

SOLBIOTE™

Bringing Sustainable Solutions to Biopharmaceuticals

Nagase Viita, the first company in the world to mass produce Trehalose, offers solutions for biopharmaceutical development through our signature brand of SOLBIOTE™. It features high-purity, low-endotoxin Trehalose (TREHALOSE SG) and Maltose (MALTOSE PH) saccharide based pharmaceutical excipients. We confidently offers a stable supply of SOLBIOTE™ as an integrated manufacturer of the Trehalose and Maltose, guaranteeing exceptional quality.



Achieving Equitable Well-Being for All

SOLBIOTE™ Commitment:

- Stability solutions
- Exceptional quality
- Sustainable manufacturing and stable supply

Stability Solutions:

- SOLBIOTE™ is an excellent protein stabilizer
- Protects cells, nucleotides, and exosomes against damage from drying, freezing, and thawing
- Preserves the quality of antibody therapeutics and vaccines during storage and distribution



Exceptional quality:

- High-purity and low-endotoxin
- Complies with the global regulatory requirements of the pharmaceutical industry
- Achieve superior quality with our extensive knowledge and expertise in saccharide production

TREHALOSE SG

- Highly purified trehalose dihydrate crystalline with a low endotoxin specification
- Does not participate in the Maillard reaction
- Remarkable heat and acid resistance
- High in glass transition temperature (T_g , T'_g)

MALTOSE PH

- Highly purified maltose monohydrate crystalline with a low endotoxin specification
- Good water solubility
- Compatible with oils

Applications

- Stabilization of antibodies, peptides, and vaccines for injection
- Stabilization of exosomes
- Additive for culture medium (e.g. stem cells)
- Preservation of platelets

Applications

- Active ingredient for infusion fluid
- Solubility enhancer and stabilizer of freeze-dried anti-cancer agents for injection
- Stabilizer of Immunoglobulins
- Carbon source of culture medium

Grade		Injection Grade	
Product Name		TREHALOSE SG	MALTOSE PH
Purity		≥99.0% (Trehalose)	≥98.0% (Maltose)
Endotoxin		<0.3 EU/g	<0.6 EU/g
Regulatory Approval	JP	✓	✓
	USP-NF	✓	
	Ph. Eur.	✓	
	CP	✓	✓
	US DMF	Type IV	Type II
	China DMF	F20170000105 (A)	F20200000041 (I)
Other	Kosher	✓	✓
	Halal	✓	✓

Sustainable manufacturing and stable supply:

- Utilize starch and enzymes derived from soil microorganisms
- Trehalose dihydrate crystalline and maltose monohydrate crystalline are highly purified with a low endotoxin specification
- No solvents listed in ICH Q3C Class 1, 2 or 3 are used through manufacturing processes
- Our integrated manufacturing process ensures exceptional quality control and a stable supply by overseeing the procurement of raw materials, to saccharide production and purification in our factory in Japan.

Procurement of raw materials and resources



Our commitment to responsible procurement ensures raw materials (e.g. starch) are obtained without deforestation or human rights violations.

Environmentally friendly saccharide production



Utilizing starch and enzymes, Trehalose and Maltose are produced efficiently through strategic inventory management and manufacturing planning; minimize waste and CO₂ emissions, and preserve water resources.

Purification and recrystallization



Process of purification and recrystallization to produce highly purified Trehalose and Maltose with a low endotoxin specification.



For our dedication to sustainable manufacturing, human rights, and procurement, we have been awarded a Platinum rating by EcoVadis, a sustainability survey organization in France covering over 180 countries. Platinum is the highest rank, given to the top 1% of over 130,000 companies assessed. We sincerely continue to commit sustainability and social responsibilities towards a better future of the people and the Earth.

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