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.

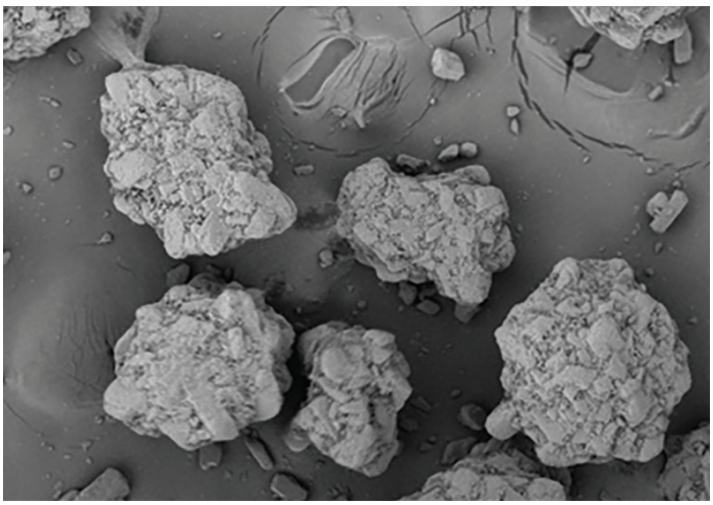
BioHale Trehalose Dihydrate is well suited to provide solution-state stabilization, as well as cryo- and lyo-protection for biomolecules to use in parenteral, inhalation and ophthalmic applications.

Stabilizing agent

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



The combination of the molecular structure and physico-chemical properties of Trehalose Dihydrate provides stability to fragile biomolecules in aqueous solutions and during lyophilization.

Product Information

- 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: ~107°C

Product Specifications

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

Chemical Type	Chemical Name	CAS No.	Catalog No.	Size
Sugar	BioHale Trehalose Dihydrate USP-NF, EP, JP, ChP, Low Endotoxin	6138-23-4	1181599	20 KG

DFE pharma

Uncompromised Quality and Security of Supply

BioHale high purity and low endotoxin excipients from DFE Pharma facilitate the stabilization of biomolecules, reducing the loss of activity and improving efficacy.

- Multi-compendial specifications compliant with USP-NF, JP, ChP monographs
- Produced in state-of-the-art, FDA-inspected manufacturing facilities in accordance with ICH Q7, which provides cGMP guidance for the manufacturing of APIs
- Active purification steps ensure excipients are independent of raw material variation
- Proven track record of delivery with production capacity in full control of process

spectrum® CHEMICAL MFG CORP

SCAN ME

Shop now at SpectrumChemical.com/BioHale

L0142_01