

Catalog Number: 3564

Product Description: Corning® Disposable 3L Spinner Flask, Side Arm Accessory, GL45 thread, 0.2um membrane

Component Materials:

- Cap - Virgin High Density Polyethylene, meets *USP, Class VI* requirements for plastic containers and closures. Heavy metal free (meets CONEG requirements) color concentrate.
- Filter - 25mm/0.2µm Acrylic proprietary formulation, meets Class VI requirements for Biological Test for Plastics.
- Tubing - Chemically resistant, heat sealable, thermoplastic elastomer, meets *USP, Class VI* requirements for plastic containers and closures
- Luer Fitting - Polypropylene fitting and cap, meets *USP, Class VI* requirements for Biological Test for Plastics.

Product Dimensions:

- Cap Diameter - 45mm (1.77in) Cap Height - 25.3mm (1.0in)
- Tolerances - +/- 0.050in

BSE/TSE:

This product complies with the latest revision of EMEA 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 EMEA/410/01.

Non-Pyrogenic:

Tested and met the criteria established in the current version of ANSI/AAMI 72, Bacterial Endotoxins – Test methodologies, routing monitoring, and alternatives to batch testing” and USP <85>, “Bacterial Endotoxins Test”. The acceptance level for product is ≤ 0.50 EU / ml or ≤ 20 EU / device.

Sterilization:

The lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (AAMI TIR 33) *Sterilization of health care products-Requirements for validation and routine control-Radiation sterilization* Sterility Assurance Level: SAL 10⁻⁶

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 manufacture; Next 2 digits - Year of manufacture; Last 3 digits - Batch identification.

Rev No: 10

3/2/2022