

## PERRY JOHNSON LABORATORY ACCREDITATION, INC.

# Certificate of Accreditation

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

## Geneva Laboratories, Inc.

1001 Proctor Drive, Elkhorn, WI 53121 980 Proctor Drive, Elkhorn, WI 53121

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

## ISO/IEC 17025:2005

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 January 2009):

### Microbiological, Chemical, and 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: Issue Date: Ex September 15, 2016 September 15, 2016 Nov Accreditation No.: Certificate No.:

*Expiration Date:* November 30, 2018

Accreditation No.: 78413

L16-384

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: <u>www.pjlabs.com</u>



Certificate of Accreditation: Supplement

Geneva Laboratories, Inc.

1001 Proctor Drive, Elkhorn, WI 53121 980 Proctor Drive, Elkhorn, WI 53121 Contact Name: Sharon Smith Phone: 262-723-5669

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

#### 1001 Proctor Drive, Elkhorn, WI 53121

Microbiological F Pharmaceutical Products and Personal Care ProductsMedical devices, Pharmaceutical Products and Personal Care ProductsCytotoxicityISO 10993-5Presence/AbsenceChemical FBacterial EndotoxinUSP <85>Biological FPackage IntegrityASTM F1929Dislogical FPhysico-chemicalUSP <661>IntracutaneousISO 10993-10Acute Systemic ToxicityISO 10993-10Ocular IrritationISO 10993-10Closed Patch SensitizationISO 10993-10Dermal SensitizationISO 10993-10Class VI: -Intracutaneous -SystemicUSP <88>-Intracutaneous -Intracutaneous -SystemicUSP <88>-Intracutaneous -Intracutaneous -SystemicUSP <88>Oral Mucosa IrritationISO 10993-10Vaginal Mucosa IrritationISO 10993-10Primary Skin IrritationISO 10993-10Primary Skin IrritationISO 10993-10Primary Skin IrritationISO 10993-10Primary Skin IrritationISO 10993-10	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
Products and Personal Care ProductsParticle CountUSP <788> Package IntegrityBiological FPackage IntegrityASTM F1929Biological FPhysico-chemicalUSP <661> IntracutaneousOcular IrritationISO 10993-10Acute Systemic ToxicityISO 10993-10Ocular IrritationISO 10993-10Penile Mucosa IrritationISO 10993-10Closed Patch SensitizationISO 10993-10OlogertyClass VI: -Intracutaneous-IntracutaneousSo 10993-10Oral Mucosa IrritationISO 10993-10Primary Skin IrritationISO 10993-10Primary Skin IrritationISO 10993-10	Microbiological <sup>F</sup>	Pharmaceutical	Cytotoxicity	ISO 10993-5	Presence/Absence
Personal Care ProductsParticle CountUSP <788>Package IntegrityASTM F1929Physico-chemicalUSP <661>IntracutaneousISO 10993-10Acute Systemic ToxicityISO 10993-11Ocular IrritationISO 10993-10Penile Mucosa IrritationISO 10993-10Dermal SensitizationISO 10993-10Oclass VI:USP <88>-Intracutaneous-Systemic-Intracutaneous <t< td=""><td>Bacterial Endotoxin</td><td>USP &lt;85&gt;</td></t<>			Bacterial Endotoxin	USP <85>	
ProductsPackage IntegrityASTM F1929Chemical <sup>F</sup> Physico-chemicalUSP <661>Biological <sup>F</sup> IntracutaneousISO 10993-10Acute Systemic ToxicityISO10993-11Ocular IrritationISO 10993-10Penile Mucosa IrritationISO 10993-10Closed Patch SensitizationISO 10993-10Dermal SensitizationISO 10993-10Class VI:USP <88>-Intracutaneous-Systemic-Intracutaneous-Systemic-Intracutaneous-Systemic-Intracutaneous-Systemic-IntraductionISO 10993-10Oral Mucosa IrritationISO 10993-10Vaginal Mucosa IrritationISO 10993-10Primary Skin IrritationISO 10993-10			Particle Count	USP <788>	
Biological FIntracutaneousISO 10993-10Acute Systemic ToxicityISO 10993-10Acute Systemic ToxicityISO 10993-10Ocular IrritationISO 10993-10Penile Mucosa IrritationISO 10993-10Closed Patch SensitizationISO 10993-10Dermal SensitizationISO 10993-10Class VI:USP <88>-Intracutaneous-Systemic-Intramuscular-Intramuscular-Intraducosa IrritationISO 10993-10Oral Mucosa IrritationISO 10993-10Vaginal Mucosa IrritationISO 10993-10Primary Skin IrritationISO 10993-10			Package Integrity	ASTM F1929	
Acute Systemic ToxicityISO10993-11Ocular IrritationISO 10993-10Penile Mucosa IrritationISO 10993-10Closed Patch SensitizationISO 10993-10Dermal SensitizationISO 10993-10(GPMT)Class VI:Class VI:USP <88>-Intracutaneous-Systemic-IntramuscularImplantationISO 10993-10Oral Mucosa IrritationISO 10993-10Vaginal Mucosa IrritationISO 10993-10Primary Skin IrritationISO 10993-10	Chemical <sup>F</sup>	-	Physico-chemical	USP <661>	
Ocular IrritationISO 10993-10Penile Mucosa IrritationISO 10993-10Closed Patch SensitizationISO 10993-10Dermal SensitizationISO 10993-10(GPMT)Class VI:Class VI:USP <88>-Intracutaneous-Systemic-Intramuscular-Intramuscular-ImplantationISO 10993-10Oral Mucosa IrritationISO 10993-10Vaginal Mucosa IrritationISO 10993-10Primary Skin IrritationISO 10993-10	Biological <sup>F</sup>		Intracutaneous	ISO 10993-10	-
Penile Mucosa IrritationISO 10993-10Closed Patch SensitizationISO 10993-10Dermal SensitizationISO 10993-10(GPMT)Class VI:USP <88>-Intracutaneous-Systemic-Systemic-Intramuscular-ImplantationISO 10993-10Oral Mucosa IrritationISO 10993-10Vaginal Mucosa IrritationISO 10993-10Primary Skin IrritationISO 10993-10			Acute Systemic Toxicity	ISO10993-11	
Closed Patch SensitizationISO 10993-10Dermal SensitizationISO 10993-10(GPMT)USP <88>-Intracutaneous-Systemic-Intramuscular-Intramuscular-ImplantationISO 10993-10Oral Mucosa IrritationISO 10993-10Vaginal Mucosa IrritationISO 10993-10Primary Skin IrritationISO 10993-10			Ocular Irritation	ISO 10993-10	
Dermal Sensitization (GPMT)ISO 10993-10Class VI:USP <88>-Intracutaneous -SystemicIntramuscular -Implantation-Oral Mucosa IrritationISO 10993-10Vaginal Mucosa IrritationISO 10993-10Primary Skin IrritationISO 10993-10			Penile Mucosa Irritation	ISO 10993-10	
(GPMT)USP <88>-Intracutaneous -Systemic -Intramuscular -Intramuscular -Implantation			<b>Closed Patch Sensitization</b>	ISO 10993-10	
-Intracutaneous -Systemic -Intramuscular -Implantation-Oral Mucosa IrritationISO 10993-10Vaginal Mucosa IrritationISO 10993-10Primary Skin IrritationISO 10993-10				ISO 10993-10	
Vaginal Mucosa IrritationISO 10993-10Primary Skin IrritationISO 10993-10			-Intracutaneous -Systemic -Intramuscular	USP <88>	
Primary Skin Irritation ISO 10993-10			Oral Mucosa Irritation	ISO 10993-10	
			Vaginal Mucosa Irritation	ISO 10993-10	]
Muscle Implantation ISO 10993-6			Primary Skin Irritation	ISO 10993-10	
			Muscle Implantation	ISO 10993-6	]



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#### 980 Proctor Drive, Elkhorn, WI 53121

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	Medical devices,	Ames	ISO 10993-3	Presence/Absence
Proo	Pharmaceutical Products and Personal Care Products	Hemolysis	ISO 10993-4	
		Antimicrobial Effectiveness	USP <51>	
		Microbiological Examination of Nonsterile Products: Enumeration and Tests for Specified Microorganisms	USP <61> USP <62>	
		Sterility Test	USP <71>	
		Bioburden Test	ISO 11737-1	

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