

**Corning Incorporated
Life Sciences**

Registered
ISO 9001:2008

Product Description

Catalog Number: 3564

Product Description: Corning® Disposable 3L Spinner Flask, Side Arm Accessory, GL45 thread, 0.2µm 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 - 0.2µm (Versapor) acrylic copolymer membrane, meets *USP, Class VI* requirements for plastic containers and closures.
- Tubing - C-Flex 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 - +/- .050 in.

Sterilization:

The lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (AAMI TIR 27) *Sterilization of health care products-Requirements for validation and routine control-Radiation sterilization*
Sterility Assurance Level: SAL 10⁻⁶

Pyrogens:

This vessel has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72:2002/(R)2010 *Bacterial Endotoxins - Test methodologies, routine monitoring, and alternative to batch testing*.
Results: ≤ 0.1 EU/mL (≤ 4EU/device)

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

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 veterinary medicine products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

Performance Testing:

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

Visual Attributes:

Visual examination of the product.

Packaging:

Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.

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: 7