Priscilla Zawislak Abstract (IPEC-Americas)

Excipient Stability – Different Approaches

Pharmaceutical industry regulations and guidelines regarding stability are often intended for final drug products and APIs. Applying these standards and regulatory requirements, e.g. accelerated stability testing and testing under extreme conditions, for final drug products and APIs to excipients presents challenges for excipient makers and users. These challenges can impact stability testing programs, the supply chain and regulatory compliance, making it difficult to import excipients into many countries and result in product being unnecessarily discarded. Stability during storage and transport is a significant concern for the pharmaceutical industry to ensure patient safety. Excipients are often not as sensitive to environmental conditions as drug products and APIs. This presentation will discuss why excipient stability needs to be evaluated differently and why certain regulatory requirements for stability testing should be modified for excipients.