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Paediatric Formulation: Design and Development

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The development of paediatric medicines can be challenging since this is a different patient population with specific needs. A medicine designed for use in paediatric patients must consider the following aspects: patient population variability; the need for dose flexibility; route of administration; patient compliance; excipient tolerability. For example, the toxicity of excipients may differ in children compared to adults and children have different taste preferences. Globally, about 75% of drugs do not carry regulatory approval for use in children; worldwide, many medications prescribed for the treatment of paediatric diseases are used off-label, and less than 20% of package inserts have sufficient information for treating children. This book provides an update on both state-of-the-art methodology and operational challenges in paediatric formulation design and development. It aims at re-evaluating what is needed for more progress in the design and development of age-appropriate treatments for paediatric diseases, focusing on: formulation development; drug delivery design; efficacy, safety, and tolerability of drugs and excipients.

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