Pharmaceutical technology platforms for the development of tailored paediatric dosage forms

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Thereafter the entry into force of the Paediatric Regulation in 2007 [1], the unit of Pharmaceutical Technology and Regulatory Affairs (Phartecolab) of the University of Bari Aldo Moro began to explore and develop paediatric dosage forms using innovative, lab-made and scalable platforms such as microfluidics, prilling technology and direct powder extrusion 3D printing to produce tailored products with features that meet the specific requirements of children. The development of appropriate drug formulations for the paediatric age still represents a challenge and an unmet need. In fact, more than 50% of medications on the market are not taken as advised and around one tenth of prescriptions for children are either off-label or unlicensed. To fill in the gap, legislative and regulatory acts have been issued to promote high quality research for paediatric medicines development and availability. Hence, when developing a paediatric formulation, it is important to consider that, for each of the five age groups, the medication must be optimized considering differences in the physiology and anatomy of each age group, pharmacodynamics and pharmacokinetics, as well as issues related to therapy acceptability and handling. Phartecolab has long been attentive to these paediatric needs and, thanks to the diverse expertise of its researchers on established and new formulation approaches, investigated and developed paediatric formulations, that could improve therapy outcomes by increasing patient adherence. By partnering with private and public entities, several unmet paediatric needs have been examined in several studies regarding the development of tailored formulations for children. These studies focused on: 1) Solving biopharmaceutical problems (solubility and dissolution issues) with pharmaceutical technology-based strategies, especially using pristine or chemical modified cyclodextrins [2]; 2) Reformulation of repurposed drugs for paediatric use and particularly formulations for the treatment of paediatric rare diseases by using nano-delivery systems produced by microfluidics [3]; 3) Design and development of oral formulations with high appeal in children such as micro-particulates and mini tablets through prilling/vibration techniques and direct powder extrusion 3D printing, respectively [4-5].
The achieved research journey will be summarized in this report through the presentation of some of the main case studies investigated by Phartecolab in recent years.

References

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