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Rational use of oral lipid-based systems in the development and life cycle management of poor water soluble drugs: Biopharmaceutical considerations and case studies

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Lipid-based systems are widely used in drug development and life cycle management to enhance the solubility, dissolution and oral bioavailability of poor water soluble drugs (BCS II and IV) with several drug products on the market. Despite the progress, however, a pharmaceutical formulator is often contemplating with a number of questions: a) why to consider lipid-based systems over other approaches? b) When lipid excipients and formulations can be applied based on the physicochemical properties of the drug substance? c) What specific lipid formulations and dosage forms to use for expeditious proof of concept studies? This presentation will address these questions and discuss best practices in the pharmaceutical industry. Physicochemical characteristics of lipid excipients and formulations along with a biopharmaceutical rationale for their use with poorly soluble drugs will be presented during the first part of the talk. Specific dosage forms, such as, liquid filled hard and soft gelatin capsules, as well as solid dosage forms (tablets and capsules) incorporating lipid formulations will be addressed during the second part of the presentation and compared against certain desired product development characteristics. Then, case studies with BCS II and IV drugs, will highlight biopharmaceutical benefits using lipid formulations which include, improved pharmacokinetics, promotion of lymphatic absorption and inhibition of intestinal metabolism and efflux pumps. The talk will conclude with lessons learned and future perspectives in the field.

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