



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

AZZUR LABS, LLC
4125 Independence Dr, Suite 5
Schnecksville, PA 18078
Katie Neetz Phone: 484 550 7709

BIOLOGICAL

Valid To: October 31, 2019

Certificate Number: 3484.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following test on raw materials, excipients, intermediate and finished products for the pharmaceutical, pharmacy, dietary supplement, human cells, tissue products, and medical device industries.

<u>Test - Quantitative</u>	<u>Test Method</u>	<u>Protocol</u>
Antimicrobial Effectiveness Testing	USP<51>; EUPh 5.1.3; CTFA M3; CTFA M4	Protocol_015; Protocol_020; Protocol_021
Conductivity	USP<645>; EUPh Water, Purified	Protocol_012
Enumeration Tests: Total Aerobic Microbial Count and Total Combined Yeast and Mold Count	USP<61>; EUPh 2.6.12	Protocol_009; Protocol_010 (Suitability)
Enumeration of Biological Indicators	USP<55>	Protocol_003
Environmental Monitoring Analysis – Viable Air, Viable Surface (Plates/Swabs)	ISO 14698; USP<1116>; USP<797>; CAG-009	Protocol_001; Protocol_002
Endotoxin – Chromogenic Technique	USP<85>	Protocol_008
Microbial Enumeration of Water – Heterotrophic Plate Count, Coliforms, Fluorescent Pseudomonas Group	USP<1231>	Protocol_005
pH	USP<791>; EUPh Water, purified	Protocol_012

<u>Test – Quantitative (continued)</u>	<u>Test Method</u>	<u>Protocol</u>
TOC	USP<643>	Protocol_007
<u>Test – Qualitative</u>	<u>Test Method(s)</u>	<u>Protocol(s)</u>
Identification Bacteria, Yeasts & Molds – Biochemical/ Microscopic Fungal Analysis	USP<1113>	Protocol_006
Media Fill Analysis (for compliance with FDA – Aseptic Processing Guidelines)	USP<797>; USP<71>	Protocol_004
Recovery of Biological Indicators	USP<55>	Protocol_003
Sterility Testing – Bacteriostasis & Fungistasis	USP<71>	Protocol_017; Protocol_018 (Suitability, B&F)
Tests for Specified Organisms	USP<62>; EUPh 2.6.13	Protocol_009; Protocol_010 (Suitability)

WITHDRAWN





Accredited Laboratory

A2LA has accredited

AZZUR LABS, LLC

Schnecksville, 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 April 2017).



Presented this 29th day of November 2017.

A blue ink signature of the President and CEO, written over a horizontal line.

President and CEO
For the Accreditation Council
Certificate Number 3484.01
Valid to October 31, 2019
Revised June 13, 2019

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