Corning Incorporated
Life Sciences

Product Description

Catalog Number: **4488**

Product Description: **PIPETTE, 10ML, PPW, PS, S, IND, 50/BAG**

Component Materials:

Pipette	-	Polystyrene meets *USP, Class VI* requirements for plastic containers and closures. Polystyrene also meets *USP Cytotoxicity Test <87>.*
Mouthpiece Plug	-	Polyester, meets *USP Cytotoxicity Test <87>.*
Ink	-	Orange / black, meets *USP Cytotoxicity Test <87>.*

Packaging Material:

Paper	-	Cellulose
Film	-	Multilayer coextruded film

Product Dimensions:

Overall Length	-	13.55 in.+/- 0.150 in.	Tip ID	-	0.060 in.
Max Working Volume	-	13 mL	Mouthpiece OD	-	0.310 in.
Volumetric Accuracy	-	+/- 2% stated full volume	Pipette OD	-	0.375 in.
Tolerances of ID & OD	-	+/- 0.015 in.			

Regulatory Compliance - Product manufactured in a facility that is registered to the current version of ISO 9001 or ISO 13485.

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}.

Non-Pyrogenic - Tested and met the criteria established in the current version of ANSI/AAMI ST 72, "Bacterial Endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing" and USP <85>, "Bacterial Endotoxins Test". The acceptance level for product is ≤ 0.10 EU/ml or ≤ 4 EU/device.

BSE/TSE – 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.

DNase/RNase Free - Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10^{-7} 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.

Volumetric Accuracy - Serological pipets are accurate to +/- 2% at full volume in compliance with ASTM E934, "Standard Specification for Serological Pipet, Disposable Plastic" and ISO 12771, "Plastics laboratory ware - Disposable serological pipettes".

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. Key inspections and inline tests are listed below:

Visual Inspection - Pass
Packaging Inspection – Pass
Integrity Test – Pass

Extractables – Data is available upon request (with an active NDA in place)

Lot Number Designation:
8 Digit Lot Number: First 3 digits – Julian date, start of manufacturing; Next 2 digits – Year of manufacture, Last 3 digits – Batch identification.
Or
7 Digit Lot Number: First digit – Last number of year of manufacture, Next 3 digits – Julian date, start of manufacturing, Last 3 digits – Batch identification

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