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Formulation of Orally Disintegrating Tablets for Pediatric Use: Enhancing Compliance and Therapeutic Outcomes

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ABSTRACT

Orally disintegrating tablets (ODTs) provide a patient-friendly dosage form, particularly suitable for pediatric populations who often face difficulty in swallowing conventional tablets. This paper explores formulation strategies for ODTs, including selection of superdisintegrants, taste-masking agents, and excipients to optimize disintegration time and stability. Preparation methods such as direct compression, lyophilization, and molding are discussed. The impact of excipient-drug interactions on mechanical strength, dissolution, and bioavailability is examined. Tables summarizing common excipients, their functions, and effects on pediatric ODT performance are included. Regulatory considerations and analytical approaches for quality assessment are presented. This review highlights the critical factors in developing safe, effective, and palatable ODTs for children.

Keywords: *Orally disintegrating tablets, Pediatric formulations,*

Superdisintegrants, Taste masking, Direct compression, Lyophilization, Drug stability.

INTRODUCTION

Pediatric patients often struggle with conventional oral dosage forms due to difficulty in swallowing and aversion to unpleasant tastes. Orally disintegrating tablets (ODTs) offer a practical alternative by rapidly disintegrating in the mouth, providing ease of administration, improved compliance, and faster onset of action. ODTs are designed to disintegrate within seconds without water, enhancing patient convenience. The formulation challenges include balancing rapid disintegration with adequate mechanical strength, masking unpleasant drug taste, and ensuring stability under pediatric storage conditions. This paper reviews the critical considerations, formulation strategies, preparation methods, and analytical evaluation of pediatric ODTs.

CLASSIFICATION AND EXCIPIENTS

Excipients	Function	Impact on ODT Performance
Superdisintegrants (e.g., Crospovidone, Sodium Starch Glycolate)	Promote rapid tablet disintegration	Decrease disintegration time, improve dissolution rate
Fillers/Diluents (e.g., Mannitol, Lactose)	Provide bulk and sweetness	Enhance mouth feel, affect tablet hardness and solubility
Binders (e.g., PVP, HPMC)	Provide mechanical strength	May increase disintegration time if used excessively
Lubricants (e.g., Magnesium Stearate)	Reduce friction during compression	Excessive use may retard disintegration
Flavoring Agents	Mask unpleasant taste	Improve patient acceptability
Sweeteners (e.g., Aspartame, Saccharin)	Improve palatability	Can influence solubility and stability
Coating Agents	Taste masking,	May prolong disintegration if

	stability	improperly selected

PREPARATION METHODS Direct Compression:

- Most widely used due to simplicity and cost-effectiveness.
- Tablets are prepared by blending API with excipients and compressing directly.
- Critical to ensure uniform mixing to achieve consistent disintegration.

Lyophilization (Freeze Drying):

- Produces highly porous tablets with rapid disintegration.
- Suitable for heat-sensitive drugs.
- Requires specialized equipment and is costly.

Molding:

- Tablets are prepared by moistening powders and molding into desired shape.
- Provides rapid disintegration due to high porosity.
- Limited mechanical strength compared to compression.

TABLE: COMPARISON OF ODT PREPARATION METHODS

Method	Advantages	Disadvantages
Direct Compression	Simple, cost-effective	Moderate disintegration time, requires careful excipient selection
Lyophilization	Very fast disintegration, preserves sensitive drugs	High cost, fragile tablets
Molding	Rapid disintegration, easy to taste-mask	Lower mechanical strength, not suitable for large-scale production

FACTORS AFFECTING ODT PERFORMANCE Disintegration Time:

Influenced by super disintegrant type and concentration

Tablet porosity and hardness are critical.

Taste Masking:

- Sweeteners and flavors are incorporated
- Coatings or complexation techniques may be used to mask bitter drugs.

Mechanical Strength:

- Adequate compression is required to maintain tablet integrity during handling and packaging.
- Excessive hardness may compromise disintegration.

Stability:

- Moisture-sensitive drugs require protective excipients or packaging.
- Compatibility studies prevent interactions that may reduce potency.

ANALYTICAL EVALUATION

- **Disintegration Test:** Assesses time for tablet to break down in simulated saliva.
- **Friability Test:** Evaluates mechanical strength.
- **Dissolution Testing:** Ensures complete release of API.
- **Content Uniformity:** Confirms consistent API dosage.
- **Taste Evaluation:** Sensory testing for palatability in pediatric populations.
- **Moisture Uptake Studies:** Ensures stability under humid conditions.

CASE STUDIES Ranitidine ODTs:

- Direct compression using crospovidone reduced disintegration time to <30 seconds.
- Mannitol improved mouth feel; flavoring agents enhanced palatability.

Montelukast ODTs:

- Lyophilized tablets demonstrated rapid disintegration and improved bioavailability.
- Sweeteners effectively masked bitter taste, enhancing compliance.

Paracetamol ODTs:

- Molded tablets provided rapid relief of fever in pediatric patients.
- Friability remained within acceptable limits due to optimized binder concentration.

Table: Examples Of Pediatric ODT Formulations

Drug	Preparation Method	Super disintegrant	Disintegration Time	Comments
Ranitidine	Direct Compression	Crospovidone	25 sec	Improved palatability and compliance
Montelukast	Lyophilization	Sodium Starch Glycolate	15 sec	Rapid onset, taste masked
Paracetamol	Molding	Crospovidone	20 sec	Suitable for fever management in children

REGULATORY CONSIDERATIONS

- ICH guidelines for pediatric formulations (ICH E11) emphasize safety, efficacy, and acceptability.
- Stability testing under various temperature and humidity conditions.
- Documentation of excipient safety and potential allergenicity.
- Quality control testing for uniformity, friability, and dissolution ensures consistent therapeutic outcomes.

FUTURE PERSPECTIVES

- Development of multifunctional superdisintegrants to balance rapid disintegration with mechanical strength.
- Incorporation of nanoparticles or micro particles to enhance solubility of poorly soluble drugs in ODTs.
- Personalized pediatric ODTs using 3D printing technologies to adjust doses and flavors per patient requirements.

- Green excipients and natural flavors to reduce adverse reactions and improve compliance.

CONCLUSION

Orally disintegrating tablets offer a practical and patient-friendly option for pediatric drug administration, ensuring ease of use, rapid onset of action, and improved therapeutic outcomes. Critical formulation factors, including selection of superdisintegrants, taste-masking agents, fillers, and preparation method, influence disintegration time, mechanical strength, and stability. Analytical characterization ensures quality and compliance with regulatory guidelines. Case studies demonstrate successful applications in common pediatric drugs such as ranitidine, montelukast, and paracetamol. Advances in excipient technology, lyophilization techniques, and personalized dosage forms promise to further optimize pediatric ODT formulations for safety, efficacy, and acceptability.

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