

## Low endotoxin Trehalose Compliant to EP, USP/NF, JP

### ADVANTAGES

Trehalose is a non-reducing disaccharide consisting of two molecules linked by an  $\alpha$ ,  $\alpha$ -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, at competitive prices.

### FEATURES

Trehalose demonstrates exceptional stability. It is not easily hydrolyzed by acid and the glycosidic bond is not cleaved by  $\alpha$ -glycosidase. Trehalose is typically found in the dihydrate form and it is characterized by its low hygroscopicity. The water content of the dihydrate crystal remains stable at approximately 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 ( $T_g > 100^\circ\text{C}$ ), the highest of the disaccharides. Compared to sucrose, Trehalose  $T_g$  is about  $3^\circ\text{C}$  higher. This important physicochemical property is relevant for shortening drying times dramatically.

### BENEFITS

The stabilizing benefits of Trehalose include but are not limited to:

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

### APPLICATIONS

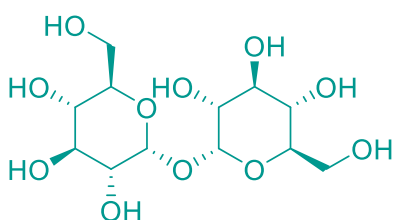
Trehalose is contained in several commercially available therapeutic products, including Herceptin®, Avastin®, Lucentis® and Advate®.



### TECHNICAL PROFILE

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

### CHEMICAL STRUCTURE



### COMPLIANCE

EP, USP/NF, JP

TEST	SPECIFICATION
Identification	IR: Corresponds to CRS spectrum
Appearance	White to almost white, crystalline powder
Specific optical rotation $[\alpha]_D^{20}$	+197° to +201° (10% <sub>w/v</sub> in H <sub>2</sub> O)
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 <sub>2</sub> O
pH	4.5 to 6.5 (10% <sub>w/v</sub> in H <sub>2</sub> O)
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

Products which are subject to patent protection are currently not offered or made available in countries where patents are in force. No orders or deliveries are possible prior to the expiry date of valid patents.

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