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The Evolution of Orodispersible Tablets: Formulation Innovations and Future Perspectives

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Abstract:

Orodispersible tablets (ODTs) have emerged as a patient-centric oral drug delivery system, revolutionizing therapy for populations with swallowing difficulties. Over the past decade, ODT technology has advanced through adoption of continuous manufacturing, novel taste-masking techniques, next-generation co-processed excipients, and personalized 3D printing. This review evaluates current trends in ODT formulation, highlights major regulatory advances, and synthesizes global market and clinical outcomes. Emphasis is placed on technological innovations, patient outcomes, and the evolving regulatory environment to provide a roadmap for future research and industry application.

Keywords: Orodispersible tablets, ODT, co-processed excipients, taste masking, 3D printing, direct compression, continuous manufacturing, and personalized medicine.

Introduction

Orodispersible tablets are designed to rapidly disintegrate in the oral cavity, addressing the needs of pediatric, geriatric, and dysphagic patients. Initially embraced for patient convenience, ODTs have become a pillar of personalized and precision medicine. The ODT market is projected to reach USD 64.34 billion by 2035 as technology becomes more sophisticated and tailored towards unique patient needs.[1]

Materials, Methods, and Search Strategy

A comprehensive review was conducted using databases such as PubMed, Scopus, and ScienceDirect, alongside regulatory guidance from the FDA, EMA, and MHRA.

Literature published between 2010 and 2025 was included, focusing on formulation technologies, clinical studies, manufacturing trends, and market reports related to ODTs. Analysis included primary research articles, meta-analyses, regulatory documents, and commercial reports.[2]

Results and Discussion

Innovations in Formulation and Manufacturing

Recent ODT advances include:

Continuous Manufacturing: Integrates process analytical technology (PAT) and automation for scalable, reproducible ODT

production. Reduces batch variability and is supported by new FDA/WHO guidance issued in 2025.

Co-Processed Excipients: Enhance compressibility, flow, and rapid disintegration, exemplified by excipients such as Ludiflash, Pharmaburst, and Prosolv ODT. Their multifunctionality streamlines formulation and supports process intensification.

Taste-Masking Technologies: Modern platforms employ advanced polymers, microencapsulation, ion-exchange resins, cyclodextrin inclusion complexes, nanotechnology-based carriers, and multi-modal approaches validated by human sensory and electronic tongue methods.

3D Printing: Personalizes drug dosing, geometry, and release profile. FDA-compliant binder jetting and semi-solid extrusion 3D printing platforms enable patient-specific tablets in clinical settings. Recent UK legislation and case studies demonstrate successful hospital-based implementation.

Smart Manufacturing: Use of IoT sensors, AI-driven analytics, robotized handling, and digital twin technology has improved efficiency and enabled real-time process adaptation for consistent product performance. [3]

Regulatory Developments

FDA, EMA, and MHRA now enforce QbD-based approval focusing on disintegration times, taste-masking validation, mechanical properties, and real-time process verification. New guidance supports continuous and on-demand 3D printing, aligning with global harmonization and risk-based quality management. [4]

Clinical Outcomes

Meta-analyses confirm that ODTs improve medication adherence and patient

satisfaction, showing clear benefit in pediatric, geriatric, and mental health populations. ODTs are recognized for comparable or improved bioavailability versus standard oral tablets. New therapeutic opportunities include high-dose, polypill, and biologic delivery, while case studies highlight reduced hospitalization and improved compliance in schizophrenia therapy. [5]

Future Trends

Key forecasted directions include:

- AI-driven formulation optimization and smart release profile design
- 4D printing and bioprinting for complex, responsive oral dosage forms
- Green chemistry, solvent reductions, and sustainable packaging
- Expansion into precision medicine and digital health integration

Conclusion

Orodispersible tablets exemplify the convergence of patient-focused design, advanced formulation science, and regulatory innovation. Rapid gains in excipient science, automation, and digital manufacturing have solidified ODTs as a leading oral drug delivery platform. Addressing future challenges in stability, sustainability, and personalized dosing will further enhance the clinical value and impact of ODTs across global health systems.

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