

VWR® DISPOSABLE SEROLOGICAL PIPETS, POLYSTYRENE, STERILE, PLUGGED

As per the manufacturer, the below product meets the following criteria:

| | |
|-----------------------------------|--------------------------------|
| North American Catalog No: | 89130-898 |
| Lot Number: | 20218003 |
| Description: | VWR PIPETTE SERO 10ML PR CS200 |
| Manufacturing Date: | July 21, 2018 |
| Expiration Date: | July 20, 2021 |

Component Materials:

| | |
|-----------------|--|
| Pipette | Polystyrene, meets USP Cytotoxicity Test <87>. |
| Mouthpiece Plug | Polyester, meets USP Cytotoxicity Test <87>. |
| Ink | meets USP Cytotoxicity Test <87>. |

Volumetric Accuracy:

This product has been tested and is accurate within +/- 2% at stated full volume.

This manufacturing lot has been sampled and tested in accordance with Standard Operating Procedures and has been released by Quality Assurance for the following characteristics:

| <u>Test/Procedure</u> | <u>Results</u> |
|-----------------------|----------------|
| Visual Attributes | Pass |
| Volumetric Accuracy | Pass |
| Packaging | Pass |

Sterilization: The lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 "Sterilization of health care products-Requirements for validation and routine control-Radiation sterilization".

Sterility Assurance Level: SAL 10⁻³

Pyrogens: The product has been tested and has met the criteria established in ANSI/AAMI ST 72:2002/(R) 2010: "Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing".

Results: <= 0.1 EU/mL (<= 4 EU/device)

DNase/RNase: The product has been tested and has met the criteria established in ANSI/AAMI ST 72:2002/(R) 2010: "Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing".

Results: <= 0.1 EU/mL (<= 4 EU/device)

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy: This product is deemed animal free by virtue of not containing materials of animal origin and/or complies with the latest revision of EMA/410/01 section 6.4.

Signed:



Jamie Ethier
VP Global Quality
VWR, Part of Avantor

Date: August 08, 2018