

USP Inhalant Ultra

USP-NF Monograph Conformance

USP 232 Cutaneous, Oral, Parenteral, & Inhalant Conformance

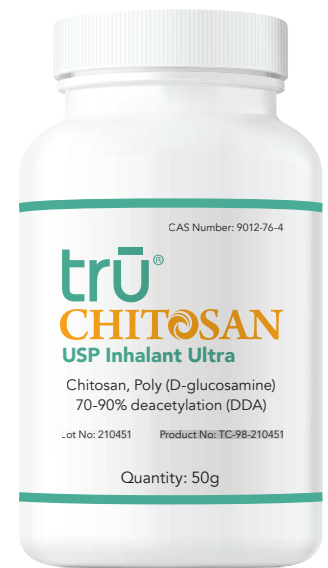
Undetectable Ubiquitous Metals (Pb, Hg, Cd, As)

Endotoxin Content ≤ 2 EU/ml (≤ 200 EU/g)

Chain of Custody/Certificate of Origin

Spectrum of NMR DDA & GPC Measured Molecular Weights

The world's finest medical application chitosan, trū Chitosan's USP Inhalant Ultra is the ultimate ultra-low endotoxin chitosan for cutaneous, oral, parenteral, and inhalant pharmaceutical delivery and internal medical device applications. trū Chitosan is extracted exclusively from shrimp exoskeleton raised in a captive, controlled environment free from pollution, disease, and antibiotics with industry-first, complete chain of custody. trū Chitosan's USP Inhalant Ultra delivers the unsurpassed quality and consistent behavior required for pharmaceutical and medical device production. Why would you risk using anything less?



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 USP Inhalant Ultra |
| CAS number | 9012-76-4 |
| Product number | 73810 >300 MWw |
| Product number | 73820 >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 | USP Inhalant Ultra | 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 | | 4.20 |

METAL CONTENT (ppm)

| Substance | USP-NF | USP 232 Inhalant | Typical Assay |
|--------------|--------|------------------|---------------|
| Lead (Pb) | ≤0.50 | ≤0.50 | 0.00 |
| Mercury (Hg) | ≤0.20 | ≤0.10 | 0.00 |
| Cadmium (Cd) | ≤0.20 | ≤0.20 | 0.00 |
| Arsenic (As) | ≤0.50 | ≤0.20 | 0.00 |

| Substance | USP-NF | USP 232 Inhalant | Typical Assay |
|---------------|--------|------------------|---------------|
| Nickel (Ni) | ≤1.00 | ≤0.60 | 0.41 |
| Chromium (Cr) | ≤1.00 | ≤0.30 | 0.03 |
| Iron (Fe) | ≤10.0 | n/a | 1.33 |

IMPURITIES

| Substance | USP-NF | Typical Assay |
|---------------------------|---------|---------------|
| Loss on drying (Moisture) | ≤5.00% | 2.54% |
| Dry matter | ≥95.00% | 96.38% |
| Residue on ignition (Ash) | ≤1.00% | 0.33% |

| 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 | <160 |
| Endotoxin EU/g | Dosage relevant | <200 | <160 |
| 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.