



PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

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

FOCUS Laboratories

2660 Alt 19N, Suite B, Palm Harbor, FL 34683

(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, Chemical, and Microbiological 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

Initial Accreditation Date:

February 17, 2023

Issue Date:

February 17, 2023

Expiration Date:

May 31, 2025

Accreditation No.:

77499

Certificate No.:

L23-137

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

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

FOCUS Laboratories

2660 Alt 19N, Suite B, Palm Harbor, FL 34683
 Contact Name: Mel Homik Phone: 610-866-7272

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	Pharmaceutical Products and Materials, Medical Devices, Health and Beauty, and Consumer Products and Materials	USP <51> Antimicrobial effectiveness Testing	FOCUS Protocols 020, 030 / SOP 3470	1 LOG to 3 LOG Reduction; D.L. = 0.5 LOG
		USP <60> Microbiological Examination of Non-Sterile Products tests for Burkholderia cepacia complex	FOCUS SOP 3451	Presence/Absence; D.L. = 1 CFU/g
		USP <61> Microbiological Examination of Non-Sterile Products Microbial Enumeration Tests	FOCUS Protocol 004 / SOP 3410	D.L. = 10 CFU/g for Aerobic Plate Count; D.L. = 1 CFU/g for membrane filtration
		USP <62> Microbiological Examination of Non-Sterile Products Tests for Specified Microorganisms	FOCUS Protocol 005 / SOP 3450	Presence/Absence
	Water / Water for Pharmaceutical purposes	Microbial Enumeration	FOCUS Protocol 001 / SOP 3850	D.L.= 1 CFU/100 mL by Membrane Filtration
	Medical Devices, Health and Beauty, and consumer products and materials	ANSI/AAMI/ISO 11737-1 Determination of a Population of Microorganisms (Bioburden)	FOCUS Protocol 014 / SOP 3411	D.L. = 1 CFU/device
	Pharmaceutical and Medical Device Products and Material	USP <71> Sterility	FOCUS SOP 1441	Sterile/Non-Sterile
	Filterable Drug Products and Materials	Sterility by SCAN RDI	FOCUS SOP 1406	
Biological ^F	Pharmaceutical, Medical Devices, Health, and Beauty Products, and Materials	USP <85> Bacterial Endotoxins	FOCUS SOP 3444	D.L. = 0.002 EU/mL or g of material
Chemical ^F	Injections and Ophthalmic Solutions	USP <788>, USP <789> Particulate Matter	FOCUS SOP 1481	D.L. =1 particle/mL
	Water and Solutions	USP <645>, USP <644> Conductivity	FOCUS SOP 3510	D.L. =1 µS/cm

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.
2. This location is linked to 177 North Commerce Way Bethlehem PA 18017 due to a share quality management system.