Low Endotoxin Trehalose

Compliant to EP, USP/NF, JP

Advantages:

Trehalose is a non-reducing disaccharide consisting of two molecules linked by an α, α-1, 1 bond. There are several properties of trehalose that make it an excellent stabilizer in biopharmaceutical formulations. In particular, trehalose is used to stabilize protein-based pharmaceuticals, such as monoclonal antibodies in injectables and other protein molecules that are often degraded by freezing, lyophilization and storage for long periods.

VIO Chemicals offers high quality low endotoxin and GMO-free Trehalose dihydrate and Trehalose anhydrous, for pharmaceutical and cosmetic applications, in a very competitive price.

Features:

Trehalose demonstrates exceptional stability. It is not easily hydrolyzed by acid and the glycosidic bond is not cleaved by α-glycosidase. Trehalose is typically found in the dihydrate form and is characterized by its low hygroscopicity. The water content of the dihydrate crystal remains stable at approximatively 9.5% during exposure to relative humidity up to 92%. During various desiccation processes, including freeze drying and spray drying, trehalose readily dries as an amorphous material with high glass transition temperature (T_g > 100°C), the highest of the disaccharides. Compared to sucrose, Trehalose's Tg is about 3°C higher. This important physicochemical property is relevant for shortening drying times dramatically.

Benefits:

The stabilising benefits of trehalose include but are not limited to:

- Monoclonal antibodies (mAbs)
- Fusion proteins
- Antibody fragments (fAbs)
- Peptides
- Stem cells
- Vaccines

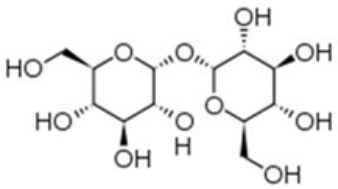
Applications:

Trehalose is contained in several commercially available therapeutic products, including Herceptin®, Avastin®, Lucentis® and Advate®.

Technical profile:

- Technical name: α,α-D-Trehalose dihydrate
- CAS No: 6138-23-4
- Empirical formula: $C_{12}H_{22}O_{11} * 2H_2O$
- Molecular weight: 342.3 + 36.0

Chemical structure:



Compliance: EP, USP/NF, JP

Test	Specification
Identity	IR: Corresponds to CRS spectrum
Appearance	White to almost white, crystalline powder
Specific optical rotation $[\alpha]_D^{20}$	+197° to +201°(10%$_{w/v}$ in H_2O)
Purity (HPLC)	min. 99.0%
Impurity A (HPLC): (+)-D-Glucopyranose (Glucose)	max. 0.5%
Impurity B (HPLC): Oligosaccharides	max. 0.5%
Each unspecified Impurity	max. 0.2%
Total impurities	max. 1.0%
Water content (KF)	9.0% -11.0%
Sulphated ash	max. 0.1%
Chlorides	max. 125 ppm
Sulfates	max. 200 ppm
Heavy metals (Ph. Eur.)	max. 5.0 ppm
Lead (Pb)	max. 1.0 ppm
Arsenic (As)	max. 0.5 ppm (XRF)
Iron (Fe)	max. 3.0 ppm (Ph. Eur.)
Copper (Cu)	max. 3.0 ppm (XRF)
Mercury (Hg)	max. 0.1 ppm (XRF or AAS)
Total nitrogen	max. 0.005%
Soluble starch	negative in 1 g
Fehling test	max. 0.1% Cu_2O
pH	4.5 to 6.5 (10%$_{w/v}$ in H_2O)
Residual solvent	Ethanol max. 5000 ppm
Bioburden	total viable counts: 100 CFU/g Yeast: max. 10 CFU/g Staphylococcus aureus, Salmonella, E. coli and Pseudomonas aeruginosa: negative in 1 g
Endotoxins	max. 2.5 IU/g
Storage conditions	15°C to 25°C
Shelf life	2 years from date of manufacture

VIO Chemicals AG
Dufourstrasse 107
CH-8008 Zurich
Switzerland
www.viochemicals.com
@VIOChemicals
/VIO Chemicals

For inquiries contact us on **+41 44 380 24 44** or send us an e-mail at **info@viochem.com**