



PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

Perry Johnson Laboratory Accreditation, Inc. has assessed the Laboratory of:

Azzur Labs, LLC

4125 Independence Drive, Suite 5, Schnecksville, PA 18078

(Hereinafter called the Organization) and hereby declares that Organization is accredited in accordance with the recognized International Standard:

ISO/IEC 17025:2017

This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (as outlined by the joint ISO-ILAC-IAF Communiqué dated April 2017):

Biological Testing
(As detailed in the supplement)

Accreditation claims for such testing and/or calibration services shall only be made from addresses referenced within this certificate. This Accreditation is granted subject to the system rules governing the Accreditation referred to above, and the Organization hereby covenants with the Accreditation body's duty to observe and comply with the said rules.

For PJLA:

Tracy Szerszen
President/Operations Manager

Perry Johnson Laboratory
Accreditation, Inc. (PJLA)
755 W. Big Beaver, Suite 1325
Troy, Michigan 48084

Initial Accreditation Date:

June 5, 2019

Issue Date:

September 30, 2019

Expiration Date:

November 30, 2021

Accreditation No.:

80916

Certificate No.:

L19-485

The validity of this certificate is maintained through ongoing assessments based on a continuous accreditation cycle. The validity of this certificate should be confirmed through the PJLA website: www.pjilabs.com



Certificate of Accreditation: Supplement

Azzur Labs, LLC

4125 Independence Drive, Suite 5, Schnecksville, PA 18078

Contact Name: Katie Neetz Phone: 484-550-7709

Accreditation is granted to the facility to perform the following testing:

| FIELD OF TEST | ITEMS, MATERIALS OR PRODUCTS TESTED | SPECIFIC TESTS OR PROPERTIES MEASURED | SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED | RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT |
|-------------------------|--|--|--|---|
| Biological ^F | Raw Materials, Excipients, intermediate and finished products for the pharmaceutical, pharmacy, dietary supplement, human cells, tissue products, and medical device industries. | Antimicrobial Effectiveness Testing | USP<51>; EUPh 5.1.3; CTFA M3; CTFA M4 | 10 CFU ³ to 250 CFU ³ With typical 1:10 dilution D.L. = Up to 10 CFU |
| | | Conductivity | USP<645>; EUPh water, purified | 0.01 μS/cm to 300 μS/cm |
| | | Enumeration Tests: Total Aerobic Microbial Count and Total Combined Yeast and Mold count | USP<61>; Euph 2.6.12; ANSI/AAMI/ISO 11737 ² | 10 CFU ³ to 250 CFU ³ With typical 1:10 dilutions D.L. = Up to 10 CFU |
| | | Environmental Monitoring Analysis- Viable Air, Viable Surface (Plates/Swabs) | ISO 14698; USP<1116>; USP<797>; CAG-009 | Settle Plates: 1 CFU to 250 CFU Bacterial plates on contact: D.L. = 1 CFU to 250 CFU Fungal plates on contact: D.L. = 1 CFU to 80 CFU |
| | | Endotoxin-Chromogenic Technique | USP<85> | D.L. = 0.01EU/ml ³ to 10 EU/ml ³ Based on product dilution |
| | | Microbial Enumeration of Water-Heterotrophic Plate Count, Coliforms, Fluorescent Pseudomonas Group | USP<1231>; Euph water, purified JP purified water ² | D.L. = 1 CFU ³ to 250 CFU ³ Based on product dilution |
| | | pH | USP <791>; EUPh Water, purified | D.L. = 0 pH to 14 pH |
| | | TOC | USP<643> | D.L. = 40 ppb to 90ppm |
| | | Identification Bacteria, Yeasts & molds- biochemical/ Microscopic Fungal Analysis | USP<1113> | Qualitative |
| | | Media Fill Analysis (for Compliance with FDA- Aseptic Processing Guidelines) | USP<797>; USP<71> | |
| | | Recovery of Biological Indicators | USP<55> | |
| | | Sterility Testing- Bacteriostasis & Fungistasis | USP<71> | |
| | | Tests for Specified Organisms | USP<62>; EupH 2.6.13 | |

1. The presence of a superscript F means that the laboratory performs testing of the indicated parameter at its fixed location. Example: Outside Micrometer^F would mean that the laboratory performs this testing at its fixed location.



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2. Additional methods other than listed above may fall under the accreditation of the laboratory. A complete listing of methods capabilities can be derived from the laboratory upon request.
3. Limit of Detection varies based on product dilution which is decided at the time of Method suitability.

