Pall Corporation

Certificate of Test

We hereby certify that

Pall® : **EMFLON® HTPFR FILTER**

Rated: **0.2 µm**

Part Number: **AB3HTPFR7PVH4**

Lot Number: **SAMPLE FOR WEBSITE**

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.

These filters are not supplied sterile.

Fabrication Integrity

Each filter element in this lot successfully passed a manufacturing Forward Flow test. The user Forward Flow limit for this product is 46.00 ml/minute using air at a test pressure of 1040 mbar (15.00 psig) when fully wetted with 60:40 (v/v) IPA:water. The Forward Flow test limit has been validated for bacterial removal by correlation of the above parameters with microbiological challenge test. Samples were also subjected to a Water Intrusion Test using air at a test pressure of 2500 mbar (36 psig) with a limit of 0.99 ml/minute. 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 **Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice** (September 2004).

Materials of Construction

The filter components have met the requirements for biological reactivity, *in vivo* , under USP <88> (for Class VI - 121ºC plastics) and *in vitro* , under USP <87> (Elution Test). 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.

This product does not contain materials of construction that are considered specified TSE or BSE risk materials according to current legislation and guidelines (reference European CPMP EMA/410/01 and Title 21 of the the U.S. **Code of Federal Regulations** (CFR) parts 189.5).

Contact Pall for further information regarding materials of construction.

Effluent Quality

Filter elements 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, after flushing, current limits under USP <788> 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 after flushing under Sterile Purified Water as determined by a Potassium Permanganate test.

pH

Meets internal specifications after flushing when tested in accordance with USP <791>.

Endotoxins

Meets internal specifications when an aliquot from a soak solution is tested using the Limulus Amoebocyte Lysate (LAL) reagent in according with USP <85> Bacterial Endotoxins Test.

In addition to the above tests, this product met manufacturing inspection standards and requirements for full traceability. This product is manufactured under a Quality System certified to ISO 9001. Consider only unopened, undamaged packages for use. Further information is available by contacting Pall.

S. Bailey

Steven Bailey, Quality Manager, Pall Ilfracombe

3/April/2017

Date of Manufacture

CoT0114E rev 01

www.pall.com

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