PREFILLED SYRINGES:
THE RISE OF THE DELIVERY DEVICE PORTFOLIO

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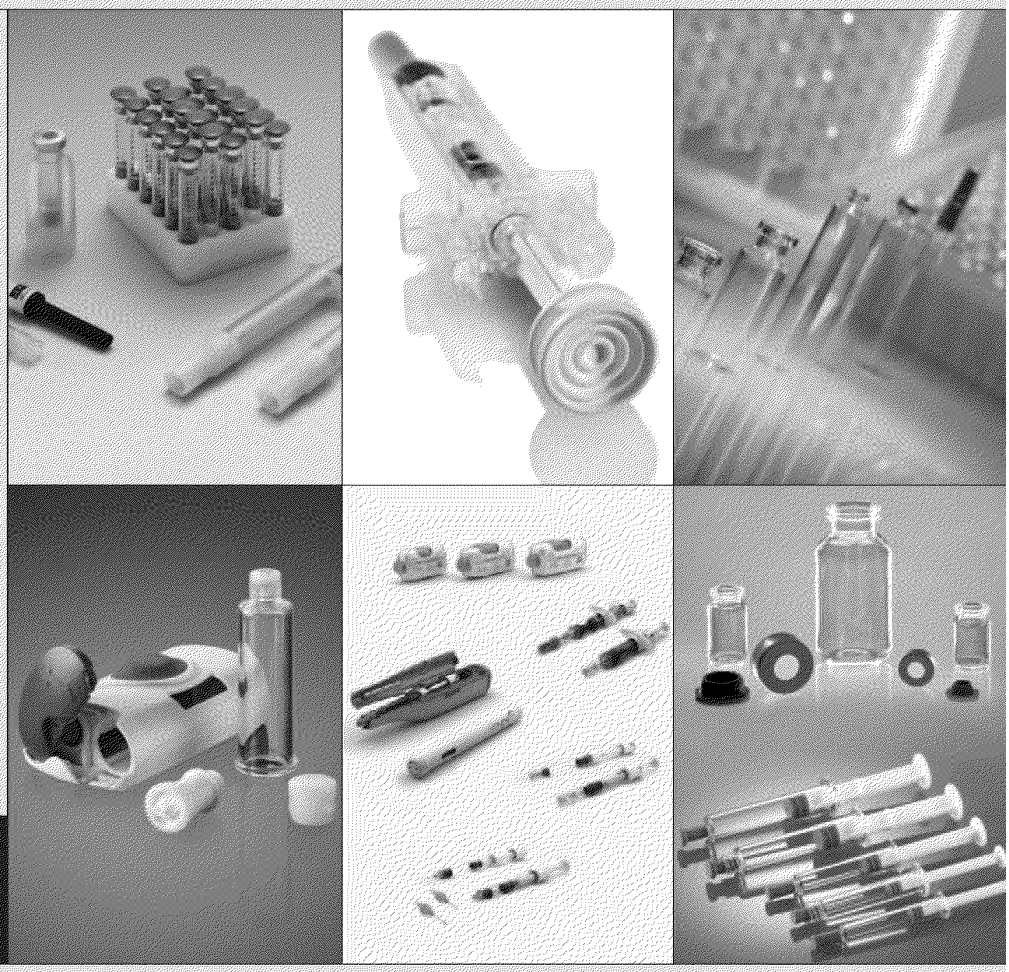

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"Prefilled Syringes: the Rise of the Delivery Device Portfolio"

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Contact: Guy Furness, Proprietor & Publisher
T: +44 (0) 1273 78 24 24
E: guy.furness@ondrugdelivery.com

MAILING ADDRESS:
Frederick Furness Publishing
48, Albany Villas, Hove, East Sussex, BN3 2RW
United Kingdom

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SPECIALTY COATING SYSTEMS™

CHALLENGES WITH PREFILLED SYRINGES: THE PARYLENE SOLUTION

In this article, Lonny Wolgemuth, Senior Medical Market Specialist, Specialty Coating Systems, Inc, concisely describes the applications and advantages of Parylenes, a series of inert polymeric coatings. In the prefilled syringes sector, Parylenes serve dual purposes being both an effective barrier material and highly lubricious coating.

LOOKING AT THE ISSUES

The chemical nature of modern drugs is becoming highly aggressive and some of these formulas tend to actually attack pharmaceutical container components. When prefilled syringes dwell in storage, two things can happen. First, a phenomenon often referred to as "stiction" occurs and the plunger doesn't slide freely upon first push. Consequently, it takes a larger than desired force to break it free. This can cause an initial uneven delivery of the drug. Second, the rubber used for the plungers may contain unwanted trace elements that can leach out of or be extracted from the stopper and contaminate the contents of the syringe, compromising the effectiveness of the medication or patient safety.

"IT SPONTANEOUSLY POLYMERISES ONTO ALL SURFACES, FORMING THE ULTRA-THIN, UNIFORM & CONFORMAL PARYLENE FILM"

A solution may be to coat syringe components with both a lubricant and a protective shield, without adding significant physical dimension to the syringe components. This, of course, rules out most of the conformal coating materials used in other industries.

The only biocompatible conformal coating that can both protect and lubricate without adding dimension to the surface is Parylene. It provides barrier protection for the syringe barrel, plunger and seals, and for the drug (see Figure 1). It is also highly lubricious, eliminating sticking plungers (see Figure 2). Parylene is widely applied on syringes to make their use easier and more precise.

UNDERSTANDING PARYLENE

Parylene is the generic name for a unique series of chemically-inert polymeric organic coatings. Several types of Parylene exist to suit a variety of applications. All are free of fillers, stabilisers, solvents, catalysts and plasticisers. As a result, the Parylenes present no leaching, outgassing or extraction issues.

Devices to be coated with Parylene are placed in a room-temperature deposition chamber. A powdered raw material, known as dimer, is placed in the vapouriser at the opposite end of the coating system. The double-molecule dimer is heated, sublimating it directly to a vapour, and the dimer vapour is then heated to a very high temperature that cracks it into a monomeric vapour. This vapour is then transferred into an ambient-temperature deposition chamber where it spontaneously polymerises onto all surfaces, forming the ultra-thin, uniform and extremely conformal Parylene film.

The entire Parylene coating process is carried out in a closed system under a controlled vacuum. The deposition chamber and items to be coated remain at room temperature through-

Lonny Wolgemuth
Senior Medical Market Specialist
T: +1 317 244 1200
E: LWolgemuth@scscoatings.com

Specialty Coating Systems, Inc
7645 Woodland Drive
Indianapolis
IN 46278
United States

www.scscoatings.com

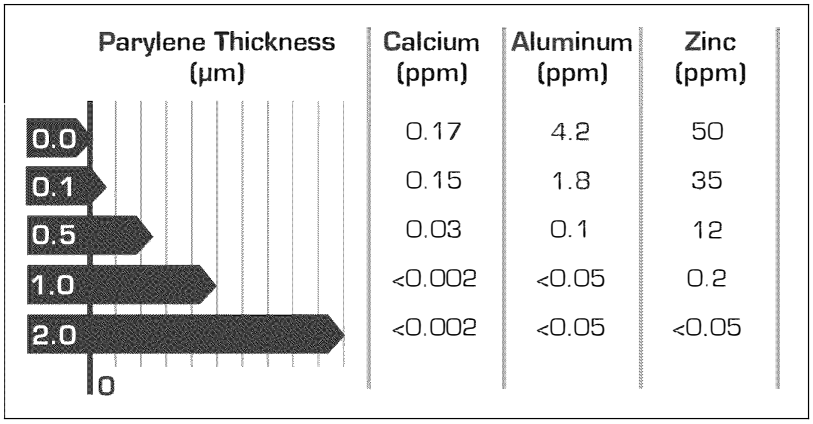

Figure 1: The effect of Parylene C coating thickness on extractable metals in rubber specimens*.

out the process. No additional curing process or steps are required.

The molecular "growth" of Parylene coatings ensures not only a uniform, conformal coating at the thickness specified by the manufacturer yet, because Parylene is formed from a gas, it penetrates into every crevice, regardless of how seemingly inaccessible. This assures complete encapsulation of the substrate without blocking, or bridging, even the smallest openings.

There are three commonly utilised variants of Parylene: C, N and Parylene HT®. Parylene N has particularly high dielectric strength and a dielectric constant that is independent of frequency. Because of its high molecular activity in the monomer vapour state, Parylene N has a greater penetrating power than Parylene C, with the ability to coat deep recesses and blind holes. Because of its lower maximum operating temperature, however, it is not suitable for applications requiring steam sterilisation.

Each Parylene has unique properties that suit it to particular medical coating applications, but Parylene C has a chlorine atom in its molecular structure resulting in modified electrical and physical properties, particularly its low permeability to moisture and corrosive gases. Because of its excellent barrier properties, Parylene C is often the first choice for protection of pharmaceutical containers, syringes and vials.

Parylene HT substitutes fluorine for the hydrogen atoms in the Parylene N molecule, resulting in some very useful attributes. Parylene HT, alone among the Parylenes, is stable in the presence of ultraviolet light, has a very high temperature capability (350°C) and has the best crevice-penetrating capability.

Parylenes N, C and Parylene HT offer similar lubricity capabilities and all are equally biocompatible. Since syringes and all types of pharmaceutical containers are typically manufactured in mass quantity, the manufacturer can have one or all components coated before sending them to the end customer, who fills and packages them for distribution.

COMPLEMENTARY APPLICATIONS

Shelf-life is important for all medications; prefilled syringes as well as pharmaceuticals in vials or bottles. For these, the more aggressive chemicals tend to attack not only the containers, but can actually cause unwanted chemicals to be extracted from the container material into the drug itself. Parylene can prevent this. It is an excellent barrier coating, protecting the container, including caps and seals, and also protecting the drug from any unwanted leaching or extractions.

"PARYLENES PRESENT NO LEACHING, OUTGASSING OR EXTRACTION ISSUES"

Some prefilled syringes have sealing mechanisms to ensure needle sterility and to prevent premature drug dispensing. These seals can occasionally form a very tight bond as it sits on the shelf. The self seal can be difficult to break. Coating these components with Parylene before assembly helps prevent seal bonding. In this case, Parylene acts as a release agent allowing the sealing material to release easily when needed.

The use of prefilled syringes, both by medical professionals and by consumers, is an extremely efficient method for dispensing drugs. Convenience, cost saving and safety aspects drive this market, particularly in the area of patient home use. Adding Parylene as a protective barrier and lubricious coating eliminates issues faced by both prefilled syringes and various pharmaceutical containers.

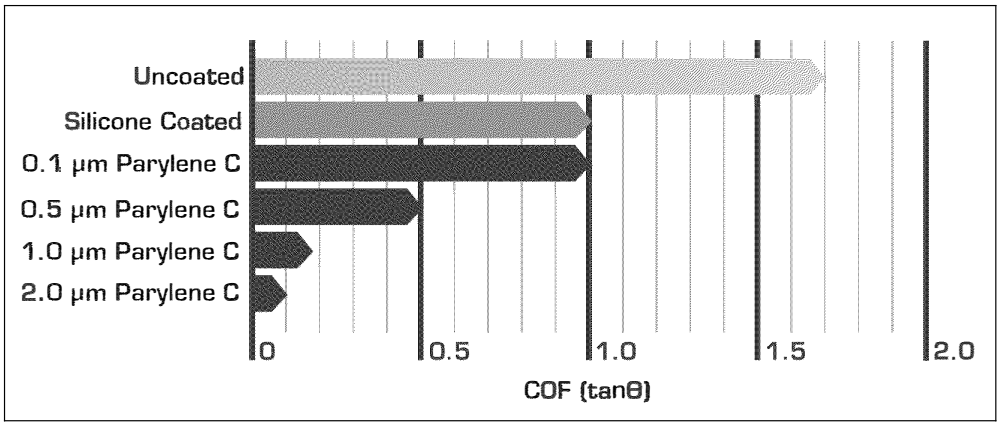

Figure 2: Co-efficient of friction measurements for Parylene-coated rubber specimens*.

** US Patent No. 4,808,453, February 28, 1989, Rombers VG et al.*