



DFE
pharma

BioHale[®]

Trehalose Dihydrate

Because stability matters

With BioHale[®] Trehalose Dihydrate we offer the highest purity excipient for the stabilization of biological molecules in biopharmaceutical formulations.

BioHale[®] Trehalose Dihydrate is a disaccharide formed by a 1,1-glycosidic bond between two α -glucose units. It is a non-reducing sugar that is not easily hydrolyzed by acid.

BioHale[®] Trehalose Dihydrate is well suited to provide solution-state stabilization, as well as cryo- and lyo-protection for biomolecules to use in parenteral, inhalation and ophthalmic applications.

Our BioHale[®] promises

- Uncompromised quality
- Security of supply
- Expert support



Ask an

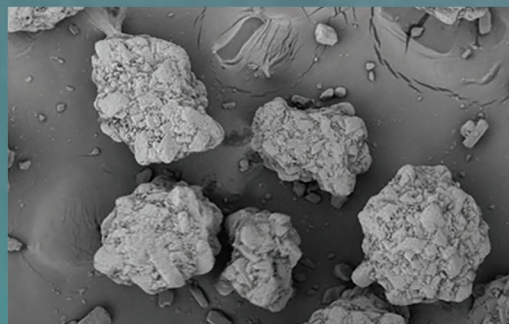


EXPERT

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BioHale®

Trehalose Dihydrate



Benefits

Stabilizing agent

BioHale® Trehalose Dihydrate is a non-reducing sugar and as such does not facilitate the Maillard reaction; therefore offers improved compatibility with amino acids and proteins compared to a reducing sugar. BioHale® Trehalose provides solution-state stabilization to fragile biomolecules. It is relatively stable under low-pH conditions compared to other disaccharides.

Cryo- and lyoprotectant

BioHale® Trehalose Dihydrate can play an important role in protecting your biologic from the freeze and dehydration stresses that occur during lyophilization. Additionally once in the lyophilized form the high glass transition temperature of BioHale® Trehalose Dihydrate can help maintain a glassy matrix and prevent re-crystallization.

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
- Tg: $\sim 107^{\circ}C$

Product specification

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

Quality

- High purity, low endotoxin grade produced by active purification process
- Manufactured in The Netherlands, Europe
- FDA inspected and state-of-the-art cGMP facility
- Multi-compendial specification 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

