Certificate of Test
For Pharmaceutical-Grade Sterilizing Filters

We hereby certify that
Pall® : EMFLON® PFR FILTER
Rated: 0.2 µm
Part Number: AB3PFR7PVH4
Lot Number: UD3560

was manufactured in a controlled environment and subjected to a high velocity flush after undergoing integrity testing. **These filters are not supplied sterile.**

Membrane Specification
The 0.2 µm filter membrane used in the filter element was released against a quantitative bubble point (i.e. "K_L") which met or exceeded 1380 mbar (20.0 psi) in isopropyl alcohol.

Materials of Construction
Representative filter components have met current requirements for Biological Reactivity, *in vivo*, under USP <88> (for Class VI - 121°C plastics). The filters are also manufactured from materials listed in the U.S. **Code of Federal Regulations** (21 CFR), parts 170 - 199. This product does not contain materials of construction that are considered specified TSE or BSE-risk materials according to current legislation and guidelines (reference CPMP EMA/410/01 and Title 21 of the U.S. **Code of Federal Regulations,** part 189.5).

Fabrication Integrity
Each filter element in this lot successfully passed a manufacturing Forward Flow test.

Recommended Storage Conditions
This product can be expected to perform within specification if stored in a manner consistent with the recommendations below. The product is stored in the original packaging at 0–30°C in a dry environment. Direct exposure to sunlight is avoided. Care is taken to avoid physical damage during handling and avoidance of thermal shock by quickly raising the temperature, especially from zero conditions. In addition, inspection before use is recommended, and if applicable to the product type and use, integrity testing prior to use is recommended.

Shelf Life
This product has a recommended shelf life of 5 years.

User Integrity Test
The user Forward Flow limit for this product is 15,80 mL/minu using air at a test pressure of 1100 mbar (16,00 psig) when fu wetted with 25:75 (v/v) tertiary butanol:water. The user Forwa Flow test limit has been validated for bacterial removal by correlation of the above parameters with microbiological challenge test. Test values for integrity testing of Pall filters m be obtained from Pall.

Bacterial Retention
Finished product has been sampled and successfully tested f retention of *Brevundimonas diminuta* (ATCC 19146), using procedures described in Pall Validation Guides and current ASTM Standard Test Method F838, in conformance with the applicable requirements of the FDA Guideline **Sterile Drug Products Produced by Aseptic Processing - Current Gooc Manufacturing Practice** (September 2004).

Robustness
Samples from this manufacturing lot maintained integrity after multiple autoclave cycles.

Effluent Quality
Filter samples from this manufacturing lot underwent the following tests:
Cleanliness: Meets with adequate safety margin after flushin current limits under USP <788> Particulate Matter in Injection with effluent counts determined microscopically. Counts serv to document conformance with the requirements for a non-fiber-releasing filter per Title 21 of the U.S. **Code of Federal Regulations** (CFR) parts 211.72 and 210.3 (b) (6).
Oxidizable Substances: Meets internal specifications after flushing as determined by a Potassium Permanganate Test.
pH: Meets internal specifications after flushing, upstream vers downstream differential not to exceed +/- 0.5 pH units, when tested in accordance with USP <791> pH.
Endotoxins: Meets current requirements under USP Water fc Injection, < 0.25 EU/ml, when an aliquot from a soak solution tested using Limulus Amoebocyte Lysate (LAL) reagent in accordance with USP <85> Bacterial Endotoxins Test.

In addition to the above tests, this product met manufacturing inspection standards and requirements for full traceability. This lot was released by Quality Control when it was verified all criteria were met. This product is manufactured under a Quality System certified tc ISO 9001. Consider only unopened, undamaged packages for use. Further information is available by contacting Pall.

April/2024

ANDREW BETTS, Quality Manager,
PALL MANUFACTURING (UK) LTD
STATION ROAD, ILFRACOMBE, EX34 8BH, UK

Date of Manufacture

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*All dates shown with --.--.---- are in DD.MM.YYYY format.

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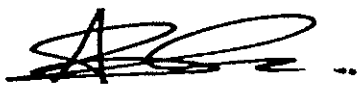
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