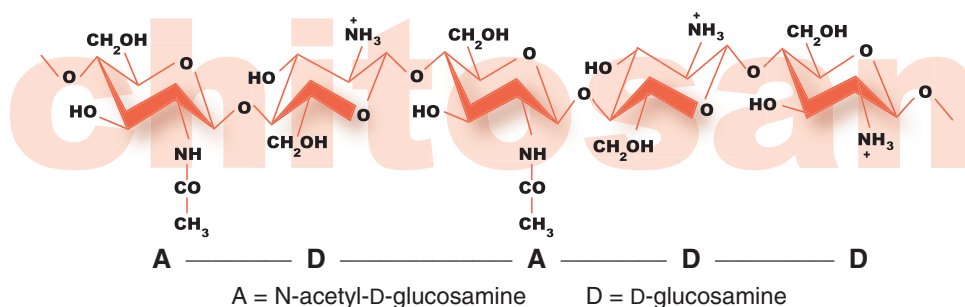


Chitosan

Chitosan is a biopolymer with a wide range of biomedical applications, including wound healing, tissue engineering and tissue repair, and local delivery of cells, drugs, proteins, genes, and other therapeutics. Currently, nasal drug delivery technology using chitosan to speed the absorption of the API shows great potential, with several applications in clinical trials. Non-viral gene delivery systems using chitosan as a carrier are also the subject of intense research activity.



Chitosan is a linear polysaccharide composed of randomly distributed β -(1 \rightarrow 4)-linked D-glucosamine (deacetylated unit; D) and N-acetyl-D-glucosamine (acetylated unit; A).

Chitosan is produced commercially by deacetylation of chitin, which is the structural element in the exoskeleton of crustaceans (crabs, shrimps, etc.). The degree of deacetylation (%DA) can be determined by NMR spectroscopy. Variation in the %DA can lead to varying functionality of chitosans in different applications.

PROTASAN™ UP Chitosan Chloride and Chitosan Glutamate Salts are readily soluble in water. The viscosity of a chitosan solution primarily depends on the average molecular weight of the polymer, which can be determined by size exclusion chromatography combined with light scattering detection. The amino group in chitosan has a pKa value of ~6.5, while the charge density is dependent upon the solution pH and the degree of chitosan deacetylation. As a positively charged biopolymer, chitosan is bioadhesive and readily binds to negatively charged surfaces such as mucosal membranes. Chitosan enhances the transport of polar drugs across epithelial surfaces, and is biocompatible and biodegradable.

Quality

PROTASAN™ UP Chitosans from NovaMatrix® are a series of ultrapurified and well-characterized water-soluble Chitosan Chloride and Glutamate Salts. There are different viscosities and %DA values developed for use in biomedical and pharmaceutical applications.

PROTASAN™ UP Chitosan Salts are manufactured and documented in compliance with GMP guidelines; ICH Q7; and ISO standards: ISO 9001:2008, ISO 13485:2003 and ISO 22442:2007.

PROTASAN™ UP Chitosan Chloride meets the standards set forth in the European Pharmacopoeia (EP 1774). PROTASAN™ UP Chitosan products satisfy ASTM F 2103 for use in tissue engineered medical products (TEMPs). The products are characterized by specified parameters reflecting the key properties and purity profile of the material. Process and final quality control are based on validated methods of analysis. Safety and toxicology data covering the chitosan salts are reported in a Drug Master File submitted to the U.S. FDA.

CHITOSAN Product Range:

The ultrapure chitosan (endotoxins ≤ 100 EU/gram) are marketed under the trade name PROTASAN™. Different viscosity (molecular weight) and degree of deacetylation ranges are available. The range of water soluble PROTASAN™ UP Chitosan Salts (chloride and glutamate) is shown below. PROTASAN™ UP products are also available for purchase in a PROTASAN™ UP Test Kit.

Ultrapure PROTASAN™ Chitosan Salts (Chloride and Glutamate)

Product	Viscosity [mPa·s]	Appr. M _w [kDa]	DA [%]	Endotoxins [EU/g]	Total viable count [cfu/g]
PROTASAN UP CL 113	< 20	< 200	75-90	≤ 100	≤ 200
PROTASAN UP CL 114	< 20	< 200	>90	≤ 100	≤ 200
PROTASAN UP CL 213	20-200	150-400	75-90	≤ 100	≤ 200
PROTASAN UP CL 214	20-200	150-400	>90	≤ 100	≤ 200
PROTASAN UP G 113	< 20	< 200	75-90	≤ 100	≤ 200
PROTASAN UP G 213	20-200	200-600	75-90	≤ 100	≤ 200
PROTASAN UP G 214	20-200	200-600	>90	≤ 100	≤ 200

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