



PYROFREE◆ Vials



Pyrogen free, sterile, ready-to-use vials and sterile stoppers for final filling applications

The Pyrofree vials product range is a unique solution providing filling processes with ready-to-use glass vials depyrogenated and sterilized according to industrial operations methods applied in vaccines, biotechnology, and pharmaceutical industries, and in hospitals. The packaging has been specifically designed for the processing of small batches such as clinical and technical lots, orphan drugs or personalized medicines. The Pyrofree vials product range offers a unique opportunity to simplify, facilitate and accelerate the filling of these products.



A pyrogen is defined as any substance that can cause a fever, such as endotoxins. The injection of endotoxins into the blood can cause severe hazard to a patient and in worst case, lead to septic shock. Depyrogenation, or the removal of pyrogens, is therefore a crucial need in the aseptic filling process of parenteral drugs. Primary packaging of injectable drugs is particularly controlled for the absence of pyrogens and any chemical agent which may alter drug substances properties and stability. In this case, sterilization of primary packaging (e.g. by ethylene oxide sterilization) represents a risk of introducing chemical agents into drug substances.

The Pyrofree vials product range addresses these needs thanks to its unique packaging technology, allowing sterilization and depyrogenation of the vials by dry heat in their primary packaging under vacuum. The Pyrofree process results in ready-to-use vials which can be used for the filling of injectable drugs without using washing and depyrogenation equipment from the filling line.

The Pyrofree vials product range consists of Type I clear glass vials of 2 mL, 5 mL, 10 mL and 20 mL, supplied with grey stoppers of 13 mm and 20 mm diameters, made of bromobutyl with Flurotec[◆] coating.



- Compliance with EP2.9.19-Test 1B and USP<788> (particles contamination)
- Compliance with EP2.6.14 and USP<85> (bacterial endotoxins)
- Compliance with EP2.6.1 and USP<71> (sterility test)

Pyrofree packaging technology can be also offered for other type of vials depending on the scope of application.

Features and Benefits

- ▶ Sterilized in their double primary packaging
 - Ready-to-use, no cleaning or validation needed
 - Time saving, manufacturing process is accelerated
 - No risk of contamination during packaging or other handling operations post sterilization or depyrogenation (vials)
 - Depyrogenation and sterilization by heat only, similar to industry manufacturing approach (no ethylene oxide residues)

- ▶ Endotoxins, particles and sterility claims according to Pharmacopeias recommendations
 - Fully validated and documented process in compliance with cGMP standards
 - Compliance with pharmaceutical regulations for the manufacturing of clinical, toxicological batches and personalized medicines
- ▶ Easy-to-tear opening system on one side of packaging bags
 - Ease of use
 - No cutting device needed, so safer in use
 - No particle generation while opening the bag
- ▶ Standard Pyrofree vials products include 2 mL, 5 mL, 10 mL and 20 mL clear glass vials
 - Most commonly used vials, tubular or molded, in commercial batches
 - Compliance with injectable applications
 - Very clean vials (Type I)
 - Ease of availability (on stock)
- ▶ Capability to provide customized Pyrofree vials products, within a defined scope
 - Full adaptability to end users' manufacturing process
 - Reduce validation requirements from clinical to commercial scale
- ▶ Packaging under vacuum without the need of a support tray
 - No trembling of vials during transport, high particles cleanliness
 - No vial breakage
 - Assurance of sterility, vial neck "closed" by the primary packaging bag
 - Immediate visual indicator of packaging integrity
- ▶ Vials packed in PEEK film (Poly Ether Ether Ketone)
 - No particles generation in vials
 - High temperature resistant
 - Chemically compatible to common antiseptic agents



Applications

The Pyrofree vials product range can be used for the filling of any products that require sterile and pyrogen-free glass vials between 2 mL and 20 mL.

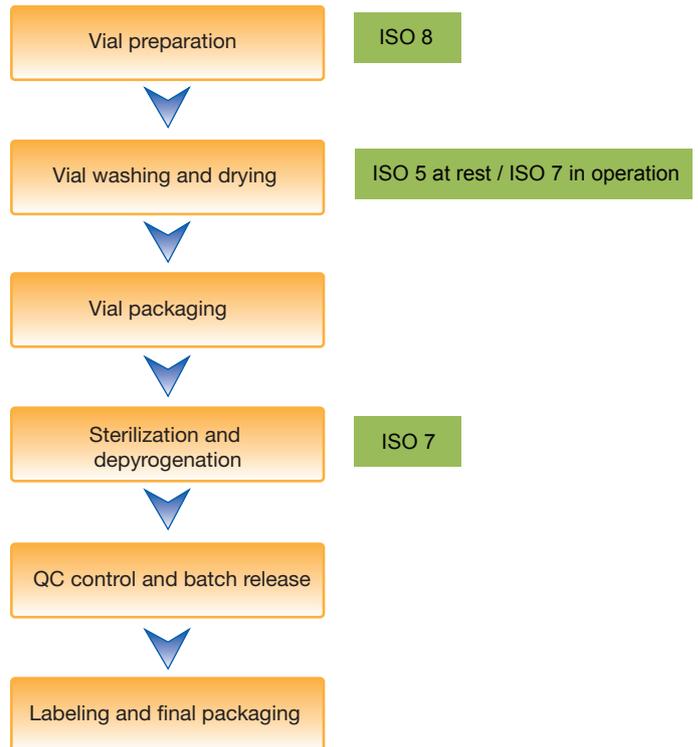
- ▶ Ready-to-use Pyrofree vials products are well adapted to vaccines, biotechnologies and pharmaceutical industries for specific applications:
 - Small batch sizes
 - Orphan drugs
 - Personalized medicines
- ▶ When the cost of purchasing or employing a depyrogenation oven or tunnel significantly impacts budget and/or process lead times are unacceptable, such as for:
 - Clinical trials drug manufacturing
 - Technical batches
 - Hospital intravenous drug preparation
- ▶ As a safety stock for commercial batches of injectable drug manufacturing, to cover for potential outage of in-line depyrogenation systems.

Quality Standards

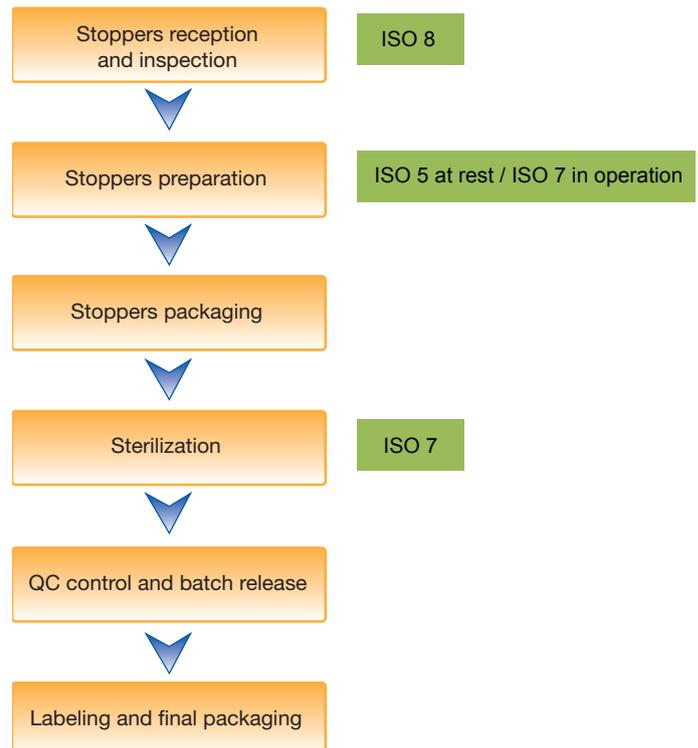
- ▶ Supplied with a Certificate of Conformity describing the quality standards and results of quality control tests performed by Disposable Lab
- ▶ Vials and stoppers meet all regulatory requirements for:
 - Particulate matter injection, EP2.9.19-Test 1B and USP<788>
 - Bacterial endotoxins, EP2.6.14, USP<85> and USP<161>
 - Sterility test, EP2.6.1 and USP<71>

Production Flow

Production steps of Pyrofree vials are described below:



Associated stoppers are also produced according to the following steps:



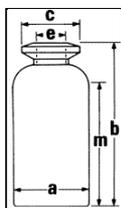
Technical Specifications

	Pyrofree vials				Sterile injection stoppers	
	2 mL	5 mL	10 mL	20 mL	13 mm	20 mm
Material of construction	SCHOTT Fiolax♦ neutral glass tubing	SGD Easy Lyo♦ glass	SCHOTT Fiolax neutral glass tubing	SGD Easy Lyo glass	Bromobutyl with Flurotec coating	Bromobutyl with Flurotec coating
Type	Type I, Tubular	Type I, Molded	Type I, Tubular	Type I, Molded	Serum, WESTAR♦RS	Serum, WESTAR RS
Color	Clear	Clear	Clear	Clear	Grey	Grey
Double Primary packaging	PEEK (PolyEther Ether Ketone) film, under vacuum				Tyvek♦ bags	
Overwrapping	PA/EvOH/PE bag, under vacuum				PA/EvOH/PE bag, under vacuum	

Product	Endotoxins level (equivalent to 0.25 EU/mL)	Particles level A: ≥ 10 µm B: ≥ 25 µm	Sterility	Shelf-life
Pyrofree vials	< 0.05 EU/mL	A: ≤ 600/vial B: ≤ 60/vial	No microbial growth	2 years
Sterile injection stoppers	< 0.5 EU/stopper	A: ≤ 6000/stopper B: ≤ 600/stopper	No microbial growth	1 year (2 years in 2017)

Dimensions (mm)

Description	Pyrofree vials			
	2 mL	5 mL	10 mL	20 mL
a	16.0	22.0	24.0	30.0
b	35.0	35.6	45.0	56.0
c*	13.0	20.0	20.0	20.0
e	7.0	11.5	12.6	11.5
m	22.0	23.7	31	42.1



* Associated sterile injection stoppers are offered with Pyrofree vials according to vial neck diameter: 13 mm stopper for 2 mL Pyrofree vials and 20 mm stopper for 5 mL, 10 mL and 20 mL Pyrofree vials.

Ordering Information

Part Number	Description	Pack Size	Pkg
PFV02ML-T	Type I clear tubular glass vials, depyrogenated and sterile, 2 mL	248	3 packs per box
PFV05ML-M	Type I clear molded glass vials, depyrogenated and sterile, 5 mL	136	3 packs per box
PFV10ML-T	Type I clear tubular glass vials, depyrogenated and sterile, 10 mL	109	3 packs per box
PFV20ML-M	Type I clear molded glass vials, depyrogenated and sterile, 20 mL	63	3 packs per box
PFST13S0150	Injection stoppers, Serum type, sterile, 13 mm	150	8 packs per box
PFST20S0150	Injection stoppers, Serum type, sterile, 20 mm	150	8 packs per box

- Pyrofree packaging can be proposed with customized vials upon request and depending on technical feasibility of the application. Please contact your local Pall single-use sales specialist for information.



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