Susan Lum Abstract

Excipients in Pediatric Medicines: A Health Canada Perspective

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Many existing medicinal formulations are not designed as suitable for children. Therefore, regulatory incentives are in place in other global markets to encourage commercial availability of pediatric formulations. Unfortunately the goals of these initiatives are difficult to realize if the technical challenges in delivering palatable pediatric products are not well managed.

Formulations for children have complex compositions in a less desirable physical state, to provide dose flexibility and to facilitate dose administration. Dosing neat drug is not a practical option in either children or adults; excipients in pediatric medicines are needed to enable adequate absorption and bioavailability for therapeutic effect with low solubility compounds.

Formulating medicines for taste, physical, chemical, microbiological and pharmacokinetic concerns requires advanced knowledge. The choice of excipients for pediatric medicines is narrow and based upon toxicity assessments, regulatory acceptability and taste masking/optimization to help the medicine go down.

This presentation will highlight issues for excipient selection in oral pediatric medicines. In addition, the regulatory perspective in excipient review, cases on specific excipient levels will be shared.