

PRODUCT SHOWCASE: Aptar Pharma's Premium Portfolio



NEW STANDARDS FOR QUALITY AND CLEANLINESS

For over 50 years Aptar Pharma's injectables specialists have led the way in developing innovative elastomer solutions. Their commitment to continuous improvement has resulted in elastomer formulations that feature best-in-class extractables and leachables profiles.

As the pharmaceutical market continues to develop ever more sensitive drugs, including biotherapeutics, the need for improved regulatory requirements increases. Aptar Pharma has risen to the challenge, delivering

"PremiumCoat™ sets the standard for film-coated stoppers with an unrivalled reduction in particulates: achieving a market-leading Particulate Count Index of 1.3."

the highest standard of cleanliness in elastomer components. Aptar Pharma's focus for both the last 12 months and the foreseeable future is quality: in R&D, customer insight and product solutions.

Aptar Pharma was the first company to provide a Drug Master File (DMF) for the Ready-to-Sterilise (RTS) process, as well as the first company to provide Ready-to-Use (RTU) stoppers to the market –

a quality standard now seen as the norm. With future commitment to quality in mind, Aptar Pharma has developed the Premium portfolio of injectable components.



Figure 1: PremiumCoat™ stoppers feature a homogenised ETFE coating to provide an unrivalled reduction in particulates.



Arnaud Fournier
Senior Business Project Manager

Aptar Pharma
Le Raspail - Paris Nord II
22 avenue des Nations
BP 59415
95944 Roissy CDG Cedex
France

T: +33 1 48 63 56 56
E: info.pharma@aptar.com

aptar.com/pharma



True experts love a challenge



Aptar Pharma Taking on injectable complexities

Isn't our industry all about taking on challenges and pushing boundaries? Imagine just how dull life would be if we never tried to be better? Settling for the perceived standard is essentially settling for second best, and no-one can afford to do that.

Rest assured, taking on a complex injectable challenge doesn't have to be a risk. For over 50 years, our injectable specialists have led the way in developing innovative elastomer solutions. Their commitment to continuous improvement has resulted in elastomer formulations, which today feature best in class extractables and leachables profiles.

But we know that isn't enough. As the pharmaceutical industry continues to develop more sensitive and expensive drugs, we need to go further. That's why we have developed the Premium portfolio of injectable components.

To find out more about how we can help you address your next injectable challenge, call **Adam Shain**, Director, Global Business Development at Aptar Pharma on **+1 908-458-1782** or email **adam.shain@aptar.com**

Delivering solutions, shaping the future.

Aptar 
pharma

“Aptar Pharma will introduce the latest developments in its Premium Portfolio when it exhibits at CPhI Worldwide in October.”

THE PREMIUM PORTFOLIO

The Premium portfolio delivers cleaner components to satisfy the ever-increasing demands of the pharmaceutical industry for inert stoppers; particularly in the delivery of more sensitive and expensive drugs, including complex proteins.

PremiumFill® is a RTS process, prior to container filling, with specifications guaranteed to Aptar Pharma’s highest quality of production, resulting in lower embedded particles, improved particulate cleanliness, and an overall reduction in defects.

All PremiumFill® manufacturing is in-line, reducing the risk of contamination during transport around the plant, thus avoiding adding intermediate storage steps in a classified manufacturing area.

PremiumCoat™ sets the standard for film-coated stoppers with an unrivalled reduction in particulates: achieving a market-leading Particulate Count Index (PCI) of 1.3, compared with the historic standard of 2.9. The coated stopper features a fluorinated polymer film (ETFE), which is applied during the manufacturing process. This approach delivers a homogenised coating, which is the established best practice method, to create the most robust and effective barrier between the drug and the stopper (Figure 1).

PremiumVision™ is a guaranteed quality commitment using an in-line, automated vision system. PremiumVision™ is designed to further validate against critical defects.

MARKET BENEFITS OF THE PREMIUM PORTFOLIO

The challenge to deliver higher standards of cleanliness in elastomer components is driven both internally and externally. As ever more complex and expensive drugs are developed, there is an absolute need to ensure that a stopper’s integrity is guaranteed. The Premium Portfolio’s commitment to lowering particulates provides for the highest standard level of guaranteed specification for laminated stoppers in the market today, meaning even greater levels of reassurance for the customer.

PREMIUMCOAT™

There are several key advantages of PremiumCoat™, most notably its aforementioned 1.3 PCI and Aptar Pharma’s deep experience in delivering gamma-irradiated stoppers. For several years Aptar’s injectables specialists had focused solely on developing elastomer formulations with extremely low extractables profiles, to the point where they are the cleanest available on the market today.

Whilst non-coated stoppers are still the component of choice for many drug formulations, there is an increasing need for the additional level of reassurance provided by coated stoppers. PremiumCoat’s homogenised ETFE coating results in a barrier which is both more effective and easier to inspect with automated vision systems. The process also ensures that only the area that comes into contact with the drug is treated, guaranteeing closure with the vial.

The Ready-to-Sterilise product, PremiumCoat™ is designed for organisations that have sterilisation facilities in place. It is compatible with steam sterilisation and uses Aptar Pharma’s proprietary washing process. The Ready-to-Use version comes already gamma radiation sterilised, providing the customer with convenience and flexibility. This approach leads to a reduction in the number of human operations as well as improved productivity, as the stoppers may be used immediately and can be directly used in RABS or isolators. There are significant economic advantages too in terms of a reduced investment in equipment required, negated maintenance costs and reduced stock levels.

PREMIUM PORTFOLIO EXHIBIT AT CPHI

Aptar Pharma will introduce the latest developments in its Premium Portfolio when it exhibits at CPhI Worldwide in Frankfurt in October. In addition to exhibiting at CPhI, Arnaud Fournier, Aptar Pharma’s Senior Business Project Manager, will be delivering a Pharma Insight Briefing entitled “Setting New Standards for Coated Stoppers”. His presentation will take place on day two of CPhI.

ABOUT THE COMPANY

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



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