Labmix24 GmbH
Kesseldorfer Rott 24
46499 Hamminkeln
Germany

Tel: +49 (0) 2852 96064 00
Fax: +49 (0) 2852 96064 24
Web: www.labmix24.com
E-Mail: info@labmix24.com

USP Excipients Workshop: Safety Assessments for Excipients in Generic Drugs: A Regulatory Perspective (On-Demand)

Art. ID	USP-EXC-WS-08
Unit	Each
Deliverydetails	No Dangerous Good

Description

Excipients in generic drug products are evaluated from clinical and nonclinical perspectives to ensure that they do not alter the safety profile of the formulation as compared to the Reference Listed Drug.
 FDA Pharmacology/Toxicology Review of the proposed level of an excipient includes an evaluation of toxicology data to support the dose, route of administration, duration of exposure and patient population (Webcast 34 minutes)