

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.
 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.
 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)