

## **VWR® SEROLOGICAL PIPETS**

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

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North American Catalog No:	89130-896
EU Article No:	612-4950
Lot Number:	21816030
Description:	VWR PIPETTE SERO 5ML PR CS200
Manufacturing Date:	8/5/2016
Expiration Date:	8/5/2019

## **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:

Test/Procedure	Results	
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<sup>-3</sup>

**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)

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.

Signed:

Ken Crossley Manager

Quality Assurance Date: August 17, 2016