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|  Life Sciences | Affected Site(s): US : MA : Tewksbury; US : NC : Durham | | Document Number: LSR00219 | |
| | Description: Generic Serological Pipettes 1mL-50mL | | Revision: 3 | Page: 1 of 3 |

Generic Serological Pipettes

FEATURES:

Easy-to-read high contrast graduations

Color-coded pipets

Negative graduations

Reverse graduations (except 1 mL)

Polyester fiber plug

Individually wrapped and bulk packaging options

CLAIMS:

Volumetric Accuracy – Serological pipets are accurate to ± 2% at full volume in compliance with ASTM E394, “Standard Specification for Serological Pipet, Disposable Plastic” and ISO 12771, “Plastics Laboratory Ware – Disposable Serological Pipettes”.

Sterility – Product has been sterilized and dosimetrically released per the requirements of ANSI/AAMI/ISO 11137, “Sterilization of Health Care Products – Radiation”. Product meet a minimum Sterility Assurance Level (SAL) of 10⁻³.

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 – Tested and met the criteria established in the current version of United States Pharmacopeia (USP) Chapter<85>, “Bacterial Endotoxins Test”. The acceptance level for product is ≤ 0.125 EU/ml or ≤ 5 EU/device.


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/μL for DNase and 10⁻⁹ Kunitz units/μL for RNase.

BSE / TSE – Product complies with the latest revision of EMA/410/01 “Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products” by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

Quality Control Testing – Representative product samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release.

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LOT NUMBER DESIGNATION (7-DIGITS):

First digit – Last number of year of manufacture; next 3 digits – Julian date, start of manufacturing; last 3 digits – batch identification

SHELF LIFE:

3-years from date of manufacture

REGULATORY COMPLIANCE:

These pipets are manufactured under the current ISO 13485 Standards, and the current FDA Quality System Regulation 21 CFR Section 820.

TABLE I: MATERIALS

| COMPONENT | MATERIAL |
|-----------|------------------|
| PIPET | POLYSTYRENE (PS) |
| PLUG | POLYESTER FIBER |

TABLE II: PRODUCT AND PACKAGING CONFIGURATION

| SIZE (mL) | INCREMENTS | OVERFILL CAPACITY | REVERSE GRAD | COLOR | CAT. NO. | PACKAGING | CASE QTY | PACK QTY |
|-----------|------------|-------------------|--------------|---------|----------|---------------|----------|----------|
| 1 | 1/100 mL | .4 mL | | YELLOW | 357770 | PAPER-PLASTIC | 1000 | 100 |
| | | | | | 357776 | BULK | 1000 | 25 |
| 2 | 1/100 mL | .8 mL | ✓ | GREEN | 357771 | PAPER-PLASTIC | 1000 | 100 |
| | | | | | 357777 | BULK | 1000 | 25 |
| 5 | 1/10 mL | 2.5 mL | ✓ | BLUE | 357772 | PAPER-PLASTIC | 200 | 50 |
| | | | | | 357778 | BULK | 500 | 25 |
| 10 | 1/10 mL | 3 mL | ✓ | RED | 357773 | PAPER-PLASTIC | 200 | 50 |
| | | | | | 357779 | BULK | 500 | 25 |
| 25 | 1/4 mL | 7 mL | ✓ | MAGENTA | 357774 | PAPER-PLASTIC | 200 | 50 |
| | | | | | 357780 | BULK | 200 | 20 |
| 50 | 1 mL | 10 mL | ✓ | BLACK | 357775 | PAPER-PLASTIC | 100 | 25 |

TABLE III: PRODUCT DIMENSIONS

| SIZE (mL) | OVERALL DIMENSIONS | | | | TIP | | | MOUTHPIECE | | | EXTRUSION | | |
|-----------|--------------------|---------------|---------------|----------------|-----------------|---------------|---------------|----------------|---------------|---------------|------------------|----------------|----------------|
| | A | B | C | D | L | ID | OD | L | ID | OD | L | ID | OD |
| 1 | 279.40 11.00" | 3.35 .132" | 4.65 .183" | 4.65 .183" | N/A | 1.67 .066" | 3.35 .132" | N/A | 2.96 .117" | 4.65 .183" | N/A | N/A | N/A |
| 2 | 282.58 11.13" | 3.73 .147" | 6.27 .247" | 6.27 .247" | N/A | 1.63 .064" | 3.73 .147" | N/A | 4.17 .164" | 6.27 .247" | N/A | N/A | N/A |
| 5 | 348.51 13.72" | 3.35 .132" | 8.03 .316" | 8.03 .316" | 37.36 1.471" | 1.57 .062" | 3.35 .132" | N/A | 6.01 .236" | 8.03 .316" | 311.15 12.25" | 6.01 .236" | 8.03 .316" |
| 10 | 346.81 13.65" | 3.30 .130" | 8.05 .317" | 9.61 .370" | 37.36 1.471" | 1.57 .062" | 3.35 .132" | 22.23 .875" | 5.72 .225" | 7.62 .300" | 285.75 11.25" | 7.95 .313" | 9.60 .378" |
| 25 | 310.90 12.24" | 4.78 .188" | 7.62 .300" | 15.16 .597" | 39.24 1.545" | 2.36 .093" | 4.78 .188" | 25.91 1.02" | 5.08 .200" | 7.62 .300" | 249.35 9.82" | 13.43 .529" | 15.16 .597" |
| 50 | 368.17 14.50" | 5.49 .216" | 7.62 .300" | 17.78 .700" | 39.24 1.545" | 3.18 .125" | 5.49 .216" | 27.94 1.10" | 5.59 .220" | 7.62 .300" | 301.12 11.86" | 16.00 .630" | 17.78 .700" |

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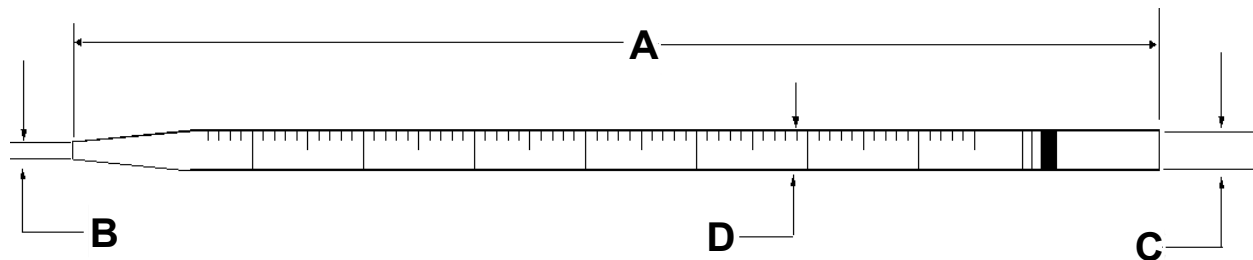
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L = length ID = interior diameter OD = outside diameter N/A = Not Available

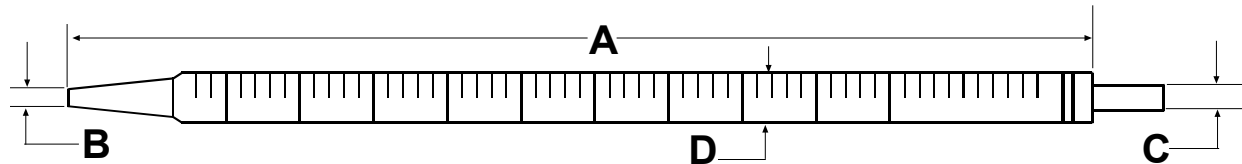
Top/bottom dimensions = millimeters/inches

REPRESENTATIVE DIAGRAMS:

1mL, 2mL and 5mL



10mL, 25mL and 50mL



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