Corning Incorporated Life Sciences

Registered ISO 9001:2008

Certificate of Compliance

Catalog Number: 431222

Lot Number: 14714041

Product Description: Corning® syringe filter, regenerated cellulose (RC) membrane, 0.20 µM pore size,

25 mm diameter, individually packaged

Component Materials:

Housing
 Membrane
 Polypropylene, meets *USP*, *Class VI* requirements for plastic containers and closures.
 Regenerated Cellulose (RC), 0.20 μM pore size, meets *USP*, *Class VI* requirements for

plastic containers and closures.

Sterilization:

This lot has been irradiated and dosimetrically released based on the *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization*.

Sterility Assurance Level: SAL 10⁻⁵

Pyrogens:

The product has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72: Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing. Results: less than 0.1EU/mL

HPLC Certified:

The product has been tested to ensure there are no extraneous peaks in the UV range.

This manufacturing lot has been sampled and tested in accordance with Standard Operating Procedures and has been released by Quality Assurance for the following characteristics:

Test/Procedure:

Membrane Bubble Point Integrity
Housing Burst Pressure Test
Pressure Hold Test
Bacterial Challenge Test
Visual Attributes
Pass
Pass
Packaging
Results:
Pass
Pass
Pass
Pass
Pass
Pass
Pass

Expiration Date:

This product has an expiration date of 3 years from the date of manufacture for the attributes contained within this certificate.

Lot Number Designation:

8 Digit Lot Number: First 3 digits - Julian date of manufacture; Next 2 digits - Year of manufacture; Last 3 digits - Run number for that year

Revision Date:

06-02-14

Wendy Lintsch

Wendy Loitsch Quality Manager

Rev No: 4