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Lipid-based pharmaceutical formulations for patient-centric product development

Statement of the Problem: Lipids and lipid-based excipients are increasingly applied for development of patient-centric products. Their application in the pharmaceutical formulations covers a wide range, from taste-masking of oral dosage forms with modified; both immediate- and extended release profile to development of advanced nanoparticles for pulmonary or parenteral route of drug administration. Despite of this diversity in application, the drug release instability and the lack of mechanistic understanding of it still prevent the larger-scale application of lipidic excipients. This abstract provides a comprehensive overview on the complex solid state behavior of lipids and describes methods for monitoring this behavior for obtaining reliable and reproducible dosage forms.

Methodology & Theoretical Orientation: Solid state behavior of lipids was studied as the response to the composition of formulation and to the critical parameters of the applied product manufacturing process, using X-ray diffraction, PLM and DSC. The applied processes were hot-melt coating for taste-masking and high pressure homogenization for preparation of nano-suspensions. Quality by Design (QbD) tools was used for monitoring the manufacturing process.

Findings: The instability of lipidic formulations can be addressed to both changes in molecular and supra-molecular levels. Changes in molecular level mainly contain polymorphic transformation and alteration in crystallite thickness which can be monitored by careful selection of formulation composition and process parameters. Certain surfactants can be used as modifier, influencing the kinetic character of polymorphic transition of lipids. Process temperature can be monitored to control both crystallite growth kinetics and polymorphic transition. Understanding the micro phase separation of formulations containing emulsifier is necessary and will help to improve the selection of pharmaceutical formulations.

Biography

Sharareh Salar-Behzadi completed her Diploma in Pharmacy and PhD in Pharmaceutical Technology at University of Vienna. She has an experience of "Formulation and process development for production of solid dosage forms". She worked on several pharmaceutical manufacturing methods, among them solvent free hot-melt fluid-bed technology, wet fluid-bed granulation, roller compaction and methods for development of nano lipid carriers. She works at Research Center Pharmaceutical Engineering (RCPE) GmbH since 2012 as Project Lead for scientific execution of projects for formulation engineering and development of particulate dosage forms. Her research focuses on "Development of personalized-medicine with advanced stability based on lipid-based excipients.

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