Fact Sheet

Impurities in Pharmaceuticals

Impurities are either process or manufacturing impurities in an active pharmaceutical ingredient (API) or in pharmaceutical product manufacturing.

What are Impurities?

Process impurities can come from incomplete chemical processing and reactions, carry over of catalysts or prior process steps. Manufacturing impurities can come from any manufacturing equipment such as gaskets, corrosion, or seals, etc.

Toxicology Risk Assessment

A Toxicological Risk Assessment is a research-based evaluation comprised of four activities:

- hazard identification and data evaluation
- exposure assessment
- dose-response analysis
- risk characterization

The risk assessment is based on a chemical characterization of the test article, published information from the toxicological literature, and tolerable exposure limits, which may be adopted from published guidelines or derived on the basis of available toxicology data. The methods for toxicological risk assessment are, in general, described in Impurities in New Drug Substances, New Drug Products, Residual solvents, and Elemental Impurities Q3A-D guidance; however, the risk assessment must consider special topics and regulatory guidance which may be published on specific devices.

The objective of a toxicological risk assessment is to evaluate the potential health risks associated with exposure to impurities, contaminants, or other residues in a drug product. Based on the data from a chemical characterization, the risk assessment is to make a determination as to whether the release of chemicals during the use of a drug formulation may represent a toxicological risk that is unacceptable from a regulatory perspective. Manufacturing particulates and impurities are often managed by literature research and risk assessments of known material. Process impurities, if unknown, need to be assessed by GLP toxicity testing for regulatory submission along with a risk assessment.

IES Services

IES understands the impurities issue and its regulatory implications. We offer a full-service toxicology group that can assist you in identifying potential issues and prepare regulatory documents. IES can provide literature searches, assessments, management of toxicity testing, and risk assessment preparation.

For more information call or email:

Nicholas Roden, DrPH, CHMM
Toxicologist
NRoden@iesengineers.com
(215) 375-0858 (Mobile)

IES Engineers
1720 Walton Road
Blue Bell, PA 19422
(610) 828-3078
www.iesengineers.com

Robert DeLuca
Senior Occupational Toxicologist
RDeluca@iesengineers.com
(267) 642-8286 (Mobile)