

Corning Incorporated - Life Sciences
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Refer to website for regional contact information.

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Product Name : Plate 384w 120ul Wht 50cs	Manufacture Date : 2019-12-03
Catalog Number : 353988	
Lot ID : E19103K9	
Expiration Date : 2023-10-03	

Quality Management System - Complies with the current version of the ISO 9001 Standard.

Non-Pyrogenic - Validated per FDA guidelines on Pyrogen and Endotoxins testing. The acceptance level for product is ≤ 0.03 EU/ml.

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".

Tissue Culture - Tested for the ability to promote cell attachment and proliferation of mammalian cells. The intra-plate CV $\leq 10\%$ for acceptance.

Human DNA Free - Tested by PCR method and found to be free of detectable human DNA contamination. The assay detection limit is hDNA 5pg.

DNase/RNase Free - Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 1.3×10^{-8} Kunitz units/ul for DNase and 5.0×10^{-11} 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.

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



ANDREW J (ANDY) FRANKS
CMO Quality Manager