



PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

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

Prime Analytical Laboratories, LLC
4055 Nelson Ave., Concord, CA 94520

(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):

Microbiological and Chemical 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

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

Initial Accreditation Date:

March 04, 2023

Issue Date:

March 04, 2023

Expiration Date:

April 30, 2025

Accreditation No.:

119492

Certificate No.:

L23-179

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.pjllabs.com



Certificate of Accreditation: Supplement

Prime Analytical Laboratories, LLC

4055 Nelson Ave, Concord, CA 94520

Contact Name: Ms. Hana Taylor Phone: 925-235-1470

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
Microbiological ^F	Cosmetics, pharmaceutical products, and biologics	Antimicrobial preservative effectiveness test for USP and EP selected organisms: <i>E. coli</i> <i>Staphylococcus aureus</i> <i>Candida albicans</i> <i>Pseudomonas aeruginosa</i> <i>Aspergillus niger</i>	USP <51> EP 5.1.3	D.L. = <10 CFU/mL or CFU/g
	Microbiological Examination of Nonsterile Products	<i>Burkholderia cepacia</i> Complex	USP <60>	Presence/Absence
	Pharmaceutical raw materials, non-sterile products, liquids and powders and medical devices.	Total Aerobic Plate Count Yeast and Mold Count	USP<61>	D.L = <10 CFU/mL or CFU/g
	Pharmaceutical raw materials, non-sterile products, liquids and powders, and dietary supplements	<i>E. coli</i> <i>Staphylococcus aureus</i> <i>Pseudomonas aeruginosa</i> <i>Salmonella enterica</i> <i>Clostridium spp.</i> <i>Candida albicans</i>	USP<62>	Presence/Absence
	Nutritional and Dietary Supplements, raw materials and finished products.	Total Aerobic Plate Count Yeast and Mold Count	USP <2021>	D.L = <10 CFU/mL or CFU/g
	Nutritional supplements: raw materials and finished products	<i>E. coli</i> <i>Staphylococcus aureus</i> <i>Salmonella enterica</i> <i>Clostridium sporogenes</i>	USP <2022>	Presence/Absence
Chemical ^F	Water For Injection	Endotoxin	USP <85>	<0.01 EU/mL
	Liquid and gel products	pH	USP <791>	pH 1 to 14
	Water and cleaning validation samples	Conductivity	USP <645>	0 to 1000 μS/cm @25°C
	Raw Material Identification	Cyclosporine Compounded Theophylline Solution by HPLC	USP <621>	90.0% to 110.0%

- 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.