

Corning Incorporated - Life Sciences
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Refer to website for regional contact information.

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Product Name	: Elplasia Round Bottom, Flask, 12K, 850/650, ULA, I		
Catalog Number	: 4537	Manufacture Date	: 2023-09-15
Lot ID	: 25823003		
Expiration Date	: 2026-09-15		

Quality Management System - Complies with the current version of the ISO 9001 Standard and the FDA CFR 21 Part 820, current Good Manufacturing Practices (cGMP).

BSE/TSE - Product complies with the latest revision of EMA/410/01 "Note for Guidance on minimising 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 met the criteria established in the current version of ANSI/AAMI ST 72, "Bacterial Endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing" and USP <85>, "Bacterial Endotoxins Test". The acceptance level for product is ≤ 0.10 EU/ml or ≤ 4 EU/device.

Sterility - 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^{-3} .

Tissue Culture - Tested for the ability to promote the growth and formation of 3D cellular spheroids of mammalian suspension cells in culture.

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
- Leak Test - Pass

- This product met Corning Incorporated - Life Sciences' high standards of quality at the time of batch/lot release.



Erika S Barnhart
Plant Quality Manager