Pall Corporation

Certificate of Test

For Pharmaceutical-Grade Sterilizing Filters

We hereby certify that

Pall® : **EMFLON® PFR FILTER**

Rated: **0.2 µm**

Part Number: **MCY4463PFRPH4**

Lot Number: **IY8328**

was manufactured in a controlled environment and subjected to a high velocity flush after undergoing integrity testing. The filter membrane used in the filter element has a quantitative bubble point (i.e. "K_L") which met or exceeded 1380 mbar (20.0 psi) in isopropyl alcohol.

Fabrication Integrity

Each filter element in this lot successfully passed a manufacturing Forward Flow test. The user Forward Flow limit for this product is 2.00 ml/minute using air at a test pressure of 1100 mbar (16.00 psig) when fully wetted with 25:75 (v/v) tertiary butanol:water. The Forward Flow test limit has been validated for bacterial removal by correlation of the above parameters with microbiological challenge test. Recommended test values for integrity testing of Pall filters as installed must be obtained from Pall. Samples from this manufacturing lot also maintained integrity after multiple autoclave cycles.

Bacterial Retention

Finished product has been sampled and successfully tested for retention of an acceptable challenge microorganism, using procedures described in Pall Validation Guides and correlated to ASTM Standard Test Method F838-05, in conformance with the applicable requirements of the FDA Guideline **Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice** (September 2004).

Materials of Construction

The filter components have met the specifications for biological tests listed in the current revision of the **United States Pharmacopeia** (USP) for Class VI - 121°C plastics. These filters also are made from materials listed for food contact usage per Title 21 of the U.S. **Code of Federal Regulations** (CFR) parts 170-199. Contact Pall for further information regarding materials of construction.

Effluent Quality

Filter element samples from this manufacturing lot underwent the following tests and the lot was released by Quality Control when it was verified that their respective criteria were met:

Cleanliness

Meets with adequate safety margin the current USP limits under Particulate Matter in Injections with effluent counts determined microscopically. Counts serve 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 the current USP requirement under Sterile Purified Waters as determined by a Potassium Permanganate test after flushing.

pH

Meets the current USP limits under Sterile Water for Injection after flushing.

Pyrogens

Meets with adequate safety margin the current USP requirements under Bacterial Endotoxins Test as determined using the Limulus Amoebocyte Lysate (LAL) reagent with an aliquot from a soak solution.

In addition to the above tests, this product met manufacturing inspection standards and requirements for full traceability. **These filters are not supplied sterile.** Consider only unopened, undamaged packages for use. Further information is available by contacting Pall.

S. Bailey

Steven Bailey, Quality Manager, Pall Ilfracombe

8/April/2016

Date of Manufacture

CoT0037E rev 03

www.pall.com

Filtration. Separation. Solution. *SM*