

USP Excipients Workshop: Risk Based Evaluation of Drug Product Quality: Impact of Excipients (On-Demand)

Art. ID	USP-EXC-WS-07
Unit	Each
Deliverydetails	No Dangerous Good

Description

Formal risk assessment is a natural progression of the FDA 21st Century Quality Initiative.
 Formal risk management approaches are being used in Abbreviated New Drug Application (ANDA) review to ensure that all high-risk areas receive appropriate scrutiny to ensure the availability of high-quality generics.
 Mitigation of high-risk areas may necessitate stringent controls of critical material attributes of excipients.
 Formal risk management will also streamline the review of lower-risk areas to ensure review timelines under the reauthorized FDA Generic Drug User Fee Amendments. (Webcast 33 minutes)