

Catalog Number: 11500

Product Description: Corning® TRANSFER CAP, 5L ERL, STERILE, MPC

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.

Accessories:

Tubing - C-Flex, Thermoplastic Elastomer, meets USP, Class VI requirements for containers and closures.

Filter - 50mm/0.0um Polytetrafluoroethylen (PTFE), meets USP, Class VI requirements for Biological Plastics.

Diptube - High Density Polyethylene, meets USP, Class VI requirements for plastic containers and closures.

Product Dimensions:

Length of Diptube:	- 12.75in	Length of Tubing:	- 38.8in
Tolerances	- +/-0.05 in	Diameter of Cap	- 4.16in

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} .

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.

Non-Pyrogenic - Tested and has met the criteria established in the current version of ANSI/AAMI ST 72, Bacterial Endotoxins - Test methodologies, routine monitoring, and alternative to batch testing". The acceptance level for product is ≤ 0.25 EU/mL (≤ 10 EU/device).

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

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.

Rev 1