

**USP Excipients Workshop: Bridging Justifications: Supporting the Safety of Excipients in Generic Drug Products (On-Demand)**

Art. ID	USP-EXC-WS-09
Unit	Each
Deliverydetails	No Dangerous Good

Description

A bridging justification is an approach for safety assessments in which toxicology data for one or more compounds are applied to a different compound.<br> Important elements of a bridging justification include the similarity and difference between excipients, existing nonclinical and clinical data, data gaps and the proposed context of use.<br> The U.S. Office of Generic Drugs reviews bridging justifications within ANDAs to ensure excipient safety. Each case is unique, but similar principles apply. (Webcast 30 minutes)