

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

## <u>USP Excipients Workshop: Safety Assessments for Excipients in Generic Drugs: A Regulatory Perspective (On-Demand)</u>

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.<br/>
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)