



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

WUXI APPTEC, INC.
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Philadelphia, PA 19112
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BIOLOGICAL

Valid To: May 31, 2019

Certificate Number: 3141.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on bio-pharmaceutical raw materials, intermediates, and finished products:

Test/Technology

Test Method(s)

Virology

In Vitro Assay for Adventitious Virus

Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals, US FDA (1993); Characterization and Qualification of Cell Substrates and Other Biological Material Used in the Production of Viral Vaccines for Infectious Disease Indications, US FDA (2010). Eg 33864

Detection Assay for Bovine/Equine/Porcine Adventitious Virus

WuXi AppTec Method 33281 (Bovine and Porcine) 30217 (Equine)

Co-Cultivation of Test Article for Detection of Retrovirus

Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals, US FDA (1993) (30201)

Replication Competent Viral Assay

WuXi AppTec Method 30698

Titration Assay to Determine Potency of Virus

WuXi AppTec Custom Developed and Validated Methodology (Eg 30099)

Test/Technology

Molecular Biology¹

Virus Detection by qPCR

Determination of Residual Host Cell DNA by qPCR

Detection of Mycoplasma by PCR

Reverse Transcriptase Assay

Analytical¹

Determination of Protein Concentration by UV Spectrophotometry

Determination of Protein Concentration by Absorbance using BCA

Determination of Process Residuals by ELISA

Size Exclusion Chromatography (SEC) of Monoclonal Antibodies for Monomer

pH and Appearance

Osmolality

¹These portions of the scope meet the A2LA P112 *Flexible Scope Policy*.

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Accredited Laboratory

A2LA has accredited

WUXI APPTec, INC.

Philadelphia, PA

for technical competence in the field of

Biological Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated 8 January 2009).



Presented this 25th day of May 2017.

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President & CEO
For the Accreditation Council
Certificate Number 3141.01
Valid to May 31, 2019
Revised June 08, 2017

For the tests to which this accreditation applies, please refer to the laboratory's Biological Scope of Accreditation.