CORNING

Certificate of Compliance

Corning Incorporated - Life Sciences
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Salt Lake City UT 84107 USA
www.corning.com/lifesciences
Refer to website for regional contact information.

Product Name	:	0.5ML,BLOCK,STERILE,10/50		
Catalog Number	:	3956	**Manufacture Date**	: 2024-12-06
Lot ID	:	34124000		
Expiration Date	:	2027-12-06		

Quality Management System - Complies with the current version of the EN ISO 13485 Standard.

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^{-5} Kunitz units/ul for DNase and 10^{-9} Kunitz units/ul for RNase.

Sterility - 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^{-3}.

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
Packaging Inspection - Pass

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

PCR Inhibition - Tested with real time Polymerase Chain Reaction and found no inhibition of real time PCR with a Ct comparison of ≤.5XCTPosCtrl-Ct.

Anthony Sloan
Quality Manager

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