



Compatibility of Pharmaceutical Solutions and Contact Materials: Safety Assessments of Extractables and Leachables for Pharmaceutical Products

By Dennis Jenke

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Compatibility of Pharmaceutical Products and Contact Materials

Dennis Jenke

Important safety aspects of compatibility for therapeutic products and their manufacturing systems, delivery devices, and containers

Compatibility of Pharmaceutical Products and Contact Materials helps pharmaceutical, toxicology, analytical, and regulatory affairs professionals assess the safety of leachable and extractable chemicals associated with drug product packaging, manufacturing systems, and devices. The most comprehensive resource available, its coverage includes the strategies, tactics, and regulatory requirements for performing safety assessments, along with the means for interpreting results.

Structured around a logical framework for an extractables and leachables safety assessment and closely linked to the pharmaceutical product development process, *Compatibility of Pharmaceutical Products and Contact Materials* directly addresses the fundamental questions of "what activities need to be performed to completely, efficiently, and effectively address the issue of product safety from an extractables and leachables perspective?" and "when do the various required activities need to be performed?" Specifically, the chapters describe:

- Pertinent regulations and practical ways to meet guidelines
- Coordinating manufacturing, storage, and delivery systems development and qualification with therapeutic product development
- Materials characterization and the materials screening process
- Component and/or system qualification (illustrated by several case studies)
- Performing validation/migration studies and interpreting and reporting the

results

- Creating a product registration dossier and putting it through regulatory review
- Product maintenance (Change Control) from an extractables and leachables perspective
- Likely future developments in extractables and leachables assessment

Additionally, the book's appendix provides a database, including CAS registry numbers, chemical formulas and molecular weights of extractable/leachable substances that have been reported in the chemical literature.

Detailing the interconnected roles played by analytical chemistry, biological science, toxicology, and regulatory science, *Compatibility of Pharmaceutical Products and Contact Materials* supplies a much-needed, comprehensive resource to all those in pharmaceutical product or medical device development.



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Editorial Review

Review

"The book provides a very detailed review of approaches for generating and further investigating extractables and leachables results, with advice on the levels of investigation appropriate to each stage of product development." (*BTS Newsletter*, Summer 2010)

Review

"The analogy of extractables and leachables to the bogeyman hiding in the closet is so true and telling, whether experienced with leachable studies or not the issues are well communicated. Nomenclature is established, in the author's vernacular, which describes pharmaceutical contact materials and key terms enabling a clear understanding of the objectives of compatibility assessments. Excellent examples of extractables studies, correlations and risk assessments are given and the classification of extraction strategies puts into perspective the purpose for acquiring the data. The appendix listing materials and their associated extractables is a valuable reference tool for chemists, toxicologists and regulators involved with qualifying contact materials used with pharmaceutical products. This is a comprehensive and practical guide for both the novice and the knowledgeable. A great read!" --Diane M. Paskiet, Associate Director of Scientific Affairs, West Pharmaceutical Services

From the Inside Flap

Compatibility of Pharmaceutical Products and Contact Materials

Dennis Jenke

Users Review

From reader reviews:

Alex Lynch:

Here thing why this Compatibility of Pharmaceutical Solutions and Contact Materials: Safety Assessments of Extractables and Leachables for Pharmaceutical Products are different and dependable to be yours. First of all reading a book is good but it depends in the content from it which is the content is as tasty as food or not. Compatibility of Pharmaceutical Solutions and Contact Materials: Safety Assessments of Extractables and Leachables for Pharmaceutical Products giving you information deeper including different ways, you can find any reserve out there but there is no book that similar with Compatibility of Pharmaceutical Solutions and Contact Materials: Safety Assessments of Extractables and Leachables for Pharmaceutical Products. It gives you thrill studying journey, its open up your own personal eyes about the thing that will happened in the world which is possibly can be happened around you. It is possible to bring everywhere like in park your car, café, or even in your means home by train. Should you be having difficulties in bringing the published book maybe the form of Compatibility of Pharmaceutical Solutions and Contact Materials: Safety Assessments of Extractables and Leachables for Pharmaceutical Products in e-book can be your substitute.

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Jim May:

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