

## The Importance of Lubricity Coatings

In this issue of *The Source*, we discuss the importance of lubricity coatings on closure systems.

An optimal closure system must be compatible with the packaged drug and facilitate administration. It should also provide optimal performance prior to and during the filling process to achieve best results and maximum filling rate. To enhance filling line performance, lubricity coatings are applied to the elastomeric components.

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

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## Considering the Steps Before Injection

Elastomeric components used for primary pharmaceutical packaging are naturally sticky. Applying lubricity coatings to the surface of the components reduces the coefficient of friction, improving breakloose extrusion and insertion force, as well as overall machinability.

Two types of lubricity coating are generally used. One is the application of free silicone oil during the washing process. A newer technology, B2-Coating, is a silicone oil-based spray coating.

### Silicone Oil Application

West Pharmaceutical Services applies a clear, colorless polydimethylsiloxane (Dow Corning 360 Medical Fluid) to closures after they are molded and trimmed. In Europe, West uses silicone oil with a viscosity of 1,000 centistokes in accordance to Ph.Eur. requirements for lubricity coatings. In the United States, West uses silicone oil with a viscosity of 350 centistokes to meet the requirements of the USP.

Silicone oil can be applied to elastomeric closures in several ways. For standard application, a silicone oil and water emulsion is injected into the pharmaceutical washer at the end of the cycle and distributed by tumbling. The same process is used for the Westar® RS (ready-to-sterilize) products. A mechanically generated emulsion of silicone oil and Water For Injection (WFI) is added to the washer during the final rinse. Different silicone levels are available depending on the functional needs of the container closure system.

### Potential Negative Effects of Silicone Oil on Parenterals

Although silicone oil is commonly used, the level of application must be optimized. Excessive silicone may result in:

- **Beading:** An aesthetic problem caused by transfer of silicone oil from closures to the glass walls of parenteral containers above the liquid line. Water droplets bead on the surface and are considered aesthetically undesirable.
- **Turbidity:** A condition where silicone oil adsorbs onto a lyophilized drug and creates a haze upon resolution. For proteins, it has also been reported that small, subvisible silicone oil chaplets lead to aggregation, resulting in hazing.
- **Particles:** Silicone can coalesce in aqueous solutions to form droplets. These droplets are detected as solid particulate matter when tested using light obscuration particle counting instrumentation. This can lead to final product failures for particulate matter. All failures using light obscuration methods should be evaluated using the appropriate optical microscopy methods to avoid unjustified particle failures as the result of silicone oil.

### Alternatives to Siliconisation

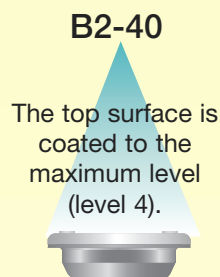
To reduce the above mentioned risks, West recommends B2-Coating. This coating is based on high molecular polydimethylsiloxanes that are cross-linkable on the surface of rubber closures by UV light. B2 is sprayed on the closures before they are trimmed. The controlled process ensures an even distribution on each stopper and does not alter their chemical or biological properties. The

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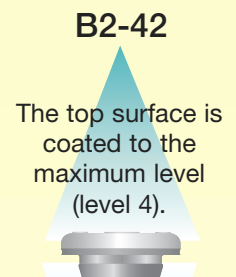
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B2-Coating can be applied to both the top and plug side of the stopper, or to one side only, in three strengths. Using B2-Coating provides the opportunity to eliminate conventional silicone oil and has most of the desired functions of traditional siliconisation plus the following benefits.

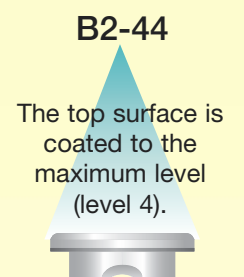
1. The availability of B2-Coating in various levels on the plug and top surface of closures provides customers the opportunity to select the optimal degree of coating, especially for the drug contact side.
2. Because of B2-Coating's properties and West's controlled manufacturing process, the potential for release of subvisible particles is extremely reduced.
3. A consistent amount of fixed silicone on the surface ensures reduction in tackiness and enhanced machinability of



The bottom surface is not coated (level 0).



The bottom surface is coated to half the maximum level (level 2).



The bottom surface is coated to the maximum level (level 4).

elastomeric closures; siliconising is not required.

4. B2-Coated stoppers have been found to improve the insertion forces of certain stopper/glass combinations when compared to silicone coated closures
5. B2 can be applied to all configurations and formulations.

## Global market and regulatory acceptance of B2-Coating

B2-Coated products are widely used by global pharmaceutical companies in all of the major market areas of Europe, Japan and the United States. B2-Coating is filed in a Drug Master File with the U.S. Food and Drug Administration.

## Filling Line Choice Dictates Stopper Packaging

An important decision 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 sterilise or ready to use. The packaging in which the stoppers are delivered should be able to go directly into the controlled envi-

ronment 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 regulatory risk. Isolators require stoppers that are supplied in packaging that allows the transfer of the sterile components directly into the isolator without compromising the isolator's sterile environment or the integrity of the components. Sterilisable 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 sterilisable bag that can be placed directly into a steam steriliser. The stoppers remain in the bag for transfer into the filling line.

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

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