

Catalog Number: 430182

Product Description: 100ml GRAD,CYLINDER,STERILE,50/CS

**Component Materials:**

- Cylinder - Virgin Polystyrene, meets *USP Class VI* requirements for plastic containers and closures.
- Dust Cover - Virgin High Density Polyethylene

**Product Dimensions:**

- Height with Dust Cover - 8.08 in. I.D. of Cylinder - 1.14 in.
- Height without Dust Cover - 8.05 in. O.D. of Cylinder - 1.26 in.
- Tolerances - +/- 0.05 in.

**Animal Content** - Product does not contain materials of animal origin.

**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". The acceptance level for product is  $\leq 0.10$  EU/ml or  $\leq 4$  EU/device.

**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".

**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  $10^{-6}$ .

**Volumetric Accuracy** - Tested for volumetric accuracy. Met +/- 2% for acceptance.

**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

**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.

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