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A Critical Review of Orodispersible Tablet Technologies: From Taste-Masking to Personalized 3d-Printed Drug Delivery Systems

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Abstract:

Orodispersible tablets (ODTs) represent a paradigm shift in oral drug delivery, enabling rapid disintegration and administration without water. The field has experienced rapid transformation in 2025 through continuous manufacturing, advanced taste-masking strategies, next-generation co-processed excipients, and the emergence of personalized 3D printing. ODTs have evolved beyond simple patient compliance tools toward sophisticated, patient-centric, and precision-engineered delivery systems. This review critically examines the latest technological and clinical advances in ODTs, including AI-driven design, nanotechnology integration, regulatory evolution, clinical applications, market trends, and future perspectives. The review synthesizes recent data, case studies, and regulatory updates, providing valuable insights for scientists, formulators, clinicians, and pharmaceutical stakeholders committed to advancing oral drug delivery technologies.

Keywords: Orodispersible tablets, ODT, taste-masking, co-processed excipients, personalized medicine, 3D printing, pharmaceutical manufacturing, and patient-centric design.

Introduction

Orodispersible tablets (ODTs) are solid dosage forms designed for rapid disintegration in the oral cavity, typically within 30 seconds, without the need for water.

Initially developed to aid pediatrics, geriatrics, and dysphagic patients, ODTs in 2025 have become emblematic of the intersection between technological innovation, patient-centered product development, and precision medicine. The global ODT market is experiencing robust growth, projected to reach USD 64.34 billion by 2035, driven by an aging population, rising incidence of chronic diseases, and growing demand for patient-friendly formulations. Pharma 4.0 initiatives, regulatory harmonization, and expanded therapeutic indications further accelerate market expansion and innovation.[1]

Manufacturing Technologies for ODTs

Continuous Manufacturing

Continuous manufacturing has become a major disruptor for ODT production, enhancing process efficiency, scalability,

and quality by leveraging real-time process analytical technology (PAT). Advantages include reduced batch variability, lower cost, and the agility to rapidly respond to evolving market demand and personalized medicine applications. New WHO and FDA guidelines, published in 2025, emphasize dynamic process control and real-time quality monitoring, enabling continuous manufacturing to meet stringent global regulatory expectations. [2]

Freeze-Drying and Spray Drying

Freeze-drying (lyophilization) is widely used for heat-sensitive drugs, producing highly porous ODTs with rapid disintegration and excellent mouthfeel. Modern freeze-drying is fully automated, precise, and energy-efficient. Spray drying, ideal for poorly soluble drugs, is a scalable method that delivers porous powders suitable for direct compression into ODTs, supporting robust process control and formulation flexibility. [3]

Direct Compression and Smart Manufacturing

Advances in co-processed excipients—such as Ludiflash, Pharmaburst, and Prosolv ODT—mean that direct compression remains simple, robust, and cost-effective, even for complex ODT formulations. The integration of IoT sensors, AI-driven process analytics, and smart automation (Pharma 4.0) further optimizes quality, reduces human error, and enables dynamic adjustments for consistent product performance. [4]

3D Printing (Additive Manufacturing)

Personalized 3D-printed ODTs are now feasible in hospital and community settings, using binder jetting and semi-solid extrusion (SSE) technologies. These techniques allow precise dose control, geometric customization, polypill formation, and patient-specific therapeutic regimens. Clinical validation and emerging regulatory pathways have expanded their use, particularly for pediatrics, geriatrics, and rare diseases. [5]

Taste-Masking Strategies

Modern ODTs employ a spectrum of taste-masking approaches:

- **Polymer Coating**: Thin pH-sensitive coatings prevent exposure of bitter APIs to taste buds, dissolving only after the tablet is swallowed.
- **Microencapsulation/Microspheres**: Encapsulate APIs within lipid or polymer matrices for controlled release.
- **Ion-Exchange Resins**: Form complexes with bitter APIs, which release only in the acidic gastric environment.
- **Inclusion Complexes (Cyclodextrins)**: Trap lipophilic drug moieties, preventing detection by taste receptors, while enhancing bioavailability.
- **Hot-Melt Extrusion & Solid Dispersions**: Disperse drugs in carrier matrices to minimize bitter taste and enhance solubility.
- **Nanotechnology-Based Masking**: Nanoparticles and nanocrystals protect APIs and control release kinetics for superior palatability and efficacy.
- **Combination & Sensory Evaluation**: Often, methods are combined and validated via electronic tongue and in vitro saliva assays for optimal effectiveness. [5]

Role of Co-Processed Excipients

Co-processed excipients are multifunctional materials engineered to optimize powder flow, compressibility, rapid disintegration, and taste-masking within a single system. Examples include F-Melt, Pharmaburst, and Prosolv ODT, which are specifically designed for direct compression and

continuous manufacturing environments. These excipients facilitate robust, reproducible production with strong mechanical integrity, minimal friability, and fast disintegration (<30 seconds). Their multifunctionality reduces formulation complexity, supports high-dose API incorporation, and enables compatibility with a broad range of APIs and manufacturing technologies. [6]

Personalized 3D Printing of ODTs

3D printing allows for:

- **Patient-Specific Dosing**: Customization from micrograms to high-dose formulations based on real-time patient metrics.
- **Geometric & Functional Customization**: Patient-preferred shapes, colors, and surface features (e.g., Braille, QR codes), as well as complex internal structures for modified release.
- **Combination Therapies**: Polypills containing multiple APIs with separate release profiles.
- **On-Demand Manufacturing**: Production of individualized therapies in clinical and community pharmacies, and even in unique environments like space missions.
- **AI Integration**: Deep learning and automated formulation optimization enable prediction of critical outcomes and accelerate product development.

Regulatory and Quality Perspectives

The FDA, EMA, and MHRA now provide detailed guidelines for ODT approval, focusing on quality-by-design (QbD), real-time PAT, patient-centric product profiles, and robust risk management. Specific criteria include:

- Disintegration time (<30 sec)
- Hardness and friability for mechanical strength
- Content uniformity and dose accuracy
- Taste-masking validation
- Bioequivalence studies

Continuous manufacturing and 3D printing require dynamic validation and traceability systems, with harmonization efforts addressing persistent regional disparities.

Sustainability, GMP compliance, and patient-focused labeling are prioritizations for regulators in 2025. [7]

Market and Clinical Impact

Market Growth: ODT market projected to reach USD 64.34 billion by 2035, with a CAGR of 7.3–11.5%.

Clinical Efficacy:

ODTs are bioequivalent to standard formulations and improve patient-reported outcomes, especially in pediatric, geriatric, and psychiatric populations. Real-world data demonstrate improved medication acceptance, reduced nursing burden, and cost-effectiveness for chronic diseases and polypharmacy.

Therapeutic Opportunities: Expansion into cardiovascular, neurology, allergy, antiemetic, and high-dose applications, with new frontiers in biologics, gene therapy, and personalized medicine.[8]

Table 1: Comparative Characteristics of Modern ODTs (2025)[1]

Characteristic	Traditional ODT	3D-Printed ODT	Continuous Manufacturing ODT
Disintegration time	<30 sec	<10 sec	<30 sec
Max dose	250 mg	>750 mg	500 mg
Taste masking	Basic/coatings	Multi-modal	Multimodal
Personalization	Batch-level	Patient-specific	Batch/series-level
Manufacturing scalability	High	Low/Medium	Very High

Recent Case Studies

- **Schizophrenia Therapy**: ODT users had 64.5% lower hospitalization and improved compliance compared to conventional tablet users.
- **Riluzole & Sildenafil ODTs**: Bioequivalence confirmed with conventional forms, matching therapeutic outcomes.
- **High-Dose Meloxicam ODT**: Achieved rapid disintegration and robust mechanical strength using novel co-processed excipients and direct compression. [9]

Future Directions

- **Digital Twin & AI Formulation**: Predictive modeling for enhanced development and patient matching.
- **4D Printing & Bioprinting**: Dynamic release profiles and biological API delivery.
- **Sustainable Manufacturing**: Green chemistry, solvent recovery, energy-efficient processes, and biodegradable packaging.
- **Regulatory Innovation**: On-demand, point-of-care manufacturing pathways and harmonized, global digital traceability.[10]

Conclusion

By 2025, ODTs have evolved into precision-engineered, patient-centric drug delivery platforms leveraging AI, nanotechnology, and additive manufacturing. Their proven clinical, regulatory, and commercial impact ensures ODTs will continue to lead oral drug delivery innovation. Addressing stability, scale-up, and regulatory convergence—while pursuing personalized, sustainable approaches—will shape the next era of orodispersible tablet advancement.

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