

BioHale[®] Trehalose Dihydrate

Expanding excipient excellence
to Biopharma



With **BioHale[®] Trehalose Dihydrate** we offer the highest purity excipient for the stabilization of biologics to be used in biopharmaceutical formulation. BioHale[®] Trehalose Dihydrate is a disaccharide formed by a 1,1 linkage of two d-glucose molecules. It is a non-reducing sugar that is not easily hydrolyzed by acid, and the glycosidic bond is not cleaved by α -glucosidase.

BioHale[®] Trehalose Dihydrate is suitable in formulations for inhalation or ophthalmic application. In particular, it is commonly used for the lyoprotection of therapeutic proteins, especially for parenteral administration. Other applications include use as stabilizing agent during the freeze-thaw and lyophilization of liposomes; and for stabilization of blood cells as well as monoclonal antibodies.

Beyond our excipient portfolio, customers benefit from our technical solutions and regulatory support to unlock their competitive advantage. Our BioHale[®] excipients comply with the global regulatory requirements of the pharmaceutical industry (Ph. Eur., USP-NF, JP, ChP) and hold a Chinese Drug Master File (cDMF).

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BioHale® Trehalose Dihydrate

Benefits

Stabilizing agent

BioHale® Trehalose Dihydrate is a non-reducing sugar and does not react with amino acids or proteins, inhibiting the Maillard reaction. It is relatively stable under low-pH conditions compared to other disaccharides.

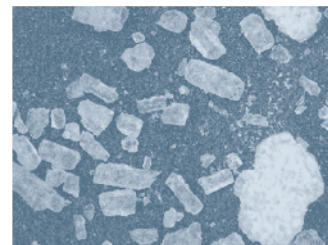
There are two theories for the stabilisation of biologics by Trehalose Dihydrate: The vitrification theory (kinetic stability) and the water replacement theory (thermodynamic stability). The vitrification theory refers to immobilisation of biologics in a matrix of an amorphous Trehalose Dihydrate, whereas the water replacement theory refers

to the formation of hydrogen bonds between the hydroxyl group of the Trehalose and the polar groups of the biologic drug.

Cryo- and lyoprotectant

One of the key reasons why Trehalose is such an important bioprotectant is due to the existence of a number of polymorphs, both in the crystalline as well as amorphous states.

Given these extraordinary properties, BioHale® Trehalose Dihydrate is transformational in the stabilization process of today's biologics.



Facts

Product data

- Description: White, or almost white, crystals or crystalline powder
- Molecular Formula: $C_{12}H_{22}O_{11} \cdot 2H_2O$
- Molecular Weight: 378.33 g/mol
- CAS Number: 6138-23-4
- T_g : $-107^\circ C$

Product specification

Endotoxin	≤ 0.30 EU/g
Heavy Metals	≤ 5 ppm
Elemental Impurities	Complies with ICH Q3D
Total Impurities	$\leq 0.5\%$ (for RRT<1.0) and $\leq 0.5\%$ (for RRT>1.0)
Reducing sugars	$\leq 0.1\%$

Quality

- High purity, low endotoxin grade
- Manufactured in The Netherlands
- FDA audited and state-of-the-art cGMP facility
- Multi-compendial quality, complies with Ph. Eur., USP-NF, JP, ChP
- Chinese DMF available

Packaging sizes

- 1kg (HDPE container) with PE inner liner
- 20kg (HDPE drum) with PE inner liner

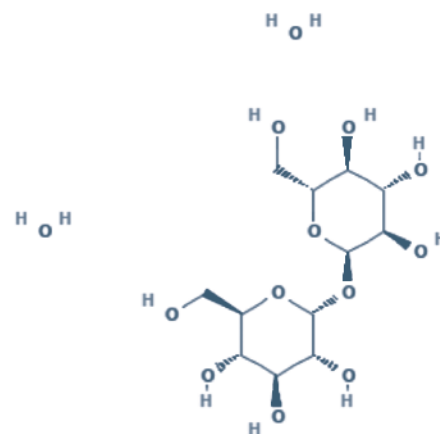


Figure 1: Structural formula of Trehalose Dihydrate

The combination of the molecular structure and physico-chemical properties of Trehalose result in a very stable disaccharide.