Corning Incorporated
Life Sciences

Registered
ISO 9001:2008

Product Description

Catalog Number: **11501**

Product Description: **Corning® ERL, 5L, Plain, Transfer Cap, Sterile, MPC**

Component Materials:

Erlenmeyer Flask	-	Virgin Polystyrene, meets, USP Class VI requirements for plastic containers and closures.
Cap	-	Virgin High Density Polyethylene, meets, USP Class VI requirements for plastic containers and closures. Heavy metal free (meets CONEG requirements) color concentrate.
Gasket	-	Thermoplastic elastomer liner, meets, USP Class VI requirements for plastic containers and closures.

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:

Height of Erlenmeyer Flask with cap	-	11.33in	Diameter of Cap	-	4.16in
Height of Erlenmeyer Flask w/o cap	-	11.24in	Diameter of Neck	-	3.88in
Diameter of Flask @ widest point	-	9.05in	Tolerances		+/-0.05 in
Length of Diptube:	-	12.75in	Length of Tubing:	-	38.8in

Sterilization - Product has been sterilized and dosimetrically released per the requirements ANSI/AAMI/ISO 11137 "Sterilization of health care products- Radiation". Products meet a minimum Sterility Assurance Level (SAL) of 10^{-6}.

Sterility - Products labeled Sterile Fluid Path have been designed to ensure sterility of the portion of the product intended for contact with fluids.

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).

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 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