

**Corning Incorporated
Life Sciences**

**Registered
ISO 9001:2008**

Product Description

Catalog Number: 431720

Product Description: Mini Bioreactor, 50mL CT, with vent cap, 25/rack, 300/cs

Component Materials:

- Tube - Virgin Polypropylene, meets USP, Class VI requirements for plastic containers and closures.
- Cap - Virgin High Density Polyethylene, meets USP, Class VI requirements for plastic containers and closures. Heavy metal free (meets CONEG req.) color concentrate.
- Filter Membrane - Sterile PTFE 0.22µm filter membrane of the screw cap meets USP, Class VI requirements for plastic containers and closures.

Product Dimensions:

- | | | | | | |
|----------------|---|------------|-----------------------|---|----------|
| Length of Tube | - | 4.501 in | I.D. (neck) | - | 1.146 in |
| Tolerances | - | +/-0.05 in | Outer Diameter of cap | - | 1.364 |

Sterilization:

This lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (TIR 33) *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization.*

Sterility Assurance Level: SAL 10⁻⁶

Pyrogens:

The products has been tested and has met the criterial established in ANSI/AAMI ST 72:2002/(R) 2010: Bacterial Endotoxin - Test methodologies, routine testing, and alternative to batch testing. Results: less than 0.1 EU/mL

RNase/DNase Testing:

This product has been and is free of any detectable RNase/DNase contamination.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product complies with the latest revision of EMEA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicine products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

Performance Testing:

Each manufacturing lot is sample and tested in accordance with Standard Operating Procedures.

- | | |
|--------------------|--|
| Centrifugation: | Centrifugation of the product, fully supported to an RCF of 12,000 RCF. |
| Leak Test: | Visual examination after centrifugation. |
| Visual Attributes: | Visual examination of the product. |
| Packaging: | Inspection for seal and barrier integrity, accurate labeling, and correct product configuration. |

Lot Number Designation:

8 Digit Lot Numbre: First 3 digits - Julian date, start of manufacturing; Next 2 digits - Year of manufacture; Last 3 digits - Batch identification.

Rev No: 2