

The Value of Product Samples

When you need samples

Customers frequently ask how they can get vial, stopper and seal samples.

A free sample kit is available at westthesource.com through the Product Sample Kit link. The kit includes valuable technical information that may help with the component selection process and with understanding regulatory requirements.

Customers qualified for the free kit may then request product samples in packs of 1,000 that are suitable for testing with the actual drug product. Please read the article to the right for information.

The sampling program is an example of West's commitment to the biopharmaceutical market. Our objective is to help biopharmaceutical companies avoid the risks in new product development. We will continue to share information and resources through the newsletter and web site.

Previous issues of *The Source* are posted at westthesource.com. Call us or send an email and we'll add you to the mailing list.

In the early stages of drug product development, biopharmaceutical companies frequently need small quantities of packaging components for evaluation.

West the Source can meet this need with 1,000-pack quantities of stoppers, seals and vials appropriate for biotech drug products.

Serum and lyophilization stoppers

The stoppers are manufactured with FluroTec® barrier film that can help reduce interaction between the stopper and the packaged drug, and are delivered ready-to-sterilize, having been prepared by the Westar® RS process.

The stoppers are molded from elastomeric formulation 4432/50 Gray, West's recommended formula for unstable and sensitive biotech drug products. The formulation is part of a Drug Master File with the FDA and it complies with all major compendia including current USP, Ph.Eur. and JP.

Flip-Off® seals

Flip-Off seals help protect seal integrity and improve shelf life of the packaged drug product. Flip-Off seals provide evidence of tampering and the button cannot be reassembled onto the seal once it has been removed.

Resin CZ® and glass vials

Resin CZ is a cyclic polyolefin recommended for oncologic or toxic drugs. It passes all major compendia including the USP and JP physicochemical

and biological tests and the Ph.Eur. physicochemical tests for polyolefins.

To order sample packs

Qualification is as simple as going online to westthesource.com and clicking on the Product Sample Kit link. You will be prompted to answer six questions that will help West determine which packaging components are most suitable for your drug product. You will receive 10 samples of a stopper, seal and vial, along with supporting technical information. All information provided to West is held in confidence and there is no charge for the sample kit.

Once you have received your sample kit, you may order 1,000-packs by submitting a Product Requirement Questionnaire (PRQ) to Technical Customer Service (TCS). TCS will use the information to make sure you are ordering the appropriate components.

You can submit a PRQ online by going to westthesource.com and clicking through the Packaging Selection tab. You may also contact TCS at 800-231-3000 and ask for Brian Brucker or Jeff Smythe.

Your products will be shipped within 48 hours of the receipt of the order. Payment for 1,000-packs can be made by a major credit card.



Filling Line Choice Dictates Stopper Packaging

One of the important decisions a biopharmaceutical company must make early in product development relates to the type of filling environment required for the drug. The options include filling in a barrier isolator (aseptic) or filling in a clean room.

The filling environment will dictate stopper processing and the type of packaging in which the stoppers are delivered. For isolator and clean room filling, customers can specify stoppers processed as ready to sterilize or ready to use. The packaging in which the stoppers are delivered should be able to go directly into the controlled environment and should facilitate the transfer of the stoppers into the filling line.

Barrier isolator filling lines help improve the assurance of product sterility, reducing production costs and reducing regulatory risk. When isolators are to be used, the method of introducing stoppers

into the sterile environment must be considered carefully. Isolators require stoppers to be supplied in packaging that allows for the transfer of the sterile components directly into the isolator without compromising the isolator's sterile environment or the integrity of the components. Sterilizable bags with rapid transfer ports are used most frequently. These bags generally have a beta port that mates with a compatible alpha port on the isolator. When the seal between the bag and isolator is secure, the stoppers are transferred into the sterile environment.

Vial stoppers used in a clean room filling line are usually delivered in a heat-sealed sterilizable bag that can be placed directly into a steam sterilizer. The stoppers remain in the bag for transfer into the filling line.

Biopharmaceutical companies should discuss filling line options with their stopper supplier and contact filler to prepare for production scale-up.

Going to AAPS?

Stop by West's exhibit (number 817) at the AAPS annual meeting, November 6 through 10 in Nashville.

You can meet with West's packaging experts and with representatives from West Monarch Analytical Laboratories.

Solutions for Drug Delivery Systems

Selecting a delivery system for nasal and inhalation drug products may require a custom solution. Such a decision should be made before the drug product goes into Phase I clinical trials.

A biopharmaceutical company may need an experienced resource to design and manufacture a multi-material delivery system. The impact of regulatory issues and filling requirements must also be considered.

For years, West has met customers' needs for custom delivery systems. With the acquisition of The Tech Group in May 2005, West has expanded its resources and its ability to serve the pharmaceutical markets.

West and The Tech Group help customers develop and commercialize drug delivery systems and can supply devices for Phase I, Phase II and Phase III clinical trials. Staff members are knowledgeable with regard to FDA requirements. They have extensive experience in contract manufacturing and work with the world's leading device and pharmaceutical companies.

For more information, call 800-231-3000 and ask for Brian Brucker or Jeff Smythe.

Free Seminar Set for San Diego

West's third Educational Series seminar for biopharmaceutical companies will be held on October 11 in San Diego at the Marriott Marina Hotel.

The free, half-day seminar features West's subject matter experts presenting technical information that will help biopharmaceutical professionals make decisions about packaging and delivery systems

as they develop and bring new drug products to market.

Seminar topics will include package selection for parenteral drugs, regulatory guidances related to parenteral packaging, and extractables/leachables.

Visit westthesource.com and click on the Educational Series link for seminar information and registration.

To learn more, contact Adrienne Williams at 610-594-3160
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Visit West online at westthesource.com



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