

Nitrosamines Impurities

Art. ID	USP-CM-1469-01
Unit	Each
Deliverydetails	No Dangerous Good

Description

Nitrosamines are a critical topic for regulators and industry given the recent safety recalls of several products containing this impurity. This one-day course will provide attendees with an understanding of current regulatory guidelines and USP General Chapter <1469> Nitrosamine Impurities. The course will provide an overview of sources of nitrosamines including their formation from the presence of other impurities and how to eliminate or reduce levels of nitrosamines. Tools to assess and control nitrosamines in drug substances and drug products as well as in depth analytical procedures in USP <1469> including the use of the USP Reference Standard and precautions to be used during procedures will also be covered. The course will also address risk assessment methodology as per ICH9, control strategy development, calculation of nitrosamine limits as per ICH M7 as well as test method performance characteristics.