

The Importance of Package Selection

In this issue of *The Source*, we introduce the important factors you should consider when selecting packaging components for your new drug product. We discuss the use of a barrier film to reduce the risk of product container interactions and the advantages of using PakScreen™ for package selection.

The Source is West's newsletter for the biopharmaceutical community. If you would like a copy of the previous issues, with articles on FDA guidances related to container closure requirements, please contact us at westthesource-eu.com.

With more than 80 years' experience, West Pharmaceutical Services is the source for parenteral packaging components, technical support and analytical laboratory services. West applies its knowledge of pharmaceutical packaging and regulatory-related laboratory testing to help biopharmaceutical companies avoid the risks in new product development and get to market without undue delay.

Selecting a Suitable Container Closure System

Bringing an innovative and novel drug product to market requires years of work and an enormous amount of money. Along the way are many important decisions that impact critical time lines. Among these is choosing a suitable container and closure for sensitive biotech drug products.

Parenteral drugs – whether serum or lyophilized – are often introduced to the market in a packaging system that consists of a vial, an elastomeric stopper and a metal seal. A thorough understanding of the regulatory guidances related to packaging components and the potential interaction between the drug and its primary packaging is essential when selecting the packaging system for your drug.

By selecting the proper packaging components, you can reduce the risk of loss caused when active ingredients, preservatives, stabilizers and buffer systems extract materials from the elastomer. Extractables can lead to aggregation and drug degradation that can cause protein unfolding.

The packaging decision you make impacts the life cycle of your drug product. The Food and Drug Administration (FDA) and product registration in the European Union requires that package

details be included in your New Drug Application (NDA) and European registrations. Changing your packaging components after initiating stability testing can be costly and can disrupt your time line because complete stability testing would be required for the alternative components.

To select an appropriate container closure system for your new drug product, you should work closely with a resource such as West Pharmaceutical Services that has specialized knowledge and expertise. Contract manufacturers are not always aware of the regulatory guidances and issues related to container closure compatibility and may not be in a position to recommend the appropriate components.

For technical information on packaging selection, contact technical customer services by email addressed to tcs.europe-asiapacific@westpharma.com.



Barrier Films can Reduce Risk and Enhance Productivity

Biopharmaceutical companies often select a stopper with a fluoropolymer film for packaging sensitive biologic products. The film creates a barrier between the drug and the closure to reduce the risks associated with drug product and container closure interactions and reduce sorption of the drug product. The film protects against many extractables that may come out of the closure over time and can lead to product degradation and aggregation. The use of a fluoropolymer film is a

significant benefit for maintaining the full strength and shelf life of high potency/low concentration proteins.

West provides stoppers with FluroTec® barrier film to help reduce the level of extractables leaching into the drug product and lower the amount of product loss through adsorption and absorption.

West FluroTec film helps protect the shelf life of packaged drugs and provides optimal needle penetration force.

The film is applied to the drug contact surface of the closure for added protection

against potential extractables and to the top of the stopper to provide lubricity for improved performance on filling lines.

The film is not applied to the portion of the stopper that contacts the lip of the vial.



The darker gray indicates the area of FluroTec film coverage. The color is for illustration purposes only; the actual stoppers are one color.

West's Recommended PakScreen™ Study

PakScreen is an investigational screening and gross compatibility study designed to help customers select pharmaceutical packaging components for new or unique applications. The following provides a general concept for a PakScreen study:

- The customer provides bulk drug product for testing
- The product is filled and packaged in several recommended package configurations
- When appropriate, the stopper contact surface area to product ratio is exaggerated
- The sample vials are inverted to maximize closure-to-product contact
- The product is stored under stressed conditions

At the end of the specified exposure of the closure to the product/placebo, eight standard tests are performed, as applicable:

- Inductively coupled plasma screening
- pH shift
- Turbidity
- Ultraviolet spectrum
- Visual inspection in high intensity light
- High performance liquid chromatography/mass spectroscopy screening
- Gas chromatography/mass spectroscopy screening
- Ion chromatography screening

West uses the PakScreen study to identify the best packaging components for the product, and we frequently work with customers to test and evaluate packaging components to determine their compatibility with particular products and applications. When a closure candidate is selected, a full drug stability program including a leachables analysis should be initiated.

For further information, please contact Claudia Petersen, Senior Manager, Biotechnology
Tel +49 (2403) 796 296, Fax +49 (2403) 796 303, Claudia.Petersen@westpharma.com.
In Asia Pacific, please contact Koh.Sok.Tiang@westpharma.com