for thermolabile drugs. However, precise optimization of excipient ratios is required to ensure tablet integrity and uniform disintegration[44].

Freeze-drying (lyophilization) produces highly porous tablets that disintegrate almost instantaneously in the oral cavity, offering superior patient acceptability and rapid onset of action. Despite these advantages, high production costs, low mechanical strength, and specialized packaging requirements limit its widespread industrial application. Spray drying generates porous excipient matrices with enhanced wettability, resulting in rapid tablet disintegration and improved dissolution of poorly soluble drugs. This technique also supports uniform taste masking but may not be suitable for heat-sensitive compounds.

Sublimation enhances tablet porosity by removing volatile components after compression, thereby promoting fast disintegration while retaining tablet hardness. Although cost-effective, this method requires careful control of processing conditions to ensure formulation stability. Molding yields tablets with smooth texture and rapid dissolution due to their porous structure; however, lower mechanical strength and handling challenges restrict their commercial use. Advanced approaches such as phase transition processing, solid dispersion systems, and nanotechnology-based formulations further improve dissolution, bioavailability, and taste masking, particularly for poorly soluble drugs. While these methods offer significant performance advantages, they often involve increased formulation complexity and higher manufacturing costs [45].

Optimization Techniques:

Quality by Design (QbD) in FDT Formulation: By concentrating on comprehending the formulation and process variables that affect product performance, Quality by Design (QbD)

offers a methodical, science-based approach to creating fast-dissolving tablets. QbD guarantees that the finished product in FDT formulation satisfies predetermined quality standards, including uniform drug content, mechanical strength, rapid disintegration, and palatability. The Quality Target Product Profile (QTPP), which comprises elements like disintegration time, dose accuracy, patient acceptability, and stability, is first defined by the QbD framework. FDT formulations become more predictable, repeatable, and scalable by implementing QbD principles, which eventually improves development efficiency and regulatory acceptance [46].

Design of Experiments (DoE): A key component of methodically examining the connection between formulation variables and performance conclusions is DoE. DoE allows for the simultaneous evaluation of several factors, such as superdisintegrant concentration, compression force, or binder type, and their interactions, as opposed to altering one factor at a time. DoE can be used to maximize disintegration time, hardness, friability, and dissolution efficiency in the context of fast-dissolving tablets. Formulators can identify ideal formulation conditions and comprehend how various factors collectively affect product quality by creating predictive mathematical models.

Statistical Optimization (Box–Behnken, Central Composite Design): Because of their effectiveness and capacity to simulate response surface curvature, sophisticated statistical tools like Box–Behnken Design (BBD) and Central Composite Design (CCD) are widely used for FDT optimization. Box-Behnken Design is cost-effective and appropriate for formulations where extreme levels could lead to instability or failure because it employs a three-level factorial approach without extreme corner points. Central Composite Design allows for accurate estimation of quadratic effects by incorporating axial points in addition to factorial and center points. These statistical designs aid in determining the best variable combinations, guaranteeing robustness, and forecasting performance in various scenarios [46].

Risk Assessment and Critical Quality Attributes (CQAs): An essential component of optimization is risk assessment, which makes sure that all possible sources of variability are found and managed. Key formulation and process risks can be identified with the use of tools like Ishikawa (fishbone) diagrams, Failure Mode and Effects Analysis (FMEA), and risk-ranking matrices. Disintegration time, wetting time, hardness, friability, dissolution rate, and taste profile are typical CQAs in FDT development. Critical Process Parameters (CPPs) like compression pressure, mixing time, and drying conditions, as well as Critical Material Attributes (CMAs) like particle size, porosity, and superdisintegrant type, have a direct impact on these CQAs.

Process Analytical Technology (PAT) Tools for Process Optimization: By making it possible real-time control and surveillance of crucial manufacturing steps, PAT improves process understanding. Near-infrared spectroscopy (NIR), Raman spectroscopy, and in-line particle size analyzers are examples of PAT tools that help evaluate blend uniformity, moisture content, and compression dynamics in fast-dissolving tablet formulation without stopping production. PAT additionally encourages continuous manufacturing approaches, where feedback systems adjust parameters automatically to preserve CQAs within desired limits. Incorporating PAT into FDT production guarantees dependable performance, increased productivity, and decreased manufacturing risk while also supporting QbD principles [47].

Clinical Implications and Therapeutic Applications:

Use in Paediatrics, Geriatrics, and Dysphagia Patients: For patients who have trouble swallowing conventional solid dosage forms, fast-dissolving tablets are an essential therapeutic option. FDTs dissolve quickly in the oral cavity, lowering anxiety and increasing medication acceptance. Pediatric patients frequently have trouble swallowing tablets and may refuse medications because of an unpleasant taste.

FDTs ensure safer swallowing, eliminate the need for water, and dissolve with little effort. FDTs are especially helpful in these vulnerable populations because they are non-invasive and simple to administer, and adherence can have a big impact on treatment results.

Applications in Emergency Medicine: In emergency medical situations where quick onset of action and ease of administration are crucial, fast-dissolving tablets are extremely valuable. Because FDTs dissolve in the oral cavity in a matter of seconds, they provide rapid pain relief for musculoskeletal injuries, acute migraine, and postoperative pain. They are a preferred option in acute care situations due to their quick disintegration, potential for pregastric absorption, and enhanced patient acceptability [48].

Bioavailability Enhancement: Fast-dissolving tablets can greatly improve the bioavailability of medications with high first-pass metabolism or poor solubility. A portion of the medication can be absorbed immediately through the buccal or sublingual mucosa after dissolving in the oral cavity, avoiding hepatic metabolism. To further improve dissolution rates and systemic availability, FDTs often include solubility-enhancing technologies like solid dispersions, nanosized particles, cyclodextrin complexes, or micellar systems. Rapid dispersion, enhanced wettability, and partial mucosal absorption all work together to improve clinical efficacy and speed up the therapeutic effect.

Safety Considerations and Patient Compliance: When using FDTs in clinical settings, patient compliance and safety are crucial factors. These dosage forms must dissolve quickly without irritating the mouth, increasing the risk of choking, or creating an unpleasant mouthfeel. Because bitterness or lingering grittiness can lower patient acceptance, particularly in children, taste masking is essential. When properly formulated, FDTs provide better compliance than traditional tablets and capsules, lowering dosage errors and enhancing treatment results for a variety of patient populations [49].

Case Studies of Marketed FDTs: The clinical benefits and broad applicability of this dosage form are demonstrated by a number of commercially available fast-dissolving tablets. Products like Claritin RediTabs® (loratadine) show how quick disintegration increases patient adherence to allergy treatment. One of the best examples of anti-emetic therapy is Zofran ODT® (ondansetron), which provides dependable relief for nausea brought on by chemotherapy or surgery in situations where swallowing difficulties are frequent. By providing a quick therapeutic response, Maxalt-MLT® (rizatriptan) exemplifies the effectiveness of FDTs in the treatment of migraines. Pediatric-friendly products, such as Advil FastMelt® (ibuprofen), demonstrate how children's acceptance is increased by a pleasant taste and quick dispersion [50].

Regulatory and Quality Considerations:

Regulatory Definitions (FDA, EMA Guidelines): To guarantee safety, effectiveness, and reliable performance, regulatory bodies like the US FDA and the European Medicines Agency (EMA) have established precise guidelines and standards for fast-dissolving or oral disintegrating tablets. According to the FDA, an oral disintegrating tablet (ODT) is a solid dosage form that dissolves quickly on the tongue typically in 30 seconds without the need for water. Regulatory submissions must use stability data, validated test procedures, and, if relevant, bioequivalency studies to show that the product satisfies these requirements. Adherence to these regulatory guidelines guarantees consistent categorization and makes it easier for FDT formulations to be widely approved [51].

GMP Considerations: Following GMP is crucial to creating tablets that dissolve quickly and consistently. FDTs need to have environmental factors like temperature and humidity carefully controlled because of their intrinsically permeable nature and lesser mechanical strength than traditional tablets. Manufacturers are required to enforce stringent quality control measures for raw materials, paying special attention to excipient compressibility, moisture content, and particle size distribution. All phases of GMP compliance, including procurement, production, testing, and packaging, guarantee that FDTs continue to function as intended for the duration of their shelf life [52].

Quality Control Parameters: Fast-dissolving tablet quality control testing includes both conventional tablet evaluation criteria and specialized tests created for their distinct features. But FDTs also need to be tested specifically for *in-vitro* dissolution profile, water absorption ratio, wetting time, and disintegration time. Other important factors include mouthfeel assessment,

taste-masking efficacy, and mechanical durability during handling. These specific tests guarantee that the tablets dissolve quickly without sacrificing patient acceptability, stability, or taste. Strict quality control reduces variability that may have an impact on therapeutic results and promotes predictable outcomes throughout batches [53].

Challenges in Scale-Up and Manufacturing: Fast-dissolving tablets' delicate design and complex composition make it difficult to scale up production. When using low-dose APIs or superdisintegrants that need to be distributed uniformly, it becomes especially important to ensure blend uniformity. Because they require exact control over temperature, drying rates, and equipment capabilities, processes like lyophilization and spray drying also present scale-up challenges. To overcome these obstacles while preserving high standards of quality during commercial-scale manufacturing processes, a combination of robust formulation design, procedure optimization, and the adoption of cutting-edge technologies like QbD and PAT are needed [54].

Recent Advances and Future Perspectives:

3D-Printed FDTs: With its unparalleled accuracy and adaptability in creating fast-dissolving tablets, three-dimensional (3D) printing has become a game-changing technology in the pharmaceutical industry. Fused deposition modelling, selective laser sintering, and binder jetting are some of the methods used to create highly porous, structurally complex tablets that quickly break down when they come into contact with saliva. Spritam® (levetiracetam), the first FDA-approved 3D-printed tablet, established a standard for the use of additive manufacturing in oral dosage forms. For patients who need customized dosages, particularly in pediatric or elderly populations, the capacity to manufacture tablets on demand offers substantial benefits. 3D-printed FDTs are anticipated to have a significant impact on precision-based and customized treatments as printing technology develops [55].

Smart Polymers and Novel Excipient Technologies: Smart polymers provide targeted drug release and controlled disintegration in response to stimuli like pH, temperature, or ionic strength. Thermo-responsive polymers, for instance, can maintain stability at room temperature while accelerating disintegration at body temperature. New excipients, like multifunctional co-processed blends (like Ludiflash®, F-Melt®, and Prosolv ODT®), provide better mouthfeel, increased compressibility, and improved flow characteristics, making formulation development easier. These excipients minimize processing complexity and maximize performance by combining filler, binder, and disintegrant qualities into a single system [56].

Personalized Medicine Applications: Fast-dissolving tablets are becoming a more significant part of the personalized medicine paradigm, which aims to customize treatment plans to each patient's unique needs [57]. Drug combinations, dissolution characteristics, and dose strength can all be customized thanks to technologies like rapid prototyping, modular formulation systems, and 3D printing. Wearable monitoring systems and other developments in digital health may soon make it possible to modify FDT formulations in real-time to better suit patient needs, opening the door to dynamic, patient-specific medication delivery [58].

Market Trends and Future Opportunities: Growing beneficial for patient’s dosage forms, an aging population, and improvements in excipient and manufacturing procedures are driving the global market for fast-dissolving tablets. Pharmaceutical companies are concentrating on broadening the FDT portfolio to include drugs for the central nervous system, gastrointestinal tract, analgesics, and antihistamines [59]. Innovations like multifunctional excipients, on demand manufacturing technologies, and FDTs based on nanotechnology are anticipated to support the industry's future development. All things considered, the future of FDTs depends on fusing personalized healthcare with technological innovations to provide safer, quicker, and more potent treatments [60].

CONCLUSION: Fast-dissolving tablets (FDTs) represent a significant advancement in oral drug delivery by offering a patient-friendly dosage form that improves compliance among pediatric, geriatric, dysphagic, and emergency-care populations. Progress in formulation science,

particularly the use of superdisintegrants, co-processed excipients, and solubility-enhancing approaches, has enabled the development of FDTs with rapid disintegration, adequate mechanical strength, and improved bioavailability. Manufacturing techniques such as direct compression, freeze-drying, sublimation, spray drying, and nanotechnology-based systems provide flexibility in formulation design, while optimization tools including Quality by Design (QbD), Design of Experiments (DoE), and Process Analytical Technology (PAT) support robust and scalable production. Clinically, FDTs offer advantages such as rapid onset of action, ease of administration, and suitability for both acute and chronic therapy, which is reflected in their growing commercial adoption. Despite these benefits, challenges related to taste masking, moisture sensitivity, large-scale manufacturing, and product stability remain. Future research is expected to focus on advanced excipient technologies, smart polymers, 3D printing, and personalized dosing strategies. Continued innovation in formulation design and regulatory harmonization will further strengthen the role of FDTs in modern pharmaceutical therapy.

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