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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 ...

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Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products 1 by Ball, Douglas J., Norwood, Daniel L., Stults, Cheryl L. M., Nagao, Lee M. (ISBN: 9780470173657) from Amazon's Book Store. Everyday low prices and free delivery on eligible orders.

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Leachables and extractables handbook : safety evaluation, qualification, and best practices applied to inhalation drug products / edited by Douglas J.

## ~~LEACHABLES AND EXTRACTABLES HANDBOOK~~

xi The establishment of data-based safety thresholds for leachables and extractables in orally inhaled and nasal drug products (OINDPs) is an important scientific advancement that helps OINDP manufacturers make knowledge-based safety and risk assessments for extractables and leachables and ensure the safety of their products for patient use.

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## ~~Leachables and Extractables Handbook: Safety Evaluation ...~~ ~~Inhalation Drug Products~~

Because leachables are non-drug-related impurities, there are increased concerns regarding the risks of inhaling them on a daily basis. This book describes the development and application of safety thresholds for Orally Inhaled and Nasal Drug Products (OINDP).

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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.

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The well-known proverb "Don't judge a book by its cover" is, at first glance, confirmed by 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 ...~~

A safety assessment for extractables or leachables is the process by which the effect of extractables or leachables on user health is established. As the issues associated with a direct assessment the leachables' effect on patient safety are significant, safety effects are typically assessed indirectly.

## ~~Identification, analysis and safety assessment of ...~~

- SCT: Safety Concern Threshold is defined as the threshold below which a leachable would have a dose so low as to present negligible safety concerns from carcinogenic and non-carcinogenic toxic effects. The safety concern threshold (SCT) for extractables and leachables has been defined as 0.15 µg/day.

~~Extractables and leachables: An Introduction~~  
Overview of Leachables and Extractables in Orally Inhaled and Nasal Drug Products.  
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Leachables and Extractables Handbook: Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products Hardcover – Import, 20 February 2012 by Daniel L. Norwood (Editor), Cheryl L. M. Stults (Editor), Lee M. Nagao (Editor), 5.0 out of 5 stars 1 rating See all formats and editions

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