

Corning Incorporated - Life Sciences  
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|---|--------------------------------------|
| <b>Product Name</b> : 1D/2D VIAL, 2.0ML, W/CAP, EXT, BK | <b>Manufacture Date</b> : 2019-07-17 |
| <b>Catalog Number</b> : 8671                            |                                      |
| <b>Lot ID</b> : 19819693                                |                                      |
| <b>Expiration Date</b> : 2024-07-17                     |                                      |

**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  $\leq 0.1$  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