Certificate of Conformance

PureFlo®
Pharmaceutical Grade
0.2 µm PTFE 65 mm DISC Capsule

Part Number: D65RF020LFLM-PH-ETO-1
Lot Number: Z5DD03006

We hereby certify that this product is manufactured in a ZenPure class 10,000 clean-room manufacturing facility that adheres to **Good Manufacturing Practices**. Quality controls are in place to assure consistent conformance to all specifications listed herein. Adherence to these specifications is ensured through lot-release, validation, and qualification testing.

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Manager of Quality Assurance
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Date of Manufacture: 04/22/2015
Date of Sterilization: 07/20/2015

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Lot Release Criteria:

This product lot was sampled and tested for conformity to the following criteria.

Filter Integrity
100% of the filters in this lot were integrity tested during the manufacturing process. In addition, finished product was sampled and shown to exhibit a 60% isopropanol/40% water bubble point of ≥1.2 bar (17.4 psi) using air at 22 °C.

Flow Rate and Pressure Drop
A representative sample of this lot was tested and determined to meet published values.

USP Bacterial Endotoxins
A representative sample of this lot was tested to confirm that an aqueous extraction of this product contains <0.25 EU/ml as determined by the Limulus Amebocyte Lysate (LAL) Test.

Specified Performance Criteria:

This product was designed, manufactured, and qualified to meet the following specifications.

Bacterial Retention
This product is quantitatively retentive towards *Brevundimonas diminuta* (ATCC #19146) at a minimum challenge level of 10^7 CFU per cm^2 of filtration area, consistent with ASTM F838-05.

Sterilization
This product can be autoclaved up to 10 cycles at 125 °C (257 °F) for 30 minutes.
Warning: This product cannot be sterilized by steam-in-place (SIP).

Materials of Construction
All components or raw materials used in this product conform to the requirements of 21CFR Part 177 and USP Class VI Biological Reactivity Tests for Plastics.

ISO 10993-5 Cytotoxicity
Extract from this product is non-Cytotoxic.

ASTM Hemolysis
Extract from this product is non-Hemolytic.

Shelf Life
This product has a minimum shelf life of 3 years after the date of manufacture. The sterilization shelf life is 1 year from the date of sterilization.

EO Cycle Condition
Cycle No. GBS, Report No. PQ-VR-ETO01-2009-0805Rev.0