

	Test Methodology	USP Monograph	tru Chitosan Product Number						
			73101	73102	73103	73201	73202	73203	
"Tunable" Properties									
DDA	%	USP NMR	≥70 to ≤95	≥90 to ≤95	≥90 to ≤95	≥90 to ≤95	≥85 to ≤90	≥85 to ≤90	≥85 to ≤90
Molecular Weight (Mw)	kDa	USP	Tunable	≥750	150-300	10-50	≥750	150-300	10-50
Viscosity	mPas	CALC	Tunable	>2750	151-350	≤7	>2750	151-350	≤7
Impurities									
Moisture	%	USP 731	≤ 5.0	≤ 5.0	≤ 5.0	≤ 5.0	≤ 5.0	≤ 5.0	≤ 5.0
Ash	%	USP 281	≤ 1.00	≤ 1.00	≤ 1.00	≤ 1.00	≤ 1.00	≤ 1.00	≤ 1.00
Protein	%	USP	≤ 0.20	≤ 0.20	≤ 0.20	≤ 0.20	≤ 0.20	≤ 0.20	≤ 0.20
Metals									
Lead (Pb)	ppm	USP Method III (231)	≤ 0.50	≤ 0.50	≤ 0.50	≤ 0.50	≤ 0.50	≤ 0.50	≤ 0.50
Mercury (Hg)	ppm	USP Method III (231)	≤ 0.20	≤ 0.20	≤ 0.20	≤ 0.20	≤ 0.20	≤ 0.20	≤ 0.20
Chromium (Cr)	ppm	USP Method III (231)	≤ 1.00	≤ 1.00	≤ 1.00	≤ 1.00	≤ 1.00	≤ 1.00	≤ 1.00
Nickel (Ni)	ppm	USP Method III (231)	≤ 1.00	≤ 1.00	≤ 1.00	≤ 1.00	≤ 1.00	≤ 1.00	≤ 1.00
Cadmium (Cd)	ppm	USP Method III (231)	≤ 0.20	≤ 0.20	≤ 0.20	≤ 0.20	≤ 0.20	≤ 0.20	≤ 0.20
Arsenic (As)	ppm	USP Method III (231)	≤ 0.50	≤ 0.50	≤ 0.50	≤ 0.50	≤ 0.50	≤ 0.50	≤ 0.50
Iron (Fe)	ppm	USP Method III (231)	≤ 10.00	≤ 10.00	≤ 10.00	≤ 10.00	≤ 10.00	≤ 10.00	≤ 10.00
Microbial Enumeration									
Endotoxins	eu/100mg	USP 85	Dosing	Dosing	Dosing	Dosing	Dosing	Dosing	Dosing
Aerobic Plate Count	cfu/g	USP 61	≤ 1000	≤ 1000	≤ 1000	≤ 1000	≤ 1000	≤ 1000	≤ 1000
Mold & Yeast	cfu/g	USP 61	≤ 100	≤ 100	≤ 100	≤ 100	≤ 100	≤ 100	≤ 100
<i>Pseudomonas aeruginosa</i>		USP 62	absent	absent	absent	absent	absent	absent	absent
<i>Staphylococcus aureus</i>		USP 62	absent	absent	absent	absent	absent	absent	absent
Identification									
		FTIR	Comparable to standard	Yes	Yes	Yes	Yes	Yes	Yes
		USP Identification Method B	Forms a gelatin mass	Yes	Yes	Yes	Yes	Yes	Yes

Properties

Grade	Pharmaceutical, Medical Device, ISO 9001 (Certificate C0497865-IS)
Manufacturer/Trade Name	tru Chitosan, a Division of The tru Shrimp Companies, Inc., Balaton, Minnesota USA
Source / Origin	Crustacean / USA Produced Shrimp, Exoskeleton Raw Material, and Final Product
FDA Registration #	3014735278 (Parimer Scientific, Easley, South Carolina USA)
South Carolina Board of Pharmacy	19735 (Parimer Scientific), Easley, South Carolina, USA
Applications	Pharmaceutical (small molecule), Medical Device
Format	Neat, Micronized Powder (1 to 600 micrometers particle size)
Appearance	White or slightly off-white
Recommended Storage Temp	15-25 °C (59-77 °F)