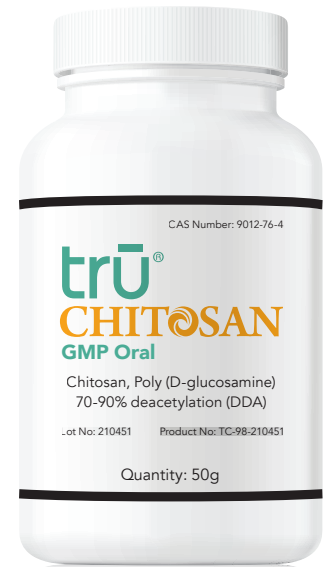


GMP Oral

USP-NF Monograph & USP 232 Referenced
USP 232 Cutaneous & Oral & Conformance
cGMP Compliant with Certificate of Analysis
Complete Chain of Custody/Certificate of Origin
Spectrum of NMR DDA & GPC Measured Molecular Weight

Every trū Chitosan lot is targeted to be our premier USP Inhalant or USP Parenteral chitosan. A slight miss of the USP-NF limits will disqualify it as USP. Still GMP, it is often superior to our competitors' best, making trū Chitosan's GMP Oral the leading chitosan for pharmaceutical and medical device research and development, exhibiting the same behavior as our USP-conforming chitosan. trū Chitosan is extracted exclusively from shrimp raised in a captive, controlled environment free from pollution, disease, and antibiotics with an industry-first, complete chain of custody. trū Chitosan's GMP Oral delivers the quality and consistent behavior required for pharmaceutical and medical device research.



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.

Product	tru Chitosan GMP Oral
CAS number	9012-76-4
Product number	73210 >300 MWw
Product number	73220 >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 Oral	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		8.38

METAL CONTENT (ppm)

Substance	USP-NF	GMP 232 Oral	Typical Assay
Lead (Pb)	≤0.50	≤0.50	0.03
Mercury (Hg)	≤0.20	≤3.00	0.00
Cadmium (Cd)	≤0.20	≤0.50	0.00
Arsenic (As)	≤0.50	≤1.50	0.00

Substance	USP-NF	GMP 232 Oral	Typical Assay
Nickel (Ni)	≤1.00	≤20.00	5.77
Chromium (Cr)	≤1.00	≤1100.00	2.07
Iron (Fe)	≤10.0	n/a	<1.00

IMPURITIES

Substance	USP-NF	Typical Assay
Loss on drying (Moisture)	≤5.00%	0.73%
Dry matter	≥95.00%	99.27%
Residue on ignition (Ash)	≤1.00%	0.17%

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

BIOLOGICAL ENUMERATION

Substance	USP-NF	Specifications	Typical Assay
Endotoxin EU/ml	Dosage relevant	>2 <10	0.02
Endotoxin EU/g	Dosage relevant	>200 <1000	0.04
Aerobic plate count	≤10 ³ cfu/g	Pass	0.00

Substance	USP-NF	Specifications	Typical Assay
Mold & yeast (cfu/g)	≤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.