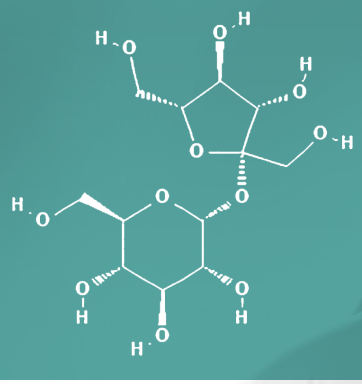


BioHale® Sucrose

Because Stability Matters

With BioHale Sucrose we offer the highest purity excipient for the stabilization of biological molecules in biopharmaceutical formulations.

BioHale Sucrose is a non-reducing crystalline disaccharide made up of glucose and fructose.

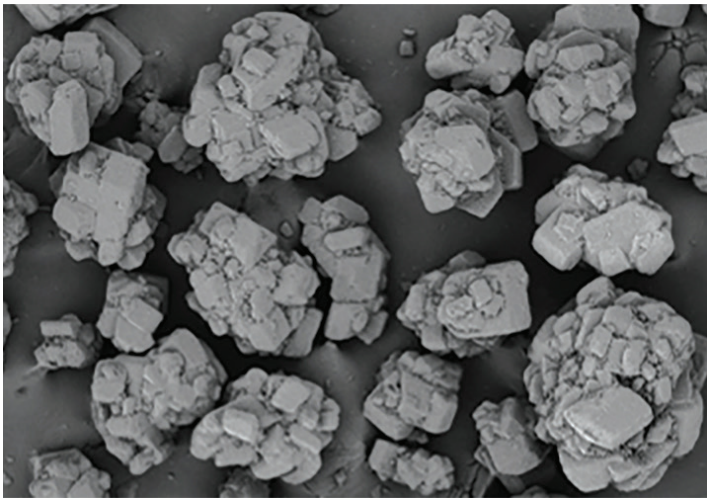
BioHale Sucrose is well suited to provide solution-state stabilization, as well as cryo and lyo-protection for biomolecules to be used in various administration forms including parenteral or ophthalmic.

Stabilizing agent

BioHale Sucrose is a non-reducing sugar and does not react with amino acids or proteins, inhibiting the Maillard reaction. BioHale Sucrose provides solution-state stabilization to fragile biomolecules.

Cryo- and lyoprotectant

BioHale Sucrose, a high purity disaccharide excipient, protects the biologic drugs from the freeze related (cryoprotectant) and drying related (lyoprotectant) stresses. This makes BioHale Sucrose particularly suitable in the stabilization process of today's biologics.



The utility and function of BioHale Sucrose are driven by its unique chemical and physical properties, especially in aqueous solutions. It provides tonicity, stabilization, cryo-preservation and protection during lyophilization.

BioHale is a registered trademark of DFE Pharma.

Product Information

- Description: White, or almost white, crystalline powder, or lustrous, colorless or white, or almost white, crystals
- Source: Plant derived, isolated from sugar beet
- Molecular Formula: $C_{12}H_{22}O_{11}$
  Molecular Weight: 342.30 g/mol
- CAS Number: 57-50-1
- Tg: ~61°C

Product Specifications

Endotoxin: . . . . . ≤ 0.25 EU/g
Heavy Metals: . . . . . ≤ 5 ppm
Elemental Impurities: . . . . . Complies with ICH Q3D
Total Impurities: . . . . . ≤ 2.0%
Reducing Sugars: . . . . . ≤ 0.07%

Chemical Type	Chemical Name	CAS No.	Catalog No.	Size
Sugar	BioHale Sucrose (Beet-Derived) USP-NF, EP, JP, ChP, Low Endotoxin	57-50-1	1178771	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