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Review Article

ADVANCEMENTS OF ORODISPERSIBLE TABLETS: A COMPREHENSIVE REVIEW

Chaitali Vinod Kannamwar*, Dr. Pankaj M. Pimpalshende, Dr. Satish B. Kosalge
Hi-Tech college of Pharmacy, Padoli, Chandrapur (M.H)

***Correspondence Info:**
Chaitali Vinod Kannamwar
Hi-Tech college of Pharmacy,
Padoli, Chandrapur (M.H)
Email:
chaitalikannamwar10@gmail.com

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ABSTRACT

Orodispersible tablets (ODTs) have become a popular and accommodating dose form that solves problems with traditional tablets and offers creative ways to distribute medications. This thorough analysis examines the most recent developments in ODTs, emphasizing their history, characterization methods, formulation strategies, applications, difficulties, and potential applications. The assessment of ODTs in comparison to traditional tablets is covered, emphasizing the special qualities that make them appropriate for a range of patient demographics. To clarify their effects on ODT disintegration and drug release, formulation techniques such as direct compression, sublimation, and the function of superdisintegrants are investigated. In order to guarantee product quality, analytical methods for characterizing ODTs such as disintegration time, hardness, and drug content uniformity are severely assessed. The review explores the diverse therapeutic areas in which ODTs can be applied, with a focus on emergency medicine, psychiatry, pediatrics, and geriatrics. Taste masking, stability, and scalability challenges are explored, offering insights into future research directions and possible breakthroughs, such as 3D printing and nanotechnology. Conclusively, this thorough study provides a great resource for researchers, pharmaceutical professionals, and clinicians who wish to gain a deeper understanding of this novel drug delivery platform by consolidating current knowledge on ODTs.

Key words: Orodispersible tablets, direct compression, sublimation, superdisintegrants.

INTRODUCTION

Orodispersible Tablets (ODTs) have revolutionized drug delivery tactics in the ever-changing world of pharmaceutical formulations (Pahwa *et al.,* 2010). ODTs are a patient-centered strategy intended to address issues with conventional oral dose forms; they are especially useful for patients in the juvenile and geriatric populations who have trouble swallowing (Sastry *et al.,* 2000). This thorough analysis seeks to shed light on the significant influence that ODTs have on patient adherence and treatment efficacy by offering an incisive examination of the development, formulation tactics, characterisation approaches, and range of uses of ODTs.The development of pharmaceutical sciences provides a backdrop against which the story of ODTs plays out. The domain has seen constant research and development

because to the demand for novel dosage forms that can handle patient-centric difficulties. This section highlights the critical role that ODTs play in contemporary drug delivery while providing a brief overview of the historical background that contributed to their conception and development.

Even though they are extensively used, conventional oral medication administration techniques have drawbacks. These obstacles include trouble swallowing, non-compliance from patients, and problems with administration in a variety of demographics. The pharmaceutical industry has started searching for innovative formulations that improve patient adherence and overall treatment outcomes after realizing these constraints (Shanmugam, 2015).

The use of ODTs has caused a paradigm shift in how medicine is delivered. ODTs are cleverly made such that they break down quickly in the mouth, eliminating the need for water. This feature not only helps with swallowing difficulties but also provides a practical and patient-friendly substitute. The entry of ODTs into the pharmaceutical industry represents a calculated step in the direction of easily accessible and customized healthcare.

Over the past few years, ODTs have become increasingly important and have broken through age-based limitations. These pills are especially useful in the pediatric and geriatric populations, where conventional dosing forms present difficulties.ODTs are more than just convenient; they also have better bioavailability, increased patient compliance, and a quick start to action.

This thorough analysis is set up to offer a detailed examination of all the different aspects of ODTs. It seeks to clarify the historical development of these tablets, clarify various formulation approaches, explore characterization methods used for quality evaluation, and examine their uses in various therapeutic areas. The assessment will also address regulatory issues, illuminate difficulties and provide insights into the future, providing a comprehensive overview of the developments in Orodispersible Tablets (Pandey and Dahiy, 2016).

Evolution of Orodispersible Tablets

Orodispersible Tablets (ODTs) represent a revolutionary development in pharmaceutical formulation, marked by ongoing innovation and a dedication to tackling patient-centered issues. The development of ODTs highlights a proactive reaction to the drawbacks of conventional oral dose forms, especially those that impede patient compliance and convenience of use (Chauhan *et al*., 2017).

Early Efforts and Emergence: The development of oral disintegrating dosage forms began in the latter half of the 20th century. In an effort to improve patient compliance, early efforts were directed at developing tablets with quick disintegration characteristics. The development of ODTs, which signaled the shift from traditional solid dosage forms to more patient-friendly substitutes, was made possible by these basic formulas (Patil *et al*., 2017).

Pioneering Technologies: The field of ODTs was significantly shaped by developments in pharmaceutical technology. The development of direct compression and freeze-drying technology opened up new possibilities for formulators to investigate. With the active pharmaceutical ingredients (APIs) intact,

these methods made it easier to create tablets with improved disintegration properties.

Superdisintegrants Revolution: Superdisintegrants were used extensively, which was a major advancement in the development of ODTs. Compounds such as sodium starch glycolate, croscarmellose sodium, and crospovidone became important components, giving formulas superior disintegration qualities. ODTs are successful because of their capacity to quickly absorb water and expand, which speeds up the breakdown of tablets in the oral cavity (Nautiyal *et al*., 2014).

Orally Disintegrating Platforms: With the development of ODTs, various platforms with distinctive formulation methodologies came into being. Among these, R.P. Scherer's (now Catalent) introduction of Zydis® ODT technology was a turning point. With the use of a freeze-drying technique, this technology produces a porous structure that allows tablets to dissolve quickly in saliva (Bhowmik *et al*., 2009).

Advancements in Taste-Masking: Improving ODTs' palatability became a priority in their development, particularly for the elderly and pediatric groups. Microencapsulation and complexation are two taste-masking techniques used in formulation strategies that have helped make ODTs more palatable to a wider range of patients.

Innovations in Film Technology: Orally dissolving films (ODFs) were created as a result of advancements in film technology during the creation of ODTs. These thin, flexible films provide a quick-dissolving, easy alternative. They are frequently pre-dosed with precise drug dosages. ODFs are prime examples of the flexibility and adaptability that define ODT formulations' ongoing progress (Savpure *et al*., 2019).

Multifunctional Approaches: Current developments in ODT evolution include multifunctional strategies that use components such as 3D printing and nanotechnology. These methods preserve the unique qualities of quick disintegration and patient convenience while attempting to maximize medication administration, bioavailability, and overall therapeutic efficacy.

Formulation Strategies for Orodispersible Tablets (ODTs): A calculated strategy is required while formulating Orodispersible Tablets (ODTs) in order to maintain the delicate balance between therapeutic efficacy, palatability, and fast disintegration. This chapter gives a thorough introduction to several formulation techniques, including sublimation, direct compression, and the crucial function of superdisintegrants. Furthermore, the effect of flavors, sweeteners, and excipients on improving patient acceptability is investigated.

Direct Compression: One popular and affordable technique for ODT formulation is direct compression. This approach entails compressing the blended active pharmaceutical ingredients (APIs) into tablets after mixing them with appropriate excipients, such as lubricants, diluents, and superdisintegrants. Formulators appreciate this strategy because of its simplicity, which is in line with the objective of attaining quick dissolution (Ladignon *et al*., 2020).

Sublimation: Techniques based on sublimation aid in the creation of ODTs with improved disintegration characteristics. This technique involves incorporating volatile substances typically subliming agents like

menthol or camphor into the pill matrix. When these chemicals are sublimated and taken orally, the resulting porous structures in the tablet facilitate fast disintegration when saliva comes into touch with it (Koizumi *et al*., 1997).

Superdisintegrants: Superdisintegrant integration is a fundamental component of ODT formulation. Sodium starch glycolate, croscarmellose sodium, and crospovidone are well-known superdisintegrants that are renowned for their remarkable swelling and water absorption capabilities. When these additives come into contact with saliva, they generate internal pressures in the tablet that cause the API to dissolve quickly (Nandhini and Rajalakshmi, 2018).

***Excipients, Flavors, and Sweeteners*:** The choice of excipients significantly influences the overall acceptability of ODTs. Diluents like mannitol and lactose contribute to the tablet's mouth feel, imparting a pleasant texture. Flavors and sweeteners play a dual role in enhancing palatability and masking the inherent bitterness of certain APIs. The incorporation of pleasant-tasting agents, such as mint or fruit flavors, and sweeteners like sucralose or aspartame, ensures a positive patient experience.

Role of Co-Processed Excipients: Co-processed excipients, generated by combining two or more individual excipients, have gained prominence in ODT formulations. These excipients offer synergistic benefits, addressing specific challenges associated with compressibility, flowability, and disintegration. Examples include Ludiflash® and Prosolv® ODT, designed to optimize disintegration time and enhance tablet robustness (Anjan *et al*., 2013).

Novel Approaches and Technologies: Innovations in formulation strategies include new methods and tools. Patient adherence is increased by coating strategies like taste-masking coatings. Furthermore, the use of 3D printing enhances the therapeutic potential of ODTs by enabling precise dose delivery and the integration of several APIs into a single tablet (Parul *et al*., 2012).

Characterization Techniques for Orodispersible Tablets (ODTs):

Thoroughly assessing the physical and chemical characteristics of orodispersible tablets (ODTs) is necessary for their effective manufacture. This section offers a thorough examination of the analytical methods that are essential for describing ODTs, with a focus on factors such drug content homogeneity, hardness, friability, and disintegration time. Furthermore, sophisticated techniques including X-ray imaging, scanning electron microscopy, and texture analysis are explored in order to attain thorough and detailed characterisation.

Disintegration Time: Disintegration time, which indicates how long it takes for a tablet to break down into tiny pieces when it comes into contact with saliva, is a crucial parameter for ODTs. The traditional disintegration testing device provides a systematic approach for evaluating how well ODTs work to achieve rapid disintegration while adhering to pharmacopeial requirements (Shirsand *et al*., 2009).

Hardness and Friability: In order to determine the mechanical strength and robustness of ODTs, hardness and friability are important factors. To make sure the tablet has enough structural integrity, the hardness test measures the force needed to break it. The

tablet's capacity to withstand abrasion during handling and transit is assessed by friability testing. Both factors influence how long-lasting and high-quality ODTs are overall (Pramod and Narendra, 2015; Srivastava and Malviya, 2011).

Drug Content Uniformity: For consistent therapeutic effects, it is imperative that the active pharmaceutical ingredient (API) be distributed uniformly across all ODTs. In order to verify compliance with predetermined limitations, drug content uniformity testing entails sampling individual tablets and evaluating the API's composition. Accurate quantification is typically achieved through the use of spectrophotometric techniques and high-performance liquid chromatography (HPLC) (Hadyah*et al*., 2019).

Texture Analysis: Understanding the mechanical characteristics of ODTs during disintegration and dissolution is possible through texture analysis. With this procedure, specialized tools are used to measure properties like adhesiveness, compressibility, and hardness. In order to assess the interaction between the tablet and saliva, texture analyzers provide a quantitative method, which helps to provide a more complex knowledge of ODT behavior.

Scanning Electron Microscopy (SEM): At high magnifications, SEM is an effective tool for observing the surface morphology and microstructure of ODTs. This method makes it possible to find any anomalies, fissures, or holes in the tablet matrix. SEM is a useful tool for learning how the manufacturing and formulation processes affect the overall structure of ODTs.

X-ray Imaging: Non-destructive X-ray imaging methods, such X-ray microtomography, provide information about the interior architecture of ODTs. The distribution of APIs and excipients, among other internal properties, can be visualized using this technique. Understanding ODT porosity by X-ray imaging helps to optimize formulation for improved disintegration and dissolving.

Applications of Fast Dissolving Tablets (FDTs):

Fast Dissolving Tablets (FDTs) are an adaptable drug delivery system with uses in a range of medical specialties. This section explores the various uses of FDTs, demonstrating how flexible they are in meeting the needs of particular patient demographics and medical situations. The special benefits of FDTs in terms of quick response and increased patient compliance are shown through case studies and examples (Malsane *et al*., 2017).

Pediatrics: FDTs provide a useful remedy in pediatrics by tackling the difficulties involved with giving children's drugs. FDTs are especially helpful for young children who might have trouble swallowing traditional pills or capsules because of their appealing taste and fast oral disintegration. This application helps pediatric populations achieve correct dosing and improves medication adherence.

Geriatrics: Because of age-related issues or underlying medical disorders, the geriatric population frequently has trouble swallowing conventional oral dosage forms. FDTs offer a convenient and easily-administered alternative, meeting the unique needs of senior individuals. FDTs dissolve quickly in

the mouth, making it easier to swallow and promoting better drug compliance in the elderly population.

Psychiatry: FDTs are a promising drug delivery option in psychiatry, where exact dosage and prompt therapeutic benefits are frequently critical. FDTs' quick start of action can help medications for mental health issues, including anti-depressant or anti-anxiety medications. Better patient compliance is encouraged by these tablets' patient-friendly design, which complies with psychiatry's therapeutic requirements (Tambe, 2018).

*Emergency Medicine:*FDTs are essential in emergency medical circumstances where timely drug delivery is necessary. Formulated as FDTs, medications for ailments such as seizures, allergic reactions, or pain control can guarantee quick delivery and start of action. The expediency frequently linked to emergency medical interventions is in line with the practicality of transporting and delivering FDTs without the requirement for water.

Examples & Case Studies: The efficacy of FDTs in various therapeutic applications is demonstrated by a number of case studies and illustrations. For example, FDTs have been effectively used to provide pediatric patients with anti-epileptic drugs, guaranteeing precise and timely dosing. FDTs have helped older people undergoing chronic therapies adhere to their prescription regimens better in the geriatric population. Psychiatric drugs that are designed as FDTs have better absorption and quicker therapeutic benefits (Sharma *et al*., 2022).

Challenges and Future Perspectives of Fast Dissolving Tablets (FDTs):

Taste Masking: Taste masking is a major problem in the creation of FDTs. The active pharmaceutical ingredient (API) tastes more noticeable when these tablets dissolve quickly in the tongue. It is imperative to ensure palatability and patient acceptance, particularly with formulations intended for younger and older patients. To address this issue, formulation techniques are investigated, such as the employment of flavoring compounds and cutting-edge taste-masking technology (Schiermeier and Schmidt, 2002).

Stability Issues: For FDTs, achieving chemical and physical stability is a difficulty. Variations in temperature, moisture content, and the way excipients and API interact can affect the tablets' overall stability and shelf life. To solve stability difficulties and guarantee the long-term survival of FDTs, formulation modifications and suitable packaging materials are crucial factors to take into account (Sreenivasa *et al*., 2005).

Scalability: Another issue with FDT manufacturing processes is their scalability.Careful optimization is needed to make the switch from laboratory-scale to large-scale manufacturing while preserving the formulation's integrity. Achieving industrial-scale homogeneity, reproducibility, and cost-effectiveness are crucial elements that must be taken care of to enable the broad use of FDTs (Sohi *et al*., 2004).

***Future Perspectives*:**

Advanced Manufacturing Technologies: The development of manufacturing technology will have a significant impact on the future of FDTs. For example, 3D printing has the potential to accurately produce dosage

forms with intricate features. This technique increases the therapeutic potential of FDTs by enabling the integration of several APIs and controlled release profiles into a single tablet (Mehta *et al*., 2010).

Nanotechnology Applications: There are chances to improve FDT performance with nanotechnology. Targeted drug delivery and enhanced bioavailability are possible using nanoscale drug delivery systems. Techniques for nanoencapsulation may help with taste-masking issues and provide controlled release patterns. Investigating the incorporation of nanotechnology into FDT formulations creates new opportunities for innovative therapeutics.

Patient-Centric Formulations: Customizing formulations to meet individual patient demands will probably be the main emphasis of future FDT advancements. Drug delivery could be revolutionized by personalized medicine approaches, in which FDT formulations are tailored according to specific patient features. To maximize therapeutic results for various patient populations, this may entail adjusting disintegration times, doses, and excipient compositions.

Biodegradable Materials: Utilizing biodegradable components in FDT formulations is consistent with sustainable and environmentally friendly methods. In order to reduce their negative effects on the environment, future formulations might investigate the use of biodegradable excipients and polymers.

Smart Drug Delivery Systems: One interesting possibility for the future is the incorporation of smart technologies into FDTs. Real-time monitoring of medication delivery and patient compliance may be made possible by the incorporation of sensors or stimuli-responsive materials. Smart FDTs can communicate with other hardware or software, giving patients and medical professional's access to important data (Jaysukh *et al*., 2009).

CONCLUSION

This thorough analysis has offered a thorough examination of the development, characterisation methods, applications, difficulties, and prospects for the future of fast dissolving tablets (FDTs). The transition of fixed-dose tablets (FDTs) from traditional dosage forms has made way for novel drug delivery methods, especially in terms of improving patient adherence and meeting a range of therapeutic requirements. To guarantee the effectiveness and quality of FDTs, characterization methods including disintegration time, hardness, friability, and drug content consistency are essential. The adaptability and promise to improve patient outcomes of FDTs are highlighted by their applications in a variety of therapeutic fields. Though there are still issues with flavor masking, stability, and scalability, new developments in fields like 3D printing and nanotechnology provide encouraging paths forward. FDTs have a bright future ahead of them, and it is expected that their continuous advancement will greatly advance the pharmaceutical sciences by providing practical and efficient solutions for a wide range of patient populations.

DECLARATION OF INTEREST

The authors declare no conflicts of interests. The authors alone are responsible for the content and writing of this article.

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Table 1: Formulations of oral tablets of other antiemetic drugs

Name of drug	Excipients use	Method of preparation	Reference
Trimethobenzamide hydrochloride	Hydroxypropylmethylcellulose, croscarmellose sodium and sodium starch glycolate	Direct compression technique	Uluhan *et al.,* 2023
Metoclopramide hydrochloride	Sodium starch glycolate, Crosscarmellose sodium, Crospovidone, Microcrystalline cellulose, Sodium saccharin, Magnesium stearate, Mannitol, Flavor (vanilla), Talc and Aerosil.	Direct compression technique	Dawadi *et al*., 2020
Ondansetron HCl	Plantagoovate, Micro crystalline cellulose, Sodium saccharine, Talc, Clove oil and Povidone.	Direct compression method	Mahant *et al*., 2017
Ondansetron	Crosscarmellose sodium, Sodium starch glycolate, Crosspovidone, Mannitol, Aspartame, Peppermint powder, Quinoline yellow lake, Trusil lemon lime ASV, Magnesium stearate	Direct compression method	Deshmukh *et al.,* 2012
Cinnarizine	Crosscarmellose sodium, Sodium starch glycolate, microcrystalline cellulose, Camphor, Sodium saccharine and Magnesium Stearate	Direct compression method	Basu *et al*., 2011
Granisetron hydrochloride	mannitol, directly compressible microcrystalline cellulose, super disintegrant, aspartame and camphor, (10%)	Vacuum drying technique	Patil and Rao, 2011
Promethazine Theoclate	Camphor, Crospovidone, β-cyclodextrin, Avicel PH102, Lactopress®, Mannitol, Talc	Direct compression method	Sharma *et al.,* 2010
Promethazine theoclate	(Ac-Di-Sol, Crospovidone, sodium starch glycolate, Avicel, Lactose, Mannitol, Mg. Stereate, Talc	Direct compression technique	Sharma S, Gupta, 2008

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