PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

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

Gillson Testing

4125 Independence Dr., Ste 5, Schnecksville, PA 18078

and hereby declares that the Organization is accredited in accordance with the recognized International Standard:

ISO/IEC 17025:2017

Whereby, technical competence has been confirmed for the associated scope supplement, in the fields of:

Chemical and Biological Testing

(As detailed in the supplement)

Accreditation claims for conformity assessment activities shall only be made from the addresses referenced within this certificate and shall apply solely to those activities identified in the related scope. This Accreditation is granted subject to the Accreditation Body rules governing the Accreditation referred to above, and the Organization hereby commits to observing and complying with those rules in their entirety.

For PJLA:

Tracy Szerszen
President

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

Initial Accreditation Date:	*Issue Date:*	*Expiration Date:*
June 05, 2019	October 03, 2025	November 30, 2027

Accreditation No.:	*Certificate No.:*
80916	L25-746

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.pjlabs.com

Certificate of Accreditation: Supplement

Gillson Testing

4125 Independence Dr., Ste 5, Schnecksville, PA 18078
Contact Name: Katie Neetz Phone: 484-550-7709

Accreditation is granted to the facility to perform the following conformity assessment activities:

FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS TESTED	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION OF ACTIVITY
Chemical	Raw Materials, Excipients, intermediate and finished products for the pharmaceutical, pharmacy, dietary supplement, human cells, tissue products, water, and medical device industries.	pH	USP <791>	pH Meter	F1, F2	F
Chemical	Raw Materials, Excipients, intermediate and finished products for the pharmaceutical, pharmacy, dietary supplement, human cells, tissue products, water, and medical device industries.	TOC	USP <643>, EU 01/2008:20244	TOC Analyzer	F1, F2	F
Chemical	Raw Materials, Excipients, intermediate and finished products for the pharmaceutical, pharmacy, dietary supplement, human cells, tissue products, water, and medical device industries.	Conductivity	USP <645>, EU 01/2021:20238	Conductivity Meter	F1, F2	F
Biological	Raw Materials, Excipients, intermediate and finished products for the pharmaceutical, pharmacy, dietary supplement, human cells, tissue products, water, and medical device industries.	Antimicrobial Effectiveness Testing	USP <51>, EUPh 5.1.3, CTFA M3, CTFA M4	Plating	F1, F2	F
Biological	Raw Materials, Excipients, intermediate and finished products for the pharmaceutical, pharmacy, dietary supplement, human cells, tissue products, water, and medical device industries.	Enumeration Tests: Total Aerobic Microbial Count Total Combined Yeast and Mold count	USP <61>, EUPh 2.6.12, ANSI/AAMI/ISO 11737-2	Plating	F1, F2	F

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Biological	Raw Materials, Excipients, intermediate and finished products for the pharmaceutical, pharmacy, dietary supplement, human cells, tissue products, water, and medical device industries.	Environmental Monitoring Analysis-Viable Air, Viable Surface (Plates/Swabs)	ISO 14698, USP <1116>, USP <797>, CAG-009	Visual inspection	F1, F2	F
Biological	Raw Materials, Excipients, intermediate and finished products for the pharmaceutical, pharmacy, dietary supplement, human cells, tissue products, water, and medical device industries.	Endotoxin	USP <85>	Chromogenic Technique	F1, F2	F
Biological	Raw Materials, Excipients, intermediate and finished products for the pharmaceutical, pharmacy, dietary supplement, human cells, tissue products, water, and medical device industries.	Microbial Enumeration of Water-Heterotrophic Plate Count, Coliforms, Fluorescent Pseudomonas Group	USP <1231> Water, Purified Monograph 04/2024:0008	Plating	F1, F2, F5	F
Biological	Raw Materials, Excipients, intermediate and finished products for the pharmaceutical, pharmacy, dietary supplement, human cells, tissue products, water, and medical device industries.	Identification Bacteria, Yeasts & molds-biochemical/ Microscopic Fungal Analysis	USP <1113>	Bruker MALDI-TOF	F1, F2	F
Biological	Raw Materials, Excipients, intermediate and finished products for the pharmaceutical, pharmacy, dietary supplement, human cells, tissue products, water, and medical device industries.	Media Fill Analysis (for Compliance with FDA-Aseptic Processing Guidelines)	USP <797> USP <71>	Visual Inspection	F1, F2	F

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Biological	Raw Materials, Excipients, intermediate and finished products for the pharmaceutical, pharmacy, dietary supplement, human cells, tissue products, water, and medical device industries.	Recovery of Biological Indicators	USP <55>	Visual Inspection	F1, F2	F
Biological	Raw Materials, Excipients, intermediate and finished products for the pharmaceutical, pharmacy, dietary supplement, human cells, tissue products, water, and medical device industries.	Sterility Testing-Bacteriostasis Fungistasis	USP <71>	Visual Inspection	F1, F2	F
Biological	Raw Materials, Excipients, intermediate and finished products for the pharmaceutical, pharmacy, dietary supplement, human cells, tissue products, water, and medical device industries.	Tests for Specified Organisms	USP <62>, EUPh 2.6.13	Plating	F1, F2, F3	F

1. Location of activity:

Location	Location
F	Conformity assessment activity is performed at the CABs fixed facility

2. Flex Code:
F0- Fixed scope item. No deviations allowed to the line item as identified, except for updating to the most recent version of an accredited standard method after verification.
F1- Laboratory has the capability to test a new item, material, matrix, or product similar in composition to item, material, matrix, or product identified on the scope
F2- Laboratory has the capability to introduce the newest revision of an accredited authoritative standard method (with no modifications) identified on the scope
F3- Laboratory has the capability to introduce a parameter/component/analyte to an accredited test method identified on the scope
F4- Laboratory has the capability to introduce a new revision of an accredited non-standard method using the same technology or technique identified on the scope
F5- Laboratory has the capability to introduce a validated method that is equivalent to an accredited method (using same technology or technique) identified on the scope