

### Certificate of Analysis

Name of Product: Myristyl-gamma-picolinium chloride (MGPC)		Lot/Batch No.: MY140J01	
		Date of Manufacture: 05/28/24	
Package Configurations: Capped (Teflon Liner) Glass (Type III) Amber Bottles		Retest Date: 05/28/27	
		Expiry Date: TBD	
		Batch Size: 12000 g	
		Quantity Released: 9256.53 g	
Storage Conditions: Store at 15 – 30 °C		Date Released: 07/30/24	
Manufacturer: Dalton Pharma Services 349 Wildcat Road Toronto, Ontario M3J 2S3		External Testing Laboratories:  NucroTechnics 2000 Ellesmere Road, Unit 16 Scarborough, Ontario M1H 2W4	
Test and Method	Specification	Result	Testing Laboratory
Appearance TM-0091, R3 Photograph of sample to be attached	White, off-white to light brown powder	Off White Powder	Dalton Pharma Services
Identification – IR TM-0189, R7	Conforms to reference spectrum	Conforms to reference spectrum	Dalton Pharma Services
Identification – Chlorides USP-NF 2024 Issue 1, <191> Use 20 mg sample in 2 mL of water	Responds to identification test for chloride	Responds to identification test for chloride	Dalton Pharma Services
Water by KF TM-0057, R12 Use 100 – 250 mg sample size	NMT 10.0%	5.2 %	Dalton Pharma Services
Assay (as-is) TM-0407, R7	90 – 100%	95 %	Dalton Pharma Services
Assay (on anhydrous basis) TM-0407, R7	98.0 – 102.0 %	99.8 %	Dalton Pharma Services

ARF# 44188


TS-0002748-88-1AA-00, R17


Page 1 of 3

VA  
07/30/24  
MK  
07/30/24

Test and Method	Specification	Result	Testing Laboratory
Purity – HPLC TM-0405, R3	NLT 98%	100 %	Dalton Pharma Services
Related Substances by HPLC TM-0405, R3	Any Individual Impurities: NMT 0.5%	RRT: 0.79; Imp: 0.10 % RRT: 1.43; Imp: 0.05 %	Dalton Pharma Services
	Total Impurities: NMT 1.0%	0.15 %	
pH (0.1% aqueous solution) TM-0788, R3	3.5 – 7.0	6.6	Dalton Pharma Services
Residue on Ignition USP-NF 2024 Issue 1, <281>	NMT 0.2%	0.0 %	Dalton Pharma Services
Chloride Content (on anhydrous basis) TM-0276, R5	10.0 – 11.8 %	10.9 %	Dalton Pharma Services
Residual Solvents TM-0510, R1	Ethyl Acetate: NMT 5000 ppm	17 ppm	Dalton Pharma Services
	Acetone: NMT 5000 ppm	18 ppm	
Bacterial Endotoxins USP-NF 2024 Issue 1, <85> STL-018 R13	≤ 1 EU/mg	< 1 EU/mg	Dalton Pharma Services
Microbial Enumeration Tests, USP-NF 2024 Issue 1 <61> STL-027 R2	Total Aerobic Microbial Count: NMT 100 CFU/g	< 100 CFU/g	Dalton Pharma Services
	Total Combined Yeast/Molds Count: NMT 100 CFU/g	< 100 CFU/g	
Melting Point USP-NF 2024 Issue 1, <741>	≥ 45 °C	51 °C	NucroTechnics
Relative Solubility in water, USP-NF 2024 Issue 1, (Description and Relative Solubility)	Report results	Freely Soluble	Dalton Pharma Services
Elemental Impurities TM-0742, R3	Lithium: NMT 25 µg/g	< 12.7 µg/g	Dalton Pharma Services
	Vanadium: NMT 1 µg/g	< 0.5 µg/g	
	Cobalt: NMT 0.5 µg/g	< 0.2 µg/g	
	Nickel: NMT 2 µg/g	< 1.0 µg/g	
	Copper: NMT 30 µg/g	< 15.2 µg/g	
	Arsenic: NMT 1.5 µg/g	< 0.8 µg/g	
	Cadmium: NMT 0.2 µg/g	< 0.1 µg/g	
	Antimony: NMT 9 µg/g	< 4.5 µg/g	
	Mercury: NMT 0.3 µg/g	< 0.2 µg/g	
	Lead: NMT 0.5 µg/g	< 0.3 µg/g	

I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated/ manufactured, including packaging and quality control at the above mentioned site(s) in compliance with applicable cGMP requirements, specifications and/or Dalton/Customer cGMP Agreement obligations. The batch processing, packaging and analysis records were reviewed and found to be in compliance with cGMP.

 _____ <b>Viktoriya Gorbatkova, Quality Control Manager</b>	Date: 07/30/24
--	----------------

 _____ <b>Anna Kukshuk, Quality Assurance Supervisor</b>	Date: 07/30/24
---	----------------



Project code:

CA-0001

Official Name

MUCPC

RF# 44189

U MY140301

KRD

06/18/24

Reviewed  
HYZ

07/02/24

