

Don't Let Extractables Interfere with Your Success

Be sure. 
Verified extractables. Assured control.

Pharmaceutical manufacturers spend years developing and testing new drug products to ensure efficacy, safety and usability by patients. Decisions on packaging and delivery may seem like an afterthought, but issues related to components, such as extractables and leachables, can impact patient safety and drug product quality.



INCREASED COMPLEXITY. INCREASED RISK.

Leachables have long been a concern in drug products, particularly because they may be harmful to the patient. As more sensitive, potent and complex formulations have made their way to market, the stakes have risen, making it ever more imperative for manufacturers to thoroughly understand the extractables profile of components.

THE PROBLEM WITH LEACHABLES

Leachables can impact the drug product and compromise patient safety. Leaching can cause the drug product to precipitate, or create a shift in pH. Leachables also may cause an interaction with the drug product or excipients, interfere with medical diagnostic tests and more.



NO BARRIER IS UNBREACHABLE FOR A LEACHABLE

While technologies such as barrier films may reduce leaching, they do not negate the need for comprehensive extractable/leachable studies. Careful component selection should be coupled with a comprehensive extractables profile to understand risk of leachables.

A CHANGING PROFILE...

Packaging changes, including processing and coating over the drug product lifecycle, may require repeat extractable work, which impacts cost, product development timelines and time to market. A single snap shot is not enough to provide an in-depth understanding of how the packaging affects the drug over time. Taking a long-range view of the process can help you avoid unforeseen problems further down the development path.



...NEEDS A COMPREHENSIVE APPROACH

A comprehensive material profile for West modern formulations, the VeriSure technical package is a living document. It includes data collected over years of substantial testing, across manufacturing locations, and with various component configurations to help allow for a deeper understanding of the components that touch the drug product.

Talk to your West representative and choose the right option for your product, and ultimately, for your patients' health.

Mitigate Risk with Maximum Understanding

The West VeriSure™ Technical Package

Using a holistic approach to extraction studies can help pharmaceutical manufacturers not only save money, but mitigate risk and manage the complexity surrounding closure qualification and extractables evaluation.

The VeriSure package eliminates uncertainty by:

- Identifying potential extractables early in the development process and minimizing your need to conduct repeat testing over time
- Maintaining ongoing knowledge of the materials used in primary packaging, including post processing treatments
- Improving the manufacturer's understanding of compatibility
- Reducing risk and expediting total development and launch timelines

Create confidence with a partner that can:

- Conduct analyses in West Analytical Services' state-of-the-art laboratories
- Rely on years of experience designing and performing extraction studies
- Leverage thorough understanding of materials and variables that can affect an elastomer extractables profile
- Use multiple solvents and techniques to encompass comprehensive range of baseline extractables

No one knows more about components than component manufacturers.

And no one knows more about component manufacturing than West—the proven industry leader for more than 90 years.

Contact West or visit www.westpharma.com today to learn how the comprehensive, elastomer specific VeriSure technical package has saved time, money and worry for pharmaceutical companies just like you.

Because you want to be sure.



West Pharmaceutical Services, Inc. | 530 Herman O. West Drive, Exton, PA 19341

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