

## Suggested pre-workshop reading material

1. Current State of Minitablet Product Design: A Review. <https://www.sciencedirect.com/science/article/pii/S0022354924000558?via%3Dihub>
2. The revival of the mini-tablets: Recent advancements, classifications and expectations for the future. <https://www.sciencedirect.com/science/article/pii/S0939641125000311?via%3Dihub>
3. FDA. Guidance for Industry Size of Beads in Drug Products Labeled for Sprinkle. (2012). <https://www.fda.gov/files/drugs/published/Size-of-Beads-in-Drug-Products-Labeled-for-Sprinkle-Rev.1.pdf>
4. WHO. TRS 970 - Annex 5: Development of paediatric medicines: points to consider in formulation. (2012) <https://www.who.int/publications/m/item/trs970-annex-5-development-of-paediatic-medicines-points-to-consider-in-formulation>
5. NMPA. Technical Guideline for Pharmaceutical Studies of Mini-tablets (Chemical Drugs) (Trial). (2024) – This is the China Guidance (in Mandarin)
6. Survey Study to Identify the Maximum Acceptable Numbers of 2 mm and 3 mm Mini-Tablets for Short-, Middle-, and Long-Term Treatments in Acutely and Chronically Sick Children of Different Age Groups Below 18 Years. (2025). <https://doi.org/10.3390/pharmaceutics17070834>
7. FDA. Oral Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations. Guidance for Industry. (2021). <https://www.fda.gov/media/149688/download>
8. MCERC 2019 Pediatric Workshop  
Paper: [https://www.sciencedirect.com/science/article/pii/S0939641121001028?dgcid=rss\\_sd\\_all](https://www.sciencedirect.com/science/article/pii/S0939641121001028?dgcid=rss_sd_all)
9. Acceptability, Swallowability, Palatability, and Safety of Multiple Film-Coated Mini-Tablets in Children Aged  $\geq 2$ - $< 7$  Years: Results of an Open-Label Randomised Study <https://pubmed.ncbi.nlm.nih.gov/36840023/>
10. Pediatric Oral Formulations: An Updated Review of Commercially Available Pediatric Oral Formulations Since 2007 <https://pubmed.ncbi.nlm.nih.gov/30447227/>
11. Understanding the Factors That Control the Quality of Mini-Tablet Compression: Flow, Particle Size, and Tooling Dimension <https://www.sciencedirect.com/science/article/pii/S0022354917308717>
12. Use of Liquids and/or Soft Foods as Vehicles for Drug Administration: General Considerations for Selection and In Vitro Methods for Product Quality Assessments <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-liquids-and-or-soft-foods-vehicles-drug-administration-general-considerations-selection-and-vitro>
13. Co-administration of Paediatric Medicines with Food and Drinks in the Context of Their Physicochemical Properties-a Global Perspective on Practices and Recommendations <https://pubmed.ncbi.nlm.nih.gov/32133550/>
14. Towards the development of a standard toolbox for compatibility testing of pediatric drug products with common dosing vehicles - Fruit juice, apple sauce, yogurt, and pudding <https://pubmed.ncbi.nlm.nih.gov/40962158/>
15. The effect of food vehicles on in vitro performance of pantoprazole sodium delayed release sprinkle formulation. Int J Pharm. 2023;635:122737 <https://pubmed.ncbi.nlm.nih.gov/36801362/>
16. Oral Drug Product Administration via Enteral Feeding Tubes: In Vitro Testing <https://pubmed.ncbi.nlm.nih.gov/38575754/>
17. Access to Pediatric-Friendly Formulation at the Time of Pediatric Labeling and After Marketing <https://publications.aap.org/pediatrics/article-abstract/157/1/e2025073604/205752/Access-to-Pediatric-Friendly-Formulations-at-the?redirectedFrom=fulltext>

18. Drug Administration via Enteral Feeding Tubes: A Landscape Analysis of Information in Drug Product Labeling  
<https://pmc.ncbi.nlm.nih.gov/articles/PMC12976560/>
19. ACCEPTABILITY OF A DOLUTEGRAVIR DISPERSIBLE TABLET AND A NOVEL ORAL FILM FORMULATION IN NEONATES  
<https://www.croiconference.org/wp-content/uploads/sites/2/posters/2025/1045-2025.pdf>
20. Maternal and health worker preferences for paediatric antiretroviral formulations in neonates exposed to HIV  
<https://www.tandfonline.com/doi/full/10.1080/09540121.2025.2592893>