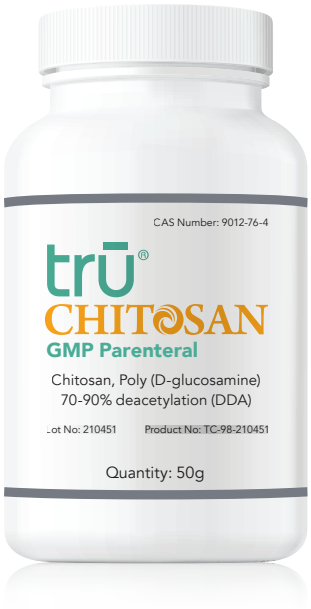
GMP Parenteral

USP-NF Monograph Referenced
USP 232 Cutaneous, Oral & Parenteral Conformance
Endotoxin Content > 2 < 10 EU/ml (> 200 < 1000 EU/g)
Complete Chain of Custody/Certificate of Origin
Spectrum of NMR DDA & GPC Measured Molecular Weight

trū Chitosan's GMP Parenteral is a chitosan for cutaneous medical device, pharmaceutical and medical device research and development, as well as veterinarian applications. trū Chitosan is extracted exclusively from shrimp exoskeleton raised in a captive, controlled environment free from pollution, disease, and antibiotics with an industry-first, complete chain of custody. trū Chitosan's GMP Parenteral delivers the unsurpassed quality and consistent behavior required for topical medical device production and parenteral research applications.



USP-NF Monograph & 232 Elemental Impurities–Limits; Drug Substance Impurities
The USP-NF Monograph and USP 232 are our respected guides to definition, analysis procedures, and impurity limits

cGMP Compliant
FDA inspected, current Good Manufacturing Practices guide production

Single Source Raw Material
Shrimp exoskeleton raw material from a single, captive, indoor, and controlled source

Consistent Behavior
Lot-to-lot consistency ensures predictable behavior for your medical application

FDA Registered Facility
Manufactured in an FDA registered and inspected facility with ISO 9001 Certification

Product of the USA
First and only producer of medical application chitosan in the United States

CHITOSAN MADE FROM A CONTROLLED SHRIMP PRODUCTION PROCESS.
Enabled by our captive breakthrough Tidal Basin® indoor aquaculture technology, our medical application chitosan is extracted and refined from pristine shrimp exoskeleton tissue with unprecedented quality and traceability. Our precisely controlled environment yields superior shrimp to produce superior chitosan that is low in endotoxins, heavy metals and other impurities making trū Chitosan the best choice for your production and research applications.

330 3rd Street | Balaton, MN 56115 | truchitosan.com

trū® CHITOSAN
an iterro® brand

trū® CHITOSAN

GMP Parenteral

Product	trū Chitosan GMP Parenteral
CAS number	9012-76-4
Product number	73310 >300 MWw
Product number	73320 >100 <300 MWw
USP-NF 197A	Forms a gelatinous mass
FTIR	Match reference
Color	White to slightly off-white
Appearance	Neat, micronized powder
Solubility	0.15% in acetic acid buffer
Appearance in solution	Clear in 1% acetic acid buffer

Characterization	GMP Parenteral	Typical Assay
Degree of Deacetylation (DDA %)	≥70% to ≤90%	Report
GPC weight avg. Mw (kDa)	≥85% to ≤115% Label	Report
GPC number avg. Mw (kDa)		Report
PDI		Report

METAL CONTENT (ppm)

Substance	USP-NF	GMP 232 Parenteral	Typical Assay
Lead (Pb)	≤0.50	≤0.50	0.03
Mercury (Hg)	≤0.20	≤0.30	0.00
Cadmium (Cd)	≤0.20	≤0.20	0.07
Arsenic (As)	≤0.50	≤1.50	0.10

Substance	USP-NF	GMP 232 Parenteral	Typical Assay
Nickel (Ni)	≤1.00	≤2.00	0.70
Chromium (Cr)	≤1.00	≤110.00	0.65
Iron (Fe)	≤10.0	n/a	1.68

IMPURITIES

Substance	USP-NF	Typical Assay
Loss on drying (Moisture)	≤5.00%	3.45%
Dry matter	≥95.00%	96.55%
Residue on ignition (Ash)	≤1.00%	0.32%

Substance	USP-NF	Typical Assay
Protein content	≤0.20%	<LOD
Allergen (Tropomyosin)	n/a	<1 ppm

BIOLOGICAL ENUMERATION

Substance	USP-NF	Specifications	Typical Assay
Endotoxin EU/ml	Dosage relevant	>2 <10	0.00
Endotoxin EU/g	Dosage relevant	>200 <1000	0.00
Aerobic plate count	$\leq 10^3$ cfu/g	Pass	0.00

Substance	USP-NF	Specifications	Typical Assay
Mold & yeast (cfu/g)	$\leq 10^2$ cfu/g	Pass	0.00
Pseudomonas aeruginosa	Absent	Absent	Absent
Staphylococcus aureus	Absent	Absent	Absent

Analysis certified by Parimer Scientific and external laboratories. Unique Certificates of Analysis (COA) and Certificates of Origin (COO) are included with each lot.

PARIMER SCIENTIFIC