# PRODUCT PROFILE: PREMIUMCOATTM

# Aptar Stelmi 🚄

# THE ALTERNATIVE COATED STOPPER FOR SENSITIVE DRUGS

Biopharmaceuticals are very sensitive in nature and prone to interaction with the rubber of the stopper. The challenge, therefore, is to maintain the integrity of the container closure while minimising interaction between the formulation and the components of the elastomeric closure system. To meet this demand Aptar Stelmi developed the  $PremiumCoat^{TM}$  range of elastomeric stoppers (Figure 1).

PremiumCoat<sup>TM</sup> is a novel range of elastomeric stoppers developed by Aptar Stelmi, launched in 2015 and designed

for the protection of sensitive and highvalue drugs, including biopharmaceuticals. Based on an approved, pure, state-of-the-art formulation, the surface of the elastomer is coated during manufacturing with a thin

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fluoropolymer film (Figure 2). This coating acts as an effective barrier to many of the extractables and leachables that can be released from the elastomer and contaminate the drug. As a result, compatibility of the drug and the closure is significantly superior with

> The first design to be released in 2015 was a 20 mm coated stopper. A PremiumCoat<sup>TM</sup> 13 mm coated stopper was introduced earlier this year widening our range of coated stoppers.

# **PROVEN INNOVATOR**

Our experience in elastomeric closures container closure systems supported the capabilities Our



Figure 1: Vials with PremiumCoat™ stoppers: the alternative coated stoppers for sensitive drugs. (Image courtesy of Aptar Stelmi)

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International Technical Center based in our headquarters in Villepinte, France. This state-of-the-art facility has been specifically designed and equipped for mechanical, functional, chemical, container closure integrity and microbiology/particle testing. A pioneer in proprietary designs and finishing processes which have now become industry standards, our team of technical and scientific specialists pursues the development of tomorrow's products and processes.

# A TRUSTED GLOBAL PARTNER FOR PREMIUM ELASTOMERIC CLOSURES

Driven by quality, service and innovation for more than 50 years, Aptar Stelmi is a trusted partner of leading pharmaceutical and biopharmaceutical companies throughout the world.

We design and manufacture elastomeric closures: stoppers for vials; and prefilled syringe and cartridge components such as plungers, needle shields and tip caps for all parenteral applications.

Whether for vaccines, existing or new drugs, applications, or delivery systems, our committed teams of experts work closely with our customers around the world to deliver fully compliant premium quality products.

A member of the AptarGroup, we benefit from the global market presence, innovation and technical capabilities of an industry leader.

# PROTECTION, EFFICACY AND SAFETY OF DRUG PRODUCTS

We strive to provide the highest quality packaging components for injectable drugs. Our consistent quality, innovation and customer service are the cornerstone of the trusted partnerships we build with our customers.

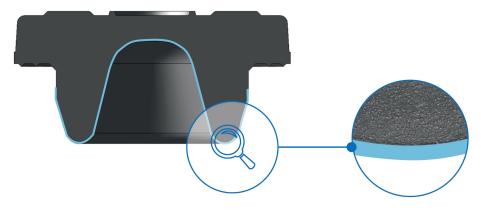


Figure 2: A barrier film covers the drug contact area. (Image courtesy of Aptar Stelmi)

# PREMIUM QUALITY SOLUTION PROVIDER

Our elastomeric closure solutions comply with the highest industry and regulatory standards. Our state-of-the-art cGMPcompliant manufacturing processes include automation, camera inspection and classified cleanrooms.

In addition, our team of experts, quality system and procedures support these production processes up to and including sterilisation - a premium quality environment for your drug products.

#### **ABOUT APTAR STELMI**

Part of the Pharma division of AptarGroup, Aptar Stelmi is a trusted partner of leading pharmaceutical companies in the design and manufacturing of elastomeric closures for parenteral applications. Driven by quality, service, and innovation for more than 50 years, Aptar Stelmi products meet the evolving drug industry demands for cleanliness, efficiency and compliance. Our prefilled syringe components and stoppers for vials are used to multiple applications in more than 70 countries worldwide.

AptarGroup, Inc, (NYSE: ATR) is a leading global supplier of a broad range of innovative dispensing systems for the beauty, personal care, home care, prescription drug, consumer health care, injectables, food and beverage markets. AptarGroup is headquartered in Crystal Lake, IL, US, with manufacturing facilities in North America, Europe, Asia and Latin America.



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