



NEW BD SCF™ PREMIUMCOAT® 1ML PLUNGER STOPPER: GLIDING TOWARDS DE-RISKED COMBINATION PRODUCT DEVELOPMENT

Here, Victoria Meyer, Senior Global Strategic Marketing Manager at BD Medical – Pharmaceutical Systems, introduces the BD SCF™ PremiumCoat® 1mL Plunger Stopper and explains how the product's role is critical in determining combination products' exposure to extractables and leachables.

The complexity and sensitivity of biopharmaceutical drugs require that specific care be taken in their development, manufacture and administration.

Because of the potentially heightened risk of unexpected interactions between the biologic drug product and its primary packaging, particular care must be taken when evaluating and selecting device materials and components. The price of unforeseen interactions can be steep, including potential product launch delays, as well as possible product recalls in the case of a combination product experiencing functional or safety challenges post-launch.¹

As a component of a combination product in constant contact with the biologic drug, the plunger stopper plays a critical role in determining the combination product's exposure to extractables and leachables. Co-solvents, surfactants, chelating agents, bulking agents, pH modifiers and other formulation ingredients typically used to stabilise biologic drugs can have an impact on the leaching of organic compounds from rubber stoppers.²

As injection device designs evolve to accommodate a broadening range of challenging drugs, often requiring the mitigation of high injection forces for delivery, the plunger stopper has the potential to contribute to the combination

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product's functional characteristics, including glide force, efficacy and safety. The choice of plunger stopper can also impact processability and manufacturing, determining the component's behaviour and functional performance during the assembly phase, as well as its compatibility with existing assembly lines.

All these considerations contribute to the plunger stopper playing an important part in the development and assembly of combination products for self-injection. It also means that the choice of plunger stopper is an important step in helping to de-risk the development and launch of biologic combination products.

BD SCF™ PREMIUMCOAT®* 1mL PLUNGER STOPPER FOR PREFILLED SYRINGES

BD has partnered with Aptar Pharma to develop the BD SCF™ PremiumCoat® 1mL Plunger Stopper: a sterile, clean and



Victoria Meyer
Senior Global Strategic
Marketing Manager
E: victoria_meyer@bd.com

BD Medical – Pharmaceutical Systems
Franklin Lakes Campus
1 Becton Drive
Franklin Lakes
New Jersey
United States

www.bd.com

“BD draws upon decades of collaboration with pharma industry leaders and understands the importance of meeting drug requirements and quality criteria to provide patients with innovative injectable therapies while helping pharmaceutical companies mitigate product development and commercialisation risks.”

ready-to-fill plunger stopper for prefilled syringes for use in the development of combination products. 1mL refers to the 1 mL “long” configuration of prefilled syringe for which the stopper has been developed.

BD draws upon decades of collaboration with pharma industry leaders and understands the importance of meeting drug requirements and quality criteria to provide patients with innovative injectable therapies while helping pharmaceutical companies mitigate product development and commercialisation risks. BD chose to partner with Aptar to leverage a commercialised rubber and film coating formulation, which has been proven in the market since 2015, thus minimising development risks. BD fully processes, tests and inspects the BD SCF™ PremiumCoat® 1mL Plunger Stopper to help limit risks, such as foreign matter contamination, and to support successful integration with BD glass prefilled syringes.

The BD SCF™ PremiumCoat® 1mL Plunger Stopper features a bromobutyl rubber formulation (6720GC) and incorporates an ethylene tetrafluoroethylene (ETFE) film coating.³ The BD SCF™ PremiumCoat® 1mL Plunger Stopper helps reduce the risk of drug-container interaction by aiming to limit extractables and leachables.⁴ With this proven formulation and film coating incorporated into the BD SCF™ PremiumCoat® 1mL Plunger Stopper, pharma partners have access to a plunger stopper solution attuned to the needs of their pipeline of sensitive drugs.

REDUCING GLIDE FORCE BY UP TO 65%**

Patient needs are a central consideration in the development of any combination product. Innovation may be required to meet a variety of challenges regarding patient and caregiver ability to deliver a biologic into the subcutaneous tissue via injection.⁵ As biologics are developed with high viscosities, ease of manual injection can become compromised due to the force required to inject using a syringe.⁶ Developers of combination products can mitigate some of these challenges by considering primary and secondary

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components that can support glide force – an important element of the injection force required to deliver viscous biologic products. As a key component of combination drug delivery systems, the BD SCF™ PremiumCoat® 1mL Plunger Stopper aims to improve delivery performance by reducing glide force and variability and helping to reduce injection time and variability with a combined prefilled syringe and disposable autoinjector solution, such as the BD Neopak™ Glass Prefillable Syringe and the BD Intevia™ 1 mL Disposable Autoinjector.

This improved functional performance aims to support the injection of high viscosity drugs in a more effective and predictable way. Testing conducted by BD shows that the BD SCF™ PremiumCoat® 1mL Plunger Stopper was able to reduce glide force by up to 65% and reduce glide force variability by up to 53%.^{7**} At the same time, activation force remains equivalent to the alternative plunger stopper.^{7†}

THREE-RIB DESIGN FOR ENHANCED CONTAINER CLOSURE INTEGRITY

BD considers plunger stoppers as an important component of an entire solution for combination products that, by design, ensures closure integrity, functional performance and reduced risk of drug-container interaction. Contributing to this performance is the BD SCF™ PremiumCoat® 1mL Plunger Stopper’s three-rib design, which reduces occurrences of no contact between the ribs of the plunger stopper and the barrel. This consistent and improved contact between the BD SCF™ PremiumCoat® 1mL Plunger Stopper ribs and the barrel supports container closure integrity to help protect the drug in a combination product.³

MANUFACTURING FLEXIBILITY WITH ENHANCED PROCESSABILITY AND ASSEMBLY

The BD SCF™ PremiumCoat® 1mL Plunger Stopper can be assembled using either a long insertion vent-tube or a vacuum-assisted short insertion tube assembly process, supporting flexibility during assembly. A study conducted by Bausch + Ströbel (Ilshofen, Germany) using high speed lines and a vent tube assembly process demonstrated that the BD SCF™ PremiumCoat® 1mL Plunger Stopper performed well below the requirements for temperature⁸ and reduced glide force.⁷ Specifically, the BD SCF™ PremiumCoat® 1mL Plunger Stopper demonstrated glide forces of 20 N, four times below the maximum requirement of 80 N. Assembly testing with the BD SCF™ PremiumCoat® 1mL Plunger Stopper also determined that the temperatures generated using the same assembly process were below 40°C, which is well below the 60°C requirement, which further supports processability performance on Bausch + Ströbel manufacturing lines. Finally, there were no undesirable defects, such as wrinkles, detected with the BD SCF™ PremiumCoat® Plunger Stopper processing during the study,⁸ all of which can impact final assembly of a combination product.

PROCESSING AND INSPECTION – ENSURING TIGHT SPECIFICATIONS

BD processes and inspects the BD SCF™ PremiumCoat® 1mL Plunger Stopper to limit foreign matter contamination. The six-step process incorporates washing, siliconisation (Silicone LIVEO™ 360 Viscosity 1000 cSt), drying and quality controls, one of which is the BD Visioguard™ 100% camera inspection process.

“With the evolution of treatments for new and existing diseases, pharmaceutical organisations are also evolving and developing sensitive vaccines, such as those for covid-19.”

Packaging includes both the Transfer Door Sterile Clean Fill (TSCF) and Bagged Sterile Clean Fill (BSCF) processes for optimum compatibility with manufacturing lines. The sixth and final step consists of sterilisation, using low-dose 12–25 kGy irradiation.

SYSTEM INTEGRATION SUPPORT DATA

The importance of pairing components with a drug is paramount as combination products seek to reconcile the viscosity, concentration and volumes associated with biologics with delivery parameters and patient requirements. To help de-risk drug-device development, BD aims to be a solutions partner that can assure and support the performance of the combined delivery system throughout development and commercial launch.

BD offers system data for delivery solutions to help support combination product development, registration and time to market. BD provides relevant technical and regulatory data for BD products, including plunger rods, backstops, plunger stoppers, prefilled syringe barrels and secondary components, such as disposable autoinjectors and safety shielding solutions. This includes system data that show specific performance metrics, such as the glide force of the BD SCF™ PremiumCoat® 1mL Plunger Stopper when combined with the BD Neopak™ Glass Prefillable syringe and the BD Intevia™ 1 mL Disposable Autoinjector, providing insights to further de-risk development of combination products.

Packages include data on functionality, extractables level (leachables on request), processability and device integrability.

A SOLUTION FOR SENSITIVE VACCINES

With the evolution of treatments for new and existing diseases, pharmaceutical organisations are also evolving and developing sensitive vaccines, such as those for covid-19. New sensitive

vaccine formulations can lead to different requirements during combination product development that can also create challenges for manufacturers. To address this need, BD is in the project initiation process of the BD SCF™ PremiumCoat® Plunger Stopper 1–3 mL for sensitive vaccine applications.

AN INNOVATIVE PLUNGER STOPPER FOR BIOLOGICS BASED ON MARKET-PROVEN TECHNOLOGY

Commercialising a combination product comes with many challenges. The BD SCF™ PremiumCoat® Plunger Stopper, whether in the 1 mL or 1–3 mL format, aims to help limit drug-component interaction while improving delivery system performance.

While the BD SCF™ PremiumCoat® 1mL Plunger Stopper offers new levels of product performance, processability and manufacturability, pharma partners can choose that performance with confidence because of the proven track record of the PremiumCoat® rubber formulation and ETFE film coating.

**PremiumCoat is a registered trademark of Aptar Pharma.*

*** When compared with an identical system combined with BD SCF™ FluroTec®∞ plunger stopper.*

∞FluroTec is a registered trademark of West Pharmaceutical Services, Inc. + Glide force and glide force variability was tested with BD Neopak™ Glass Prefillable Syringes and BD SCF™ PremiumCoat® plunger stopper system.

¥ Mean value, gliding test performed at nominal design space, in BD Neopak™ Glass Prefillable Syringe 1mL 27G filled with water for injection. Test after ageing.

ABOUT THE COMPANY

BD is a large, diverse, global medical technology company. Its Medical Pharmaceutical Systems division is the world's largest syringe manufacturer. It offers prefilled syringes, self-injection systems, safety and shielding solutions, needle technologies and associated pharma services.

REFERENCES

1. *Market Research Report on System Integration". Internal Research, 2019, Becton Dickinson.*
2. Yu X et al, "A Study of Leachables for Biopharmaceutical Formulations Stored in Rubber-Stoppered Glass Vials", *BioPharm Int*, 2010, Vol. 23(4), p 26.
3. "BD Design Input Specification". *Internal study, 2021, Becton, Dickinson and Company.*
4. "BD SCF™ PremiumCoat® 1mL Plunger Stopper simulated extractables and leachables study". *Internal study, 2019, Becton, Dickinson and Company.*
5. Collins D S et al, "Accelerating the development of novel technologies and tools for the subcutaneous delivery of biotherapeutics", *J Con Rel*, 2020, Vol. 321, pp. 475–482.
6. Li Z, Easton R, "Practical considerations in clinical strategy to support the development of injectable drug-device combination products for biologics", *MAbs*, 2018, Vol. 10(1), pp. 18–33.
7. "Pre-DV data BD SCF™ PremiumCoat® 1 mL R&D data". *Internal study, 2019, Becton, Dickinson and Company; 2019.*
8. "SCF™ PremiumCoat® Plunger Stopper: Proof of processability", *Internal study, 2020, Bausch + Ströbel.*

ABOUT THE AUTHOR

Victoria Meyer has worked at BD for more than 14 years across several business units in various commercial roles including sales, sales operations and regional marketing. Mrs Meyer is currently the Senior Global Strategic Marketing Manager, responsible for leading 1 mL product platforms across the BD Biologics portfolio. In this role, she closely partners with Research & Development and other cross-functional teams to define, develop and deliver programmes, data sets and system solutions to pharmaceutical customers to help support combination product development. Mrs Meyer earned her Master's degree in Business Administration from Columbia Business School (NY, US) and holds an undergraduate degree in economics from the College of the Holy Cross (MA, US).



THE DIFFERENCE OF **ONE DRUG DELIVERED**

WITH A GLOBAL LEADER IN PREFILLABLE DELIVERY SYSTEMS. BD partners closely with leading pharmaceutical companies to support their success from drug development to launch and beyond. With a broad portfolio of innovative drug delivery systems, a global perspective and regulatory insights, a BD Medical–Pharmaceutical Systems team can partner with you to match the optimal solutions to your product. In addition to prefilled syringes, our technologies include self-injection systems, safety and shielding solutions—which we can customize and develop to meet your precise technical requirements and the demands of your business. You can also count on our depth of regulatory knowledge, product development, medical expertise and responsive support. Discover the confidence of working with the right partner. **Discover the difference of BD.**

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