

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

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Product Name : Plate 24w Collagen I Peptide	
Catalog Number : 356271	Manufacture Date : 2019-08-23
Lot ID : 9232016	
Expiration Date : 2021-02-19	

Quality Management System - Complies with the current version of the EN ISO 13485 Standard and the FDA CFR 21 Part 820, current Good Manufacturing Practices (cGMP).

Animal Content - Product does not contain materials of animal origin.

USP Class VI Testing - All material resin is tested, qualified and shown to be non-toxic as established in the Standards USP Class VI Chapter<87>, "Biological reactivity Tests, in Vitro" and Chapter<88>, "Biological Reactivity Tests, in vivo".

Non-Pyrogenic - Tested and met the criteria established in the current version of United States Pharmacopeia (USP) Chapter <85>, "Bacterial Endotoxins Test". The acceptance level for product is ≤ 0.125 EU/ml or ≤ 5 EU/device.

Leachability - Residual unbound peptide on the vessel surface is ~ 0.01 pmoles/ cm², based on dilution factor. Once immobilized on the surface, peptides are stable as determined by Surface Chemistry Analysis.


Sterility - Product has been manufactured using aseptic processing per ISO 13408-1, "Aseptic processing of healthcare products" and tested according to USP<71>, "Sterility Tests". Each step has been validated to ensure that product meets the Sterility Assurance Level (SAL) of 10^{-3} .

Tissue Culture - Tested for the ability to promote the cell growth and attachment of mammalian cells. Cell morphology of flat and spread cells with average confluency $\geq 30\%$ and an intra-plate CV $\leq 15\%$ are required for acceptance.

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:

Cell Attachment & Growth Treatment Verification - Pass

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



AMBER AAGAARD
Quality Manager