

Certificate of Compliance

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

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Product Name : Plate 96w PDL Wht 5pk 50cs

Catalog Number : 356620 Manufacture Date : 2023-12-01

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).

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".

Tissue Culture - Tested for the attribute of cell attachment and growth utilizing an attachment-dependent mammalian cell line in a serum free media. A minimum of 1.5 times the growth as compared to a standard tissue culture control plate with \leq 15% CV is required for acceptance.

Bioburden Testing - Tested and found negative for bacteria and fungi with visual inspection after 14 days of incubated growth.

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

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

Renee E Gallagher Plant Quality Manager

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