REVIEW ARTICLE

Pediatric Orally Disintegrating Tablets: Advances in Formulation Design, Technology, and Regulatory Perspectives

Saahil Singh[1], Rupesh Warbhe[2], Abhishek Gaurav[2]

[1]Department of Pharmacology, Jawaharlal Nehru Medical College, Wardha, Maharashtra, India, [2]Department of Pharmacology, Jawaharlal Nehru Medical College, Wardha, Maharashtra, India

Abstract

The non-invasive character and wide range of usage in both medical and home environments make the oral route the main choice for drug delivery in children. Nevertheless, the discrepancies in physiology and behavior of kids and adults, particularly the underdeveloped coordination in swallowing, the very sensitive taste organ, and the partly developed gastrointestinal system, make it very hard to take conventional drug formulations and adapt them to the younger age group. A child under 6 years of age is most likely and often unable to take solid tablets and capsules, which results in poor compliance, choking risk, and inaccurate doses. Liquid formulations, though they are the common route, carry the risk of inaccurate dosing, microbial contamination, dental caries, and harmful excipients, among other drawbacks. These and other pitfalls have led to a growing interest in orally disintegrating tablets (ODTs) as they almost instantaneously dissolve in saliva, swallow with very little effort, and still provide accurate dosing and improved portability. Innovations in ODT technology, to name a few lyophilization, direct compression, spray drying, sublimation, melt granulation, and 3-dimensional printing have made it possible to perfect disintegration time, mechanical strength, and taste. Modern taste-masking strategies, such as ion-exchange resins, microencapsulation, and multilayer coatings not only improve the taste but also make it the most important factor determining the children's adherence. The application of superdisintegrants, such as crospovidone, croscarmellose sodium, and sodium starch glycolate, guarantees a very fast tablet disintegration, even for use in the case of children with low saliva output. US Food and Drug Administration, European Medicines Agency, and the World Health Organization all give prominence to the necessity of formulations that are age-appropriate and excipient safe, acknowledging ODTs as one of the most promising solutions, especially in low-resource settings where water-independent dosing increases the feasibility.

Key words: Lyophilization, orally disintegrating tablets, pediatric drug delivery, superdisintegrants, taste masking

INTRODUCTION

The most widely accepted route of drug delivery for children is oral administration due to the non-invasive nature and easy use in the hospital and home care settings.[1] It often happens that translating adult oral formulations to pediatric ones is very difficult because of the great differences in swallowing abilities, taste perception, gastric physiology, and enzyme maturity between adults and kids.[2] The differences in physiology and behavior are so significant in infants and toddlers that often age-specific formulations are required to guarantee safe and effective therapy. Children below the age of six in particular struggle with regular tablets and capsules because of not yet fully developed coordination between swallowing and breathing, and a stronger gag reflex, which means they risk either choking or not getting the proper dose, and this also makes them unwilling to take the medicine.[1] Swallowing difficulty thus tells us that there is a need for dosage forms that require hardly any swallowing effort but still provide accurate dosing.

Liquid formulations are the first choice among pediatric patients; however, the drawbacks that come with them

Address for correspondence:
Saahil Singh, Jawaharlal Nehru Medical College, Wardha, Maharashtra, India. Phone: 8976766340.
E-mail: saahilsingh5559@gmail.com

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include inaccuracies in dosing, dental problems because of sugar, potential growth of microbes, and the presence of excipients that may be harmful.[1,2] These disadvantages have led to the development of interest in the use of orally disintegrating tablets (ODTs), which disintegrate quickly in the mouth without the aid of water, thereby offering a hybrid solution that combines the logistical advantages of solid dosage forms with the ease of administration typical of liquids.[3] Recently, ODTs have gained much attention as a new chance in pediatric medicine in that they provide better uniformity of doses, ease of carrying, and lower choking risks when compared with conventional solids.[1,3]

Even though the ODT's medication was initially targeted older individuals who had trouble swallowing, the possibility of its being used as a medication for children who had the same issue or were simply unwilling to take medication, or brush their teeth, and possibly even for those who had no access to clean water, has turned it into an area of interest in pediatric pharmacotherapy.[4] Palatability, which consists of taste, texture, and mouthfeel, is pointed out as a decisive factor for children's compliance.[5] ODTs with modern taste-masking methods, such as ion-exchange resins, microencapsulation, and multilayer coatings can lessen the bitterness and, at the same time, keep the drug release kinetics unchanged.[1,6] The use of multifunctional excipients and cutting-edge technologies for taste-modulating has allowed even the most bitter and highly soluble drugs to be manufactured in child-friendly formats.

Technological innovations have transformed ODT manufacturing from the lyophilization process, and now it also includes techniques, such as direct compression, spray-drying, sublimation, melt granulation, and 3D printing.[7] All these methods assist in controlling the disintegration time, drug loading capacity, and mechanical strength of the ODTs to meet the different requirements of the pediatric population. The disintegration time, mechanical strength, friability, and sensory experience are all critical quality attributes that have to be optimized for pediatric use.[6,7] Examples of such drugs are ondansetron, cetirizine, levocetirizine, loratadine, and levetiracetam. Their respective pediatric ODT formulations show good clinical performance and are well accepted. The great adaptability of these formulations shows that clinical certainty in ODT technology as a pediatric dosage form is increasing.[1]

PEDIATRIC NEED FOR ODTs

It is difficult to administer oral medications to patients of the pediatric age group due to developmental physiology, behavioral patterns, and sensory response must be taken into account. It significantly affects the treatment result and differs greatly from that observed in adults.[1] Conventional tablets are difficult for around half of the pediatric population between the ages of two and six to swallow, which leads to inadequate drug administration and poor therapeutic outcomes.[8] This issue is even more critical in chronic conditions where daily dosing is necessary because missed doses lead to therapeutic failure.[2] However, ODTs promise to rectify this problem due to their rapid disintegration in saliva without needing to be swallowed as a whole, thus making administration easy in dysphagic children or those averse to the intake of medications.[1]

Taste is a critical component of pediatric compliance, given that children have a greater number of taste buds and are more sensitive to bitter taste.[9] Many prescription drugs, such as antibiotics, antihistamines, and antiepileptics, which are often prescribed to children, are inherently bitter. For these medications, taste-masking methods are crucial. In the oral cavity, ODTs quickly break down, reducing exposure to bitterness. To guarantee ideal palatability. Newer formulation methods, including polymer coating and microencapsulation, are also required. Clinical research shows that children prefer an ODT formulation of cetirizine, loratadine, and levocetirizine over syrups because it tastes better and is easier to administer.[1]

ODTs also support flexible dosing, thus offering the possibilities for lower tablet weights and divisible units to accommodate age-specific regimens.[3] Water-independent administration makes them particularly convenient in outdoor settings, emergency situations, and areas with limited access to clean water. This is of particular benefit in acute episodes, such as vomiting or dehydration, where oral rehydration therapies are poorly tolerated.[1] Global health programs regard the use of ODTs as one of the favored approaches to pediatric drug delivery in low-resource settings, where stability and simplicity are highly valued.[10]

TECHNOLOGICAL ADVANCES IN PEDIATRIC ODT MANUFACTURING

Recent innovations in manufacturing techniques have enhanced the disintegration, taste, strength, and stability of ODTs for pediatric use.[11] Lyophilization produces a porous tablet that offers rapid disintegration, which is very useful for children who have swallowing problems; however, the tablets produced are fragile, expensive, and dose-limited[9] [Figure 1]. Today, direct compression is the most commonly used technique because it is scalable and cost-effective, with the use of superdisintegrants able to achieve 15–30 s disintegration times with the retention of strength. Spray drying creates a porous matrix that hydrates quickly and allows for both taste-masking and the use of lipid carriers, which improves pediatric acceptance. Sublimation enhances the porosity through the removal of volatile agents, although this technique requires great care in the balancing of strength and disintegration.[11] Melt granulation and extrusion techniques are suited to active pharmaceutical ingredients (APIs) sensitive to moisture, using waxy binders to enhance

mouthfeel and stability; precise thermal control is generally required. 3-dimensional (3D) printing enables the formulation of personalized doses and shapes, and the food and drug administration (FDA)-approved Spritam represents another important milestone for pediatric ODTs.[2]

SUPERDISINTEGRANTS IN PEDIATRIC ODTs

Superdisintegrants have become important for rapid pill disintegration.[12] Synthetic agents, such as crospovidone, sodium starch glycolate, and croscarmellose sodium. They work through capillary action, swelling, and wicking, respectively [Figure 2]. It is noteworthy to note that crospovidone acts at low doses, essentially without compromising hardness; the disintegration time of sodium starch glycolate may be decreased at high concentrations due to gelation. Croscarmellose is suitable for individuals with low saliva production, which is common in the pediatric age group.[2,13,14] Other natural agents are gum karaya and fenugreek mucilage. These agents show biocompatibility but require microbial control. Excipient safety is paramount; sodium benzoate and alcohol must be avoided in pediatric formulations.[15]

Figure 1: Comparative illustration of a conventional compressed tablet left image (smooth, low porosity) and in right image, a porous orally disintegrating tablet (high internal porosity), highlighting structural factors influencing rapid disintegration

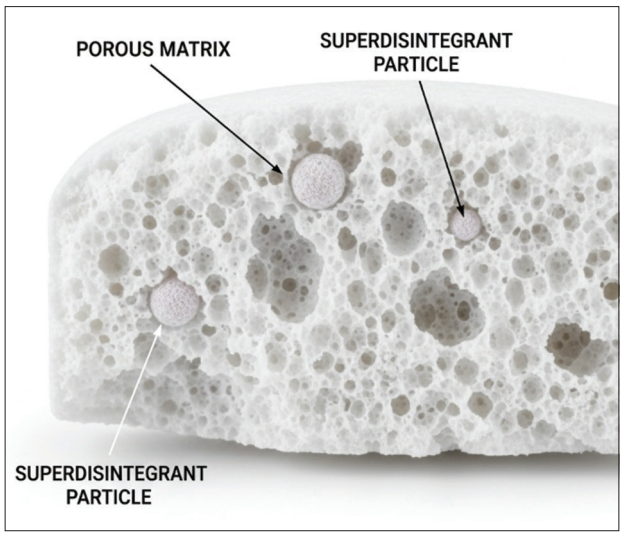

Figure 2: Schematic representation of a porous orally disintegrating tablet matrix containing embedded super disintegrant particles

TASTE-MASKING TECHNOLOGIES

Palatability is the main factor that supports pediatric compliance. Advance methods are being used, such as ion-exchange resins and microencapsulation, which hold back the API until it is swallowed.[16] The disintegration process is not greatly affected by spray coatings and cyclodextrin complexes, which, on the other hand, improve the taste. Bringing in new bitterness blockers is still very limited in pediatric practice, though it has been developed.[1,16] The authorities have issued warnings regarding the use of artificial sweeteners and solvents because of the toxicity risks associated with them.

STABILITY AND REGULATORY CONSIDERATIONS

ODTs are porous and absorbent, making them prone to moisture and microbial attacks. Therefore, protective packaging, such as alu-alu blisters and desiccant containers, is a necessity.[9,17] Melt-based ODTs may soften in heat, requiring controlled storage.[17] Regulatory agency guidance has continuously focused on safety, palatability, and excipient justification, for example, the FDA and European Medicines Agency demand pediatric study plans and pediatric investigation plans, respectively. The World Health Organization endorses ODTs because of the convenience of use without water or refrigeration in under-resourced areas.[18]

FUTURE DIRECTIONS

The metamorphosis of pediatric ODTs is primarily determined by the adaptively, securely, and durably developed technologies. Moreover, apart from providing each patient with the correct dosage, the 3D printing technique has made it possible to provide pharmaceutical preparations with different geometries and various drug release rates. The latter also means that the inconveniences associated with fixed-dose are no longer a problem, and thus, therapeutic precision is dramatically enhanced.[2] Key future directions and their clinical relevance in pediatric ODT development are summarized in Table 1. Electronic medication monitoring systems with proactive digital reminders and interchangeable patients' adherence tracking mechanisms could potentially change the monitoring of medication in the long run, especially in children's chronic diseases.[18] Research into natural, biodegradable polymers, such as plant-based gums and polysaccharides presents an opportunity to

Table 1: Future directions in pediatric ODT research and their clinical significance

Future direction	Description	Relevance to pediatric ODTs	References
3D printing-based personalized dosing	Use of additive manufacturing to tailor dose, shape, and release	Enables individualized pediatric dosing, improves compliance	[20]
Digital adherence monitoring	Mobile apps or e-health tools to track medication use	Real-time tracking can improve adherence in chronic pediatric conditions	[21,22]
Eco-friendly excipients and polymers	Use of natural, biodegradable polymers in formulations	Reduces toxicity risk; environmentally sustainable excipients	[23]
Improved taste-masking technologies	Advanced microencapsulation, bitter blockers for APIs	Increases palatability, especially for very bitter drugs in children	[24]
Global and national essential medicines integration	Include pediatric ODTs in formularies like the WHO essential medicines list	Ensures wider access, especially in resource-limited settings	[18,25]
Industry–regulator–academia collaboration	Joint efforts in innovation, guideline creation, and safety evaluation	Accelerates development, ensures regulatory compliance, and patient safety	[26]

ODTs: Orally disintegrating tablets, WHO: World Health Organization, 3D: 3-dimensional, APIs: Active pharmaceutical ingredients

improve excipient safety while supporting environmentally responsible manufacturing practices.[19] The merging of ODTs into the lists of pediatric necessary medicines worldwide and nationally will advocate for their uptake in health programs and will also provide a way to ensure their availability in less resourceful regions.[18] Collaborative efforts between industry, academia, and regulatory bodies will be crucial to drive innovation, policy reform, and clinical adoption.

CONCLUSION

With their quick onset of action, enhanced palatability, and convenience of administration, oral disintegrating tablets are a revolutionary development in pediatric medication delivery. Because they don't require water, their solid-state shape improves portability and dose precision, making them perfect for a variety of clinical and geographical settings. Their therapeutic utility and acceptance are increasing because to ongoing innovation in taste-masking, manufacturing technology, and tailored medicine. To fully exploit their potential, however, issues with medication loading, stability, cost, and a lack of infant-specific data must be resolved. ODTs are positioned to become a key component of pediatric pharmacotherapy, bridging the gap between therapeutic efficacy and child-centred design, thanks to mounting clinical evidence and expanding regulatory backing.

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