

Corning Incorporated - Life Sciences
Avenida Industrial del Norte S/N
Parque Industrial del Norte
Reynosa TAMP 88736 MEX
www.corning.com/lifesciences
Refer to website for regional contact information.

Page: 1 / 1

Product Name	: MINI BIOREACTOR, 50ML CT, W/VENT CAP,S,BK, 25/300
Catalog Number	: 431720
Lot ID	: 11225020
Expiration Date	: 2028-04-16
	Manufacture Date : 2025-04-17

Quality Management System - Complies with the current version of the EN ISO 13485 Standard and the FDA CFR 21 Part 820, current Good Manufacturing Practices (cGMP).

BSE/TSE - Product complies with the latest revision of EMA/410/01 "Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

Non-Pyrogenic - Tested and met the criteria established in the current version of ANSI/AAMI ST 72, "Bacterial Endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing" and USP <85>, "Bacterial Endotoxins Test". The acceptance level for product is ≤ 0.10 EU/ml or ≤ 4 EU/device.

USP Class VI Testing - All material resin is tested, qualified and shown to be non-toxic as established in the Standards USP Class VI Chapter<87>, "Biological reactivity Tests, in Vitro" and Chapter<88>, "Biological Reactivity Tests, in vivo".

DNase/RNase Free - Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10^{-7} Kunitz units/uL for DNase and 10^{-9} Kunitz units/uL for RNase.

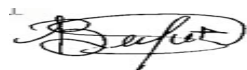
Sterilization - Product has been sterilized and dosimetrically released per the requirements of ANSI/AAMI/ISO 11137, "Sterilization of health care products - Radiation". Products meet a minimum Sterility Assurance Level (SAL) of 10^{-6} .

Sterility - Products labeled Sterile Fluid Path have been designed to ensure sterility of the portion of the product intended for contact with fluids.

Quality Control Testing - Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections and inline tests are listed below:

Visual Inspection - Pass
Functional Test - Pass

- This product met Corning Incorporated - Life Sciences' high standards of quality at the time of batch/lot release.



Benjamin Gonzalez
Quality Manager