We hereby certify that
Pall®: EMFLON® HTFPR FILTER
Rated: 0.2 µm
Part Number: AB05HTPFR2PVH4
Lot Number: SAMPLE FOR WEB SITE

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") 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 8.00 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 0.16 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).

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
CoT0114E rev 01

3/April/2017

Date of Manufacture

www.pall.com

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