trū® CHITOSAN

Certificate of Analysis

PHARMA-USP-NF

Lot #20825001

Test	Specification per USP	Result
FTIR Identity	Match Accepted Reference	PASS – Conforms
USP ID Testing	Gelatinous Mass	PASS
Tunable Properties		
Degree of Deacetylation	NLT 70.0% NMT 95.0%	PASS – 93.8%
Molecular Weight (kDa)	Report	~1,600 kDa by Inherent Viscosity*
Impurities		
Residue on Ignition	NMT 1.0%	PASS – 0.2%
Loss on Drying	NMT 5.0%	PASS – 4.2%
Residual Protein	NMT 0.2%	PASS – < LOD
Tropomyosin (Allergen) Content	NMT 1 ppm *	PASS – 0.2%
Heavy Metal		
Lead (Pb)	≤ 0.5 ppm	PASS – 0.0 ppm
Mercury (Hg)	≤ 0.2 ppm	PASS – 0.0 ppm
Chromium (Cr)	≤ 1.0 ppm	PASS – 0.2 ppm
Nickel (Ni)	≤ 1.0 ppm	PASS – 0.4 ppm
Cadmium (Cd)	≤ 0.2 ppm	PASS – 0.0 ppm
Arsenic (As)	≤ 0.5 ppm	PASS – 0.0 ppm
Iron (Fe)	≤ 10 ppm	PASS – 3 ppm
Biological Testing		
Endotoxins	NMT LOD	35.9 EU/mL 3588 EU/g
Aerobic Plate Count	≤ 2000 cfu/g	PASS
Mold & Yeast	≤ 200 cfu/g	PASS
Pseudomonas aeruginosa	Absent	PASS
Staphylococcus aureus	Absent	PASS
Physical Properties		
Appearance	Report*	White Powder
Appearance in Solution	Report*	Clear in 1% Acetic Acid
Solubility	Report*	< 1% Loading in 1% Acetic Acid

*non-USP testing

Manufactured on Aug 25, 2022
Made in South Carolina, USA

PARIMER SCIENTIFIC

NSF-ISR Registered to ISO 9001

Testing and Analysis Performed by Parimer Scientific
Retest after 3 years

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