

Strategies for the Development and Optimization of Orally Disintegrating Tablets (ODTs) to Improve Bioavailability and Patient Compliance

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Abstract

Background: Pharmaceutical scientists have developed Orally Disintegrating Tablets (ODTs) to advance patient drug acceptance and biological system availability through simplified medication delivery, especially for children and senior citizens and people who cannot swallow pills regularly. The oral disintegrating tablets dissolve in the mouth within thirty seconds or less (USP 701) while needing no additional liquid thus making them suitable for both emergency treatments. **Objective:** The research examines ODT development strategies by examining critical formulation elements and choosing the right excipients then measures approaches to boost drug availability and details manufacturing processes alongside regulatory framework demands. **Regulatory Considerations:** The production of ODTs requires adherence to FDA along with EMA and ICH guidelines that enforce rapid drug dissolution ($\geq 85\%$ within 15 minutes according to USP 711) and permitted friability ($\leq 1\%$) and ICH Q1A specified long-term stability (25°C/60% RH, 40°C/75% RH accelerated testing). The choice of direct compression along with lyophilization spray drying and three-dimensional printing systems serves as fundamental factors to develop robust fast-disintegrating tablets with controlled drug release. **Future Directions:** The development of ODTs extends into therapy areas with biologic-based substances and vaccines alongside gene therapies, therefore, enabling needle-free delivery of macromolecules peptides and monoclonal antibodies (mAbs).

Keywords: Orally disintegrating tablets, drug bioavailability, solubility enhancement, superdisintegrants, regulatory compliance, advanced manufacturing

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INTRODUCTION

The pharmaceutical technology of Orally Disintegrating Tablets (ODTs) has evolved to create dosage forms which disintegrate in the oral cavity during the span of 30 seconds while without requiring water consumption based on FDA and USP guidelines thus they provide benefits for pediatric patients as well as seniors and patients with dysphagia. The tablets achieve disintegration rapidly through their 2–4 kg/cm² hardness values which provide adequate strength properties [1]. Equitable disintegration performance can be achieved by using microcrystalline cellulose (MCC) and mannitol excipients with particle sizes ranging from 50 to 200 micrometers. The tablet disintegration time can be shortened through capillary action and swelling mechanisms by adding superdisintegrants at 2–8% w/w concentrations which include croscopovidone,

croscarmellose sodium and sodium starch glycolate [2]. The disintegration performance of ODTs depends heavily on their porosity levels that should be maintained within 10–30% and exhibit 90° or lower contact angles to enable quick liquid absorption. The tablet degradation requires a protective mechanism including aluminum blisters with desiccants to maintain a moisture content below 5% [3]. The combination of hydrophilic carriers including PEG and PVP at a ratio range from 1:1 to 1:5 within solid dispersion formulations has proven effective for enhancing solubility together with absorption [4]. The bioavailability receives additional enhancement from self-emulsifying drug delivery systems (SEDDS) when their oil-to-surfactant ratios fall between 1:3 to 1:5 because they encourage lymphatic transport and prevent first-pass drug metabolism [5].

The process of taste-masking in ODT design requires polymer coatings between 5 and 20 μm thick or ion-exchange resins at 5–10% w/w to mask bitter APIs. Direct compression remains the chief production method which needs compression forces between 5–20 kN to create unharmed and fast-disintegrating tablets [6]. The porous structures made through lyophilization processes have 0.1–0.5 g/cm^3 density that results in 5–10-second ultra-fast disintegration times. The specific printing methods of 3D technology enable precise control that ranges from 0.1 to 100 mg drug per tablet along with perfect microstructural design to shape release patterns. The USP requires ODTs to fulfill disintegration time specifications of under 30 seconds together with USP 1216 specified friability criteria of $\leq 1\%$ and content uniformity levels between 85–115% of the stated dosage [7]. Stability tests according to ICH regulations test drug-excipient interactions while projecting shelf-life by using 25°C/60% RH (long-term) and 40°C/75% RH (accelerated). Precise formulation strategies merged with innovative processing technologies and strong quality control measures will make ODT drug delivery systems maintain their effectiveness in improving therapeutic practice and patient adherence in pharmaceutical commerce [8].

CHALLENGES IN ORAL DRUG DELIVERY

Among all drug delivery approaches oral medication stands as the preferred method because it provides convenience, reduced costs and fits well with patient needs [9]. However, several challenges limit its effectiveness, particularly in terms of bioavailability, patient compliance, and formulation stability are mentioned in Table 1. The act of swallowing causes significant problems for medical drug delivery because it affects 40% of elderly patients and 30–40% of children which then leads to patient noncompliance and suboptimal treatment results [10].

ODTs represent the advanced format of patient-friendly pharmaceuticals that healthcare providers currently produce to treat dysphagia which affects both older adults and younger patients whose swallowing abilities decline because of age-related changes (Figure 1).

The requirement of water to administer standard tablets creates practical challenges especially during patient travel or while caring for bedridden individuals. Poor drug solubility and permeability remain one of the major challenges in therapeutic drug delivery because drugs belonging to Biopharmaceutics Classification System (BCS) Class II (low solubility and high permeability) and Class IV (low solubility and low permeability) make up about 40% of the market drugs and 70% of pipeline drugs [11]. The inconsistent drug absorption becomes a factor that negatively affects therapeutic drug effectiveness. Dissolution rate controls the oral bioavailability levels according to the Noyes–Whitney equation, The dissolution rate depends on dC/dt together with D and A and C_s and h . The therapeutic value of insoluble drugs demands solubility improvement methods which include nanotechnology with small particle sizes less than 500 nm as well as solid dispersions using drug–polymer ratios between 1:1 and 1:5 and cyclodextrin complexation systems formed at 1:2 molar ratios [12].

$$dC/dt = D * A * (C_s - C)/h$$

FIRST-PASS METABOLISM AND SYSTEMIC AVAILABILITY

The main drawback of oral drug delivery occurs when drugs are metabolized by the liver before they reach the bloodstream. First-pass metabolism affects between 40–60% of drugs taken by mouth and

decreases their availability for treatment [13]. The degree of first-pass metabolism appears through the following formula:

$$F = FA * (1 - EH)$$

The bioavailability calculation relies on the F value together with FA and EH factors. Pharmacological compounds which have an extraction ratio above 0.6 (including propranolol and nitrates) reach the body with substantially diminished availability. The development of buccal absorption for drugs along with nanoemulsion-based formulations with mean particle sizes from 10 to 100 nanometers has become a method of extending drug absorption despite hepatic metabolism [14].

Taste-Masking and Palatability Issues

The successful formulation of ODT requires effective taste masking because bitter tastes cause patients to become noncompliant. Scientific research reveals that pediatric patients will reject treatment medications that have an objectionable taste at a rate of 90%. The oral administration of cetirizine requires masking techniques because its threshold bitterness reaches 10 µg/mL while ranitidine needs methods for bitterness masking at 20 µg/mL. The combination of thin polymer coatings within 5–20 µm range and drug:resin ratios between 1:3 to 1:5 are commonly employed with microencapsulation for taste improvement and user acceptance in medicine delivery [15].

Stability and Moisture Sensitivity

High humidity (≥60% RH) degrades ODT formulations because mannitol and sodium starch glycolate excipients dissolve in such conditions thus reducing mechanical strength and drug performance [16]. Aluminum blisters with desiccants serve as protective packaging that reduces the occurrence of degradation. Every ODT formulation needs balanced hardness with porosity amounts to keep both product structure intact and its disintegration process swift. The combination of compression forces exceeding 20 kN leads to strong mechanical properties yet it slows down disintegration time while porosity higher than 30% produces excessive tablet friability. The pharmacopoeial standards for orally disintegrating tablets require strict definitions regarding their effectiveness and stability together with patient convenience standards [17]. USP 701 states ODTs must dissolve by the 30 second time limit to release the drug content without requiring water for dissolution. The dissolution rate of these tablets needs to satisfy USP 711 to achieve ≥85% drug release within 15 minutes for proper drug absorption. USP 1216 rules the maximum allowable percentage of friability at ≤1% in order to protect the mechanical structure when performing operations. ICHS Q1A guidelines mandate stability testing of the drug which requires keeping the product at 25°C/60% RH (long-term) and 40°C/75% RH (accelerated conditions) to evaluate its durability across different environmental scenarios. Strong evaluation procedures establish ODTs as stable effective and secure medications for their designated shelf life. The combination of nanotechnology with AI-driven formulation modeling techniques and 3D printing devices provides optimistic pathways for advanced ODTs which solve previous problems but enhance the effectiveness of treatments [18].

Table 1. Challenges and possible solutions in oral drug delivery.

Challenge	Impact	Possible solutions	Reference
Swallowing difficulty	Affects 40% of elderly and 30–40% of pediatric patients; leads to poor compliance.	ODTs, chewable tablets, buccal films.	[19]
Poor solubility & permeability	40% of marketed drugs and 70% of pipeline drugs belong to BCS Class II/IV, leading to poor absorption.	Nanotechnology, solid dispersions, cyclodextrin complexation.	[20]
First-pass metabolism	40–60% of drugs undergo hepatic metabolism, reducing systemic availability.	Buccal absorption, nanoemulsions, lipid-based formulations.	[21]
Taste masking	90% of pediatric patients reject bitter-tasting drugs like cetirizine (>10 µg/mL bitterness threshold).	Polymer coatings, ion-exchange resins, microencapsulation.	[22]
Moisture sensitivity	High humidity (>60% RH) degrades hygroscopic excipients like mannitol, affecting tablet stability.	Protective packaging (aluminum blisters, desiccants).	[23]
Disintegration vs. mechanical strength	High compression forces (>20 kN) delay disintegration, whereas excessive porosity (>30%) increases friability.	Optimal superdisintegrant selection, controlled compression force.	[24]



Figure 1. Challenges in oral drug delivery.

STRATEGIES FOR THE DEVELOPMENT OF ODTs

The development of effective orally disintegrating tablets (ODTs) demands an organized process which delivers rapid disintegration combined with adequate strength properties alongside better absorption rates and better patient satisfaction are given in Table 2. Product specifications based on USP and FDA guidelines state that ODTs should disintegrate within thirty seconds while superdisintegrants must be used between two and eight percent w/w weights. Both mechanical strength and integrity requirements are essential for ODTs during production and packaging operations as well as transport; thereby requiring hardness values within 2–4 kg/cm² and friability below 1%. Materials used for excipients – such as mannitol (50–200 µm) and microcrystalline cellulose (MCC, 50–150 µm) – are employed to achieve better compressibility along with palatability in the manufacturing process [25]. The current formulation of ODT products encounters multiple significant obstacles because APIs show inadequate solubility and because patients face first-pass metabolism effects while requiring taste-masking solutions and stability management methods. Drugs that exhibit poor dissolution properties require special formulation methods that include making nanoparticles below 500 nm and solid dispersion systems with drug-to-polymer ratios from 1:1 to 1:5 and lipid-based systems constructed using oil-to-surfactant ratios from 1:3 to 1:5. Taste-masking technology stands as a crucial element for patient adherence because it works to eliminate the bitter taste of API formulations including cetirizine when the threshold solute reaches 10 µg/mL and ranitidine at its threshold value of 20 µg/mL. Three effective methods of taste masking involve polymer coatings which should be between 5 and 20 micrometers thick and ion-exchange resins composing 5 to 10 weight percent solution and microencapsulation [26].

SELECTION OF SUITABLE DRUG CANDIDATES

Drugs fail to be suitable candidates for ODT formulations due to multiple factors including dose amount together with solubility and permeability status and stability and taste requirements. A maximum drug level of ≤20 mg remains suitable for ODTs since higher doses produce larger sized tablets which decrease patient acceptability. Mucosal absorption shows its best permeability properties with drugs that have log P values ranging between 1–3. According to the Biopharmaceutics Classification System BCS drugs that fall under Class I and Class III are best suited for ODT production, yet drugs categorized as Class II need additional treatment methods through nanoparticle formulations and amorphous dispersion and cyclodextrin complexation (1:2 molar ratio) to achieve acceptable bioavailability levels [27].

Choice of Excipients for ODT Formulation

Tablet disintegration together with palatability and mechanical strength receives substantial influence from excipients. The disintegration of tablets improves through capillary action and swelling when using superdisintegrants like crospovidone and croscarmellose sodium and sodium starch glycolate at doses from 2 to 8% w/w. Mannitol with a particle size ranging from 50–200 μm along with MCC measuring 50–150 μm function as filler and diluents to improve compressibility and add a pleasurable mouthfeel. The incorporation of hydroxypropyl methylcellulose (HPMC) Eudragit polymers and ion-exchange resins as taste-masking agents results in bitterness reduction for better patient medicine acceptance [28].

Manufacturing Technologies for ODTs

The manufacturing technique selection determines both physical characteristics and dissolution rate and stability output of orally disintegrating tablets (ODTs). Manufacturers use different methods to reach their optimum operational results. The most widespread manufacturing technique relies on direct compression which needs compression forces between 5–20 kN to obtain proper mechanical stability and speedy disintegration. Freeze-drying acts on the product to produce structures which contain porous sections and achieve densities between 0.1–0.5 g/cm^3 resulting in disintegration times of 5–10 seconds. Through molding and sublimation processes pharmaceutical products gain enhanced porosity while the dissolution rates become quicker because of their highly porous internal structure. The spray drying process enables both uniform distribution of active pharmaceutical ingredients (APIs) and provides consistent drug content as well as fast disintegration times. The combination of advanced manufacturing methods functions to boost effectiveness while enhancing stability together with improving patient satisfaction for ODT formulations [29].

Optimization Strategies for ODT Performance

For improving the efficiency of orally disintegrating tablets (ODTs) researchers need to optimize disintegration speed and dissolution rates as well as taste-concealing techniques and stability measures. The desired rapid tablet breakdown occurs when porosity levels are kept within 10–30% because it enables fast water absorption which quickens disintegration processes. Dissolution time improves using hydrophilic excipients together with superdisintegrants as well as nano-scale drug formulations (particle size $<500\text{ nm}$) that enhance drug solubility. Cross-sections of 5 to 20 micrometers are used for polymer coatings to mask bitter compounds, but drug release modifications come from using microencapsulation and ion-exchange resins at 5 to 10 weight percent and β -cyclodextrins bring taste suppression when used at 1:2 molar ratio. Drug efficacy stability demands low moisture levels below 5% to avoid product breakdown. The combination of protective packaging with desiccants inside aluminum blisters helps preserve formulation life expectancy by keeping it safe from environmental influences. The combination of mentioned strategies results in improved performance alongside patient-friendly features and extended stability which maintains the effectiveness of ODTs as present-day medicine delivery systems [30].

Regulatory and Quality Control Considerations

Orally disintegrating tablets (ODTs) need to meet strict pharmacopoeial requirements to reach commercial viability and a therapeutic success. According to USP 701, the disintegration of ODT for swish and rinse should disintegrate within 30 seconds and USP 711, the rate of dissolution at least 85% within 15 minutes to maintain optimal bioavailability. It is extremely critical for tablet integrity, being friable no higher than 1% (USP 1216) to withstand packaging and handling, and hard enough between 2 to 4 kg/cm^2 to keep a good balance between mechanical strength and fast disintegration. It follows the ICH guidelines for stability testing with long term storage at 25°C, 60% RH and at accelerated conditions of 40°C, 75% RH to ensure durability. Completing, these formulations are revolutionizing, because of emerging advancements as AI-based formulation modeling, biodegradable polymer-based ODTs, and the nanocarrier loaded systems for biologics, which offers greater efficacy, lower intolerance and broader pharmaceutical applications. ODT development takes a strategic excipient selection, cutting edge manufacturing technology and strict regulation compliant approach [31].

Table 2. Strategies for ODT development and optimization.

Strategy	Purpose	Parameters & techniques	Reference
Superdisintegrants	Enhance tablet disintegration	2–8% w/w (croscopovidone, croscarmellose sodium, sodium starch glycolate)	[32]
Fillers & Diluents	Improve compressibility & mouthfeel	Mannitol (50–200 µm), MCC (50–150 µm)	[33]
Taste-Masking Agents	Reduce bitterness & improve palatability	Coatings (5–20 µm thickness), ion-exchange resins (5–10% w/w), β-cyclodextrins (1:2 ratio)	[34]
Nanotechnology	Improve drug solubility & bioavailability	Particle size <500 nm, lipid-based carriers (SEDDS, 1:3–1:5 ratio)	[35]
Manufacturing Methods	Ensure tablet integrity & rapid disintegration	Direct compression (5–20 kN), lyophilization (0.1–0.5 g/cm ³), spray drying, 3D printing	[36]
Stability Optimization	Maintain tablet quality & extend shelf life	Moisture control (<5%), protective packaging (aluminum blisters, desiccants)	[37]
Regulatory Compliance	Ensure safety, efficacy, & approval	Disintegration (≤30 sec), dissolution (>85% in 15 min), friability (≤1%)	[38]

OPTIMIZATION STRATEGIES FOR ODT PERFORMANCE

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Disintegration and Dissolution Optimization

A quick rate of disintegration along with dissolution determines how effectively ODTs work. The disintegration process gets accelerated through superdisintegrants that contain between 2–8% weight ratio of components like croscopovidone, croscarmellose sodium, and sodium starch glycolate which increase water absorption while breaking down tablets. The disintegration process adheres to Peppas' equation as T represents the breakdown time that depends on ϵ which indicates porosity and tablet design along with the rate of liquid penetration [40].

$$T = k \times \epsilon - n$$

where, k is the disintegration rate constant and n is the swelling exponent value of the polymeric superdisintegrants. As the porosity should not be greater than 10%, it permits a fast rate of water absorption with adequate mechanical strength. Furthermore, the hydrophilic carriers including PEG, poloxamer and in solid dispersion of drug to polymer ratio of 1:1 to 1:5 are observed to enhance the solubility and dissolution rate of drug.

Enhancement of Bioavailability

Formulation of ODTs for BCS Class II and class III compounds also involve challenges due to the requirement to achieve high bioavailability in the product. There are several formulation strategies used in the improvement of solubility, dissolution rate, and absorption of the drug product so as to achieve

its delivery. Techniques – like nanoparticle engineering, solid dispersion, SEDDS or self-microemulsifying drug delivery system, and cyclodextrin inclusion complex – are valuable in handling different bioavailability issues [41]. The following are some of the methods that can be used to enhance drug solubility and absorption profile of ODT formulations (Table 3).

Table 3. Bioavailability enhancement techniques for ODTs [42, 43].

Technique	Purpose	Key parameters
Nanoparticle Engineering	Increases surface area and dissolution	Particle size <500 nm.
Solid Dispersions	Improves solubility using hydrophilic carriers	Drug-polymer ratio 1:1 to 1:5.
Self-Emulsifying Drug Delivery Systems (SEDDS)	Enhances absorption via lymphatic transport	Oil-to-surfactant ratio 1:3 to 1:5.
Cyclodextrin Inclusion Complexes	Enhances solubility of hydrophobic drugs	1:2 molar ratio.

Taste-Masking Approaches

Promoting patient compliance, particularly both in pediatric and geriatric populations, taste masking is an essential requirement of pharmaceutical formulation (Table 4). Only 10% of pediatric patients accept bitter tasting drugs such as cetirizine (bitterness threshold 10 µg/mL) and ranitidine (20 µg/mL) [44].

Table 4. Taste-masking techniques for ODTs [45–47].

Technique	Mechanism	Key parameters
Polymer Coating	Creates a barrier around bitter APIs	Thickness: 5–20 µm (HPMC, Eudragit).
Ion-Exchange Resins	Complexes APIs with resins to block taste receptors	Drug:resin ratio 1:3 to 1:5.
Microencapsulation	Encloses drug particles within lipid/polymer matrices	Encapsulation efficiency ≥90%.
Prodrug Formation	Converts bitter drugs into tasteless derivatives	Requires enzymatic conversion post-administration.

Stability and Moisture Sensitivity Considerations

ODT integrity is greatly influenced by moisture, in particular with respect to the use of moisture sensitive hygroscopic excipients – such as mannitol and sodium starch glycolate – that degrade in high humidity (>60% RH). Stability improvements are given in Table 5.

Table 5. Stability enhancement strategies for ODTs [48, 49].

Challenge	Optimization strategy	Key parameters
Moisture Sensitivity	Use of desiccants	Silica gel, molecular sieves.
Hygroscopic Excipients	Use of lyophilized ODTs	Density: 0.1–0.5 g/cm ³ .
Chemical Degradation	Modified-release polymer coatings	Ethyl cellulose, HPMC.
Temperature Sensitivity	ICH Q1A stability testing	25°C/60% RH (long-term), 40°C/75% RH (accelerated).

MECHANICAL STRENGTH VS. RAPID DISINTEGRATION

ODTs must possess high mechanical strength (hardness: 2–4 kgM²) for handling yet quickly disintegrate (<30 sec). Mechanical Strength Optimization for ODTs are mentioned in Table 6.

Table 6. Mechanical strength optimization for ODTs [50].

Factor	Optimization approach	Key parameters
Compression Force	Optimal force balance	5–20 kN.
Effervescent Disintegration	Gas generation for rapid breakdown	Citric acid + NaHCO ₃ (5–10% w/w).
3D Printing of ODTs	Microstructure control	Customizable porosity.

Regulatory and Quality Control Compliance

The market approval and batch to batch consistency of ODTs are required to comply with stringent bioequivalence studies as mandated by Council for International Organization of Medical Aids (CI-OMA) regulatory agencies such as Food and Drug Administration (FDA), European Medicine Agency (EMA), and International Commission on Harmonization (ICH). A major focus of these studies is to confirm equivalence of these key parameters for example, maximum plasma concentration, time to peak concentration, and overall drug exposure. Meeting these requirements completes safety, effectiveness and market approval for ODT formulations. Essential regulatory guidelines related to the development of ODT are summarized in the following Table 7 which also provides the appropriate quality control parameters [51, 52].

Table 7. Regulatory compliance parameters for ODTs [53].

Regulatory parameter	Required specification
Disintegration Time	≤30 sec (USP 701).
Dissolution Rate	≥85% drug release in 15 min (USP 711).
Friability	≤1% (USP 1216).
Hardness	2–4 kg/cm ² .
Moisture Content	<5%.
Stability Testing	25°C/60% RH (long-term), 40°C/75% RH (accelerated).

FUTURE TRENDS AND INNOVATIONS

Technological improvements in the Orally Disintegrating Tablet (ODT) technology are steadily enhancing drug delivery system through different solutions like AI in formulating the new tablet formulation by predicting the interaction of the excipients to come up with better stability and performances of the final product. It is possible to conserve space through 3D printing, organize individual dose and layer medication as per the patient's requirements to guarantee the individualized therapeutic efficiencies [54]. The advantages of biodegradable polymer-based ODTs include environmentally friendly because they minimize cases of compound wastage. Furthermore, because the new ODTs for biologics and vaccines and nanocarrier-based delivery systems for such formulations are emerging beyond the small-molecule drug classification, this is increasing the fitness of these formulations to patients. These optimization strategies, improved excipient selection, and regulatory guidelines of next-generation ODTs will enhance the efficacy, stability, and compliance among the patients changing the face of Pharma therapy [55].

Regulatory and Quality Control Aspects

The industry of ODTs also relies on regulatory compliance, proper quality testing, and conformity to auts to guarantee uniformity not only in terms of batch production, safety of the patient and potency of the drug. The United States Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the International Conference on Harmonization (ICH) that have laid down the criteria to assess ODTs where some of the criteria includes; the disintegration time, the rate of dissolution, uniformity, stability, types of friability, and mechanical strength [56]. USP 701 demonstrates that an ODT should disintegrate within ≤30 seconds and dissolution dissolving (USP 711) should release 85% of the drug within 15min. Taber hardness is within the range of 2–4 kg/cm², friability is ≤1%, moisture content is <5% and stability test is done at 25°C/60% RH for long-term test and 40°C/75 % RH for accelerated test. Also, the bioequivalence evaluation of ODTs to the traditional dosage forms should involve those pharmacokinetic parameters, including C_{max}, T_{max}, and AUC. FTIR, DSC, XRD, SEM and other sophisticated methods like these are used to determine compatibility of drug with excipients, polymorphism, and structural characteristics of the pure as well as in lyophilized formulations. This section describes and outlines the important regulatory and quality control measures that are needed for ODT to gain approval and acceptance in the market [57].

Regulatory Guidelines for ODTs

Various international regulatory agencies have established specific guidelines to ensure the quality, safety, and efficacy of orally disintegrating tablets (ODTs). These guidelines define critical parameters such as disintegration time, dissolution rate, stability, and mechanical integrity. Each regulatory body

mandates in-vitro and in-vivo bioequivalence studies, requiring pharmacokinetic profiling and stability testing under defined environmental conditions [58]. The following table provides an overview of the key regulatory requirements set by different agencies for ODT development and evaluation are in Table 8.

Table 8. Regulatory guidelines for ODTs [59, 60].

Regulatory Agency	Guidelines & requirements
U.S. FDA	ODTs must disintegrate within ≤ 30 seconds; require bioequivalence studies for approval.
EMA (European Medicines Agency)	Stability studies under ICH Q1A guidelines; require dissolution testing ($\geq 85\%$ release in 15 min).
ICH (International Council for Harmonization)	ICH Q8 (Pharmaceutical Development), Q9 (Quality Risk Management), Q10 (Pharmaceutical Quality System).
Indian Pharmacopoeia (IP)	Requires tablet uniformity, moisture control ($< 5\%$), and friability testing ($\leq 1\%$).
Japanese Pharmacopoeia (JP)	Disintegration testing with saliva substitute solution to mimic physiological conditions.

QUALITY CONTROL TESTING FOR ODTs

ODTs need to undergo several physicochemical and performance tests to have homogeneity, potency, and safety in the manufactured products are outlined in Table 9.

Table 9. Quality control parameters for ODTs [61].

Test	Pharmacopoeial standard	Acceptable range
Disintegration Time	USP 701	≤ 30 sec.
Dissolution Rate	USP 711	$\geq 85\%$ drug release in 15 min.
Hardness	USP 1217	2–4 kg/cm ² .
Friability	USP 1216	$\leq 1\%$ weight loss.
Moisture Content	ICH Q1A Stability Testing	$< 5\%$ (Karl Fischer Titration).
Weight Variation	USP 2091	$\pm 5\%$ for 80–250 mg tablets.
Content Uniformity	USP 905	85–115% of labeled dose.

Bioequivalence and Pharmacokinetic Studies

The FDA and EMA require bioequivalence tests through randomized crossover clinical studies involving at least 24 healthy subjects undergoing assessment under fasting and fed situations. The United States Food and Drug Administration together with the European Medicines Agency complies with bioequivalence requirements that require orally disintegrating tablets (ODTs) to prove their equivalence to traditional formulations through pharmacokinetic studies during regulatory approval. Bioequivalence testing includes evaluation of C_{max} parameters which signify peak drug plasma levels in blood because they need to maintain 80–125% reference value range for therapeutic equivalence results. A drug absorption analysis where T_{max} measures how long it takes to reach the maximum drug concentration enables the evaluation of drug onset and determines absorption speed [62]. The drug exposure duration is measured by AUC (area under the curve) which reveals the complete drug exposure during the entire period reflecting drug absorption together with the level of system distribution. Bioequivalence testing along with therapeutic outcome consistency relies on pharmacokinetic evaluations to fulfill regulatory standards [63].

ADVANCED ANALYTICAL TECHNIQUES FOR QUALITY ASSURANCE

Analytical characterization ensures drug stability, purity, and microstructural integrity are given in Table 10.

Table 10. Advanced analytical techniques for ODT Quality Assurance [64, 65].

Analytical technique	Purpose
Fourier-Transform Infrared Spectroscopy (FTIR)	Identifies drug-excipient interactions.
Differential Scanning Calorimetry (DSC)	Detects polymorphic transitions and stability issues.
X-Ray Diffraction (XRD)	Determines crystalline vs. amorphous nature of APIs.
Scanning Electron Microscopy (SEM)	Analyzes surface morphology and porosity.
Karl Fischer Titration	Measures moisture content (<5%).
High-Performance Liquid Chromatography (HPLC)	Ensures drug content uniformity.

Post-Marketing Surveillance and Pharmacovigilance

Once an orally disintegrating tablet (ODT) product is approved and introduced to the market, pharmacovigilance programs play a crucial role in tracking adverse events and ensuring long-term product quality. Post-marketing stability studies are conducted to evaluate the formulation's performance over time under varying environmental conditions. Regulatory agencies mandate annual product quality reviews (APQR) and periodic safety update reports (PSURs) to monitor key aspects such as adverse drug reactions (ADRs) in patients, long-term stability trends, and potential product recalls due to formulation inconsistencies. These measures help maintain safety, efficacy, and compliance with regulatory standards throughout the product's lifecycle [66].

Future Perspectives in Regulatory Compliance

In future, modification in ODT regulation is expected with assistance from regulatory science, AI-based quality assurance testing, and real time testing release. Progress in technology is always knitting new dimensions in designing and controlling of Orally disintegrating tablets so that these are more accurate, efficient, and stable. AI testing regulation BOTH AI and machine learning cause the identification of drug-excipient interaction and also an optimization of dissolution profiles to realize specific and constant product quality and performance in conjunction with 3D the printing of ODT formulations, it means personalized medicine delivery system. Also, smart packing that comes with RFID and IoT enhances the monitoring of the existence temperature and humidity to minimize decomposition of the drugs and to Maintain its stability at the time of storage and transportation. As for the future, these innovations define the future course of ODTs, enhance regulation, therapy outcomes, and patient safety [67].

Future Trends and Innovations in ODTs

The ODT field continues to experience steady growth with upon insertion of application of nanotechnology, 3D printing, formulation design based on artificial intelligence, eco-friendly commercializers, and first-patient dose medicine. From Table 11, future ODTs will improve on the existing systems in terms of showing better bioavailability of the drug, faster disintegration time, patient compliance, and the ability to incorporate more products such as biologics, vaccines, and combination therapies. Technological in vivo-nanoparticle engineering, smart polymers, and sophisticated techniques – such as real time release testing or RTRT – are now setting the pace of change in the form of ODT formulations so that patient compliance can be enhanced through single-dose dosing, better taste masking and stability even in extreme conditions. Upcoming generation ODTs will be incorporating smart drug delivery systems, self-dispersing nanoemulsions and the advanced formulation modeling which will help to overcome the existing drawback of oral drug delivery [68].

Table 11. Future Applications of ODTs Beyond Conventional Drugs [69, 70].

Application	Target drug type	Potential benefits
Biologic ODTs	Insulin, monoclonal antibodies, peptides	Needle-free delivery, increased patient adherence.
Vaccine ODTs	Oral COVID-19 vaccine, polio vaccine	Easy storage, non-invasive administration.
Gene Therapy ODTs	DNA/RNA-based drugs	Improved stability, reduced degradation in GI tract.

Table 12. Emerging nanotechnology-based approaches for ODTs [71, 72].

Technology	Mechanism	Advantages
Nanocrystals	Reduction of particle size to <200 nm to enhance surface area	Increased solubility and dissolution rate.
Solid Lipid Nanoparticles (SLNs)	Drug encapsulation in lipid-based carriers	Improved stability, controlled release.
Nanoemulsions	Oil-in-water or water-in-oil dispersions with droplet size <100 nm	High bioavailability, fast absorption.
Polymeric Nanoparticles	Controlled drug release via biodegradable polymers	Sustained and targeted delivery.

Nanotechnology and Drug Bioavailability Enhancement

Another main issue about the preparation of ODTs is the poor dissolution rates among the scarcely soluble drug. Nanoemulsions, nanocrystals and solid lipid nano-particles (SLNs) have been proposed as possible solutions to this. The relation between particle size and chemical dissolution rate and absorption and systemic drug availability increases when the particle size is below 500 nm. Table 12 gives Emerging Nanotechnology-Based Approaches for ODTs [73].

3D Printing for Personalized Medicine

The ODTs which are produced by using 3D printing technology can be customized with respect to accurate dosing, multiple layered release profile and varying geometrical structure of the tablets. This has a possibility of formulating specific dosages for pediatric, geriatric and patients with specific neurological disorders. The first example of using additive manufacturing in ODT production was Spritam® (levetiracetam) that has been already approved by the U.S. FDA [74].

AI-Driven Formulation Design

With the help of artificial intelligence and machine learning, the ODT development process is becoming revolutionary in terms of predicting possible interactions between drugs and excipients, possible optimum disintegration time, and stability issues. Machine learning tools predict the physicochemical property of formulations depending on the required porosity range (10–30%), which, distribution profile, and bioavailability coefficients [75].

Biodegradable and Smart Polymers

In future ODTs, biodegradable polymers that include PLA and PCL will have to be used for environmentally sensitive and sustainable drug delivery systems. Smart polymers with pH-sensitive and thermo-sensitive properties will ensure effective delivery of drugs and help to stabilize the preparation on the shelf [76].

Expansion to Biologics and Vaccines

Previous ODTs have been defined for small molecules, while the conventional approaches to generate ODTs for large molecules have not been well described until the recent formulation advances have explored biologic-based ODTs such as vaccines, peptides, and mAbs. Lyophilized ODTs include insulin, COVID-19 vaccines, and gene therapy formulations such as Allelele's Capsugel ODTs [77].

CONCLUSION

ODTs have emerged as the new generation of oral dosage forms that have revolutionized oral drug delivery and regained the patient's acceptability by providing fast dissolving dosage forms particularly in children, elderly and dysphagic patients. Of late, there has been better control over the choice of excipients, selection of formulation techniques and drug delivery systems to offer better ODTs as far as quick disintegration within 30 seconds, higher bioavailability, as well as better compliance. These problems include issues to do with solubility and permeability, overcome by means of nanotechnology, solid dispersion and self-emulsifying systems. Techniques – like polymer coatings, ion exchange, micro encapsulation – enhanced the ability to give a non-bitter metallic taste to the oral medicine so that the patient does not refuse to take it. The advancements in manufacturing techniques – such as applying

direct compression, freeze drying, spray drying, and 3D printing – have made it possible mass produce a stable ODTs accompanied by accurate dosage and modified release patterns. This is due to regulatory requirements imposed by the FDA, EMA, and ICH concerning drug content uniformity, friability, moisture content as well as stability testing. Such ODT technology's future developments are in transitioning to biologics, vaccines, and gene therapy-based formulations and applying needle-free drug delivery. New advances in Biodegradable polymers, Artificial intelligence in formulation modeling, real-time release testing, and Intelligent or smart packaging will add value to the quality control, stability and ensure regulatory compliances. With the development of the sophisticated pharma technology, the concept of ODTs will remain to revolutionize in the future through enhancing therapeutical performance, enhancing patient compliance and a sustainable solution to the delivery of medications.

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Conflict of Interest

Nil.

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