# Certificate of Conformance



PureFlo®
Pharmaceutical Grade
0.45/0.2 µm PES/PES SDP Capsule

**Part Number:** SDPS020S2H2H-S045-PH-ETO
**Lot Number:** Z5EK03954

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.

Amy Zhang
Manager of Quality Assurance
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ZenPure (Hangzhou) Co., Ltd.

Date of Manufacture: 05/25/2015
Date of Sterilization: 06/15/2015

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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 water bubble point of ≥3.5 bar (50 psi) using air at 22 °C.

**Capsule Integrity**
A representative sample of this lot was shown to meet the Minimum Burst Pressure of 8.3 bar (120 psi) at 22 °C (72 °F).

**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.

**USP Conductivity**
Effluent is tested during the manufacturing process and shown to meet the requirements for USP Sterile Water for Injection for conductivity.

## 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 25 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