

Quality Assurance Certificate

SARTOLAB BT 500

Order no. 180C5-----E
Pore Size 0.22µm
Lot no. 22014003
Exp. Date 08 / 2017

This product is developed, produced and distributed according to a Quality Management System that is certified for compliance with ISO 9001

Sartorius certifies that this product meets the following criteria:

This manufacturing lot has been sampled and tested in accordance with standard Operating Procedures and has been release for the following characteristics.

- Membrane integrity test
- Visual attributes
- Packaging

Non-Fiber Releasing Membrane

This product was manufactured using a Polyethersulfone microporous membrane which meets the criteria for non-fiber. releasing filters as defined in 21 CFR 210.3 (b) (6) of the Food Additive Amendment of the U.S. Federal Food and Drug Act.

Component Materials Toxicity

All component materials have been tested and met the requirements for United States Pharmacopeia (USP) Class VI Biological Test for Plastics, latest volume.

Membrane Gravimetric Extractable

The extractable level of the membrane was less than .50 weight percent of the membrane.

Endotoxin Level: In the validation process for this filter product, an endotoxin free water extract contained less than 0.25 EU/ml, as determined by using the Limulus Amebocyte Lysate (LAL) test according to current USP.

Sterilisation

This Product has been irradiated and dosimetrically released based upon ANSI/ AAMI / ISO 11137 recommended practices.

Sterility Assurance Level: SAL 10⁻⁵

Membrane Testing Criteria

Sartorius certifies that the membrane was tested according to :

Membrane Bubble Point Integrity

Samples were tested according to an established procedure to determine the water bubble point of the product. This lot meets the established release criteria of ≥ 3.1 bar. Bubble point values are correlated to quantitative bacterial retention requirements as specified by the U.S. Advanced Medical Technology Association (AdvaMed) and/or American Society for Testing Materials (ASTM) guidelines.

Flow Rate

Samples met a flow rate of $> 30\text{ml/cm}^2$ bar min deionised water at 20 ° C.

Bacterial Retention

Samples were quantitatively retentive at 1×10^7 CFU/cm² using *Brevundimonas diminuta* organisms using HIMA and/or ASTM guidelines.

26.11.2014

Date

Sartorius Stedim Biotech GmbH



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