

Natural Immunogenics Corporation

Department: RA, Quality Control & Laboratory Operations SOP No.: LAB-36 Rev. 15

Subject: Certificate of Analysis (COA) for Silver Hydrosol

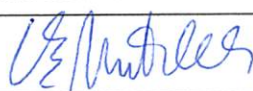
Regulatory Compliance: International regulatory standards for the manufacture of bulk material for further processing, dietary supplements, Pharmaceuticals and Medical Devices require the Issuance of a COA for each batch of product to confirm that specifications are met in terms of product identity, purity, strength and composition. Complete quality & purity testing were performed and results are recorded in the batch record. This batch is hereby certified to have been produced in accordance with the Formulary, Quality controls, Specifications and Characteristics set forth by NIC proprietary formulations. There have been no revisions or changes during the production of this batch except as noted herein.

Bulk Batch No: **A051042821**

Expiry: **03/2024**

Filled Lot: **KE002R** (100 X 4oz/118 mL)

ANALYTICAL DATA	PRODUCT SPECIFICATIONS	TEST RESULTS	TEST METHOD USED
Silver concentration by Atomic Absorption Spectroscopy (AAS)	23 ppm LC: 25.5 - 27.5 ppm	26.9	Validated Atomic Absorption Spectrophotometry: SOP LAB-65 or LAB-85
pH	5.5 to 7.5	5.5	SOP LAB-02
Conductivity (µS)	23 ppm LC: 22.0 – 32.0 µS/cm	26.8	SOP LAB-05
Endotoxin	< 0.25 EU /mL (Endotoxin units per milliliter)	<0.053	LAL assay; FDA ITG-40; SOP LAB-32
PRODUCT CHARACTERISTICS			
Color	Clear to slightly tinted	Clear	Visual
Taste	None to slightly metallic	Ingestion	
Particle size distribution	Uniform	Transmission Electron Microscopy, SOP LAB-23	
Additional testing performed on a monthly (or as needed) basis by fully accredited third-party laboratories			
Microbiology: Total Plate Count	<100 cfu / mL	USP <61>	
Mold & Yeast (Aerobic Plate Count)	<10 cfu / mL	USP <61>	
Salmonella sp, and E. coli,	Negative / 10 mL	USP <62>	
Staphylococcus aureus and Pseudomonas sp	Negative / 10 mL	USP <62>	
Burkholderia cepacia	Negative / 10 mL	USP <60>	
Carbamates	MBR: Finished Product Specifications correlated to MCLG per WHO, EPA, US FDA 21CFR165.110, Australian & Canadian standards for drinking water	EPA 531.1 or equivalent	
Heavy metals		ICP-MS by EPA 200 series; Methods: SW6020 A andSW3010A or equivalent	
Organochlorine Pesticides		EPA 508 - Method: SW3510C or equivalent	
Organophosphorous Pesticides		EPA 8270- Method SW3510C or equivalent	

	PRINT NAME	SIGNATURE & DATE
COA REVIEWED AND APPROVED BY: (Quality / Regulatory Management)	Kay Mitchen, Director of Regulatory Affairs & Quality	 May 3rd, 2021