**Bridging Unmet Needs in Pediatric Pharmacotherapy: Scientific Advances in Personalized, Age-Appropriate Formulations**

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**Background and aims.** Personalized medicine for pediatric patients remains challenged by unmet needs in the development of safe, effective, and age-appropriate formulations. Advances in pharmaceutical technology now enable better adaptation of dosage forms to the physiological and developmental characteristics of neonates, infants, and children. This work explores three innovative strategies to address these needs.

**Methods.** First, novel oral suspension vehicles based on starch-derived active suspending technology (SyrSpend) were evaluated for compatibility with over 140 active pharmaceutical ingredients (APIs). Stability studies were conducted under refrigerated and room temperature conditions for up to 90 days. Second, excipient blends for hard-shell capsules were developed using the Biopharmaceutical Classification System (BCS) as a guiding framework (DiluCap). Formulations were optimized based on solubility, permeability, and API stability using a structured algorithm. Third, orodispersible film (ODF) technology (OrPhyllo) was investigated for pediatric patients with swallowing difficulties, with focus on formulation robustness and disintegration performance.

**Results.** SyrSpend vehicles demonstrated superior content uniformity, low osmolality, and excipient safety in accordance with EMA, FDA, and WHO guidelines, confirming suitability for vulnerable pediatric groups. DiluCap formulations improved flowability, dissolution, and bioavailability of APIs from all four BCS classes, supported by powder characterization, dissolution data, and accelerated stability tests. OrPhyllo ODFs achieved rapid disintegration (<30 seconds), high mechanical integrity, and excellent physicochemical and organoleptic profiles across diverse APIs.

**Conclusion/Discussion.** These strategies illustrate how the integration of pharmaceutical sciences, biopharmaceutical principles, and pediatric-specific considerations can drive the development of safer, more effective, and personalized therapies for children. These approaches align with the AFPS 2025 theme of age-appropriate pediatric formulations and represent promising advances toward addressing long-standing challenges in pediatric pharmacotherapy.

**References:**

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