IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 1, December 2025
Impact Factor: 7.67

A Formulation Strategies for Paediatric Medication: Challenges, Approaches and Future Directions

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Abstract: *Despite major progress in ensuring the safety and effectiveness of pharmaceuticals, the development of medicines specifically suitable for children continues to be one of the most complex areas of drug development. Children are not simply smaller versions of adults; their rapidly changing physiology, growth patterns, and behavioural characteristics require specially tailored formulation approaches. This review focuses on the diverse strategies involved in the design of paediatric medicines that meet the physiological, developmental, and practical needs of patients from infancy through adolescence.*

Current regulatory requirements and guidance issued by international agencies such as the WHO, EMA, and FDA are discussed, along with key paediatric-specific physiological factors including variations in gastric pH, enzyme maturity, organ development, and body composition. The review further outlines formulation approaches for different dosage forms such as oral liquids, solid oral preparations, dispersible tablets, advanced taste-masked systems, and alternative drug delivery routes.

Special attention is given to the selection and safety evaluation of excipients using modern risk-assessment approaches, as well as methods used for palatability evaluation and the importance of accurate dosing devices. Key aspects of manufacturing, stability, and quality assurance are also highlighted, together with recent advancements such as microencapsulation and nanoparticulate drug delivery systems. By examining practical case examples and existing research limitations, this review aims to provide scientifically grounded guidance for researchers, formulators, clinicians, and regulatory authorities involved in paediatric medicine development. In addition, future perspectives focusing on innovative technologies, patient-centred formulation design, and globally harmonized regulatory frameworks are outlined to help address the continuing lack of age-appropriate medicines for children worldwide.

Keywords: paediatric formulations, taste masking, excipient safety, dosage forms, palatability, regulatory guidelines, drug delivery, nanoparticles, pharmaceutical development, age-appropriate medicine

DOI: 10.48175/568