



# **Leachables and Extractables Handbook: Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products**

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# Leachables and Extractables Handbook: Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products

## Leachables and Extractables Handbook: Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products

A practical and science-based approach for addressing toxicological concerns related to leachables and extractables associated with inhalation drug products

Packaging and device components of Orally Inhaled and Nasal Drug Products (OINDP)—such as metered dose inhalers, dry powder inhalers, and nasal sprays—pose potential safety risks from leachables and extractables, chemicals that can be released or migrate from these components into the drug product. Addressing the concepts, background, historical use, and development of safety thresholds and their utility for qualifying leachables and extractables in OINDP, the Leachables and Extractables Handbook takes a practical approach to familiarize readers with the recent recommendations for safety and risk assessment established through a joint effort of scientists from the FDA, academia, and industry. Coverage includes best practices for the chemical evaluation and management of leachables and extractables throughout the pharmaceutical product life cycle, as well as:

- Guidance for pharmaceutical professionals to qualify and risk-assess container closure system leachables and extractables in drug products
- Principles for defining toxicological safety thresholds that are applicable to OINDP and potentially applicable to other drug products
- Regulatory perspectives, along with an appendix of key terms and definitions, case studies, and sample protocols

Analytical chemists, packaging and device engineers, formulation development scientists, component suppliers, regulatory affairs specialists, and toxicologists will all benefit from the wealth of information offered in this important text.

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