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Product Name : 1D/2D VIAL, 2.0ML, W/CAP, EXT, BK	Manufacture Date : 2022-03-28
Catalog Number : 8671	
Lot ID : 36121021	
Expiration Date : 2027-03-28	

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

Animal Content - Product does not contain materials of animal origin.

Product Attribute - Validated for compliance to IATA PI 650; does not leak at a pressure differential of 95kPa in the range of -40°C to +55°C.

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".

Non-Pyrogenic - Validated per European Pharmacopoeia criteria for pyrogens and meets the requirements for classification as non-pyrogenic. The acceptance level for product is ≤ 0.1 EU/mL.

DNase/RNase Free - Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10^{-6} Kunitz units/ul for DNase and 10^{-9} Kunitz units/ul for RNase.

Human DNA Free - Tested by PCR method and found to be free of detectable human DNA contamination. The assay detection limit is hDNA 2pg.

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} .

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