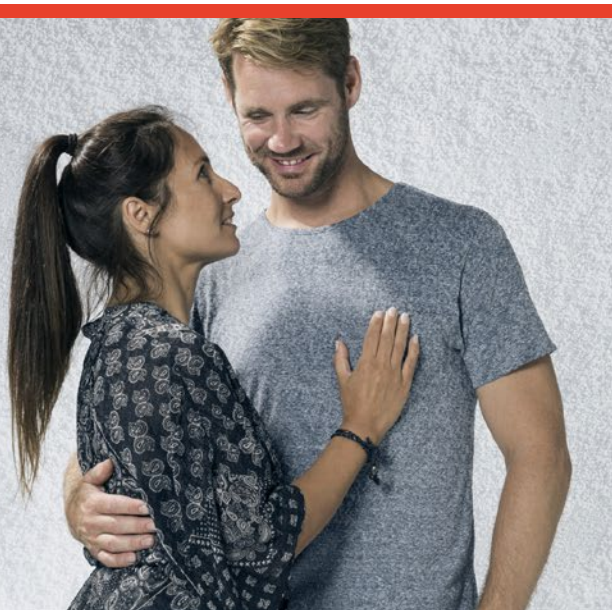
DFE pharma

BioHale® **Sucrose**

Expanding excipient
excellence to Biopharma



With **BioHale® Sucrose** we offer the highest purity excipient for the stabilization of biologics to be used in biopharmaceutical formulation. BioHale® Sucrose is a non-reducing crystalline disaccharide made up of glucose and fructose. Commonly used in the pharmaceutical industry as a stabilizer, Sucrose can be also widely used as a cryopreservative and media supplement in a variety of cell-based bioprocesses. Additionally, BioHale® Sucrose is preferred in applications where solubility or viscosity issues are of supreme importance.

BioHale® Sucrose is well suited to provide solution-state stabilisation, as well as cryo- and lyo-protection for therapeutic proteins as excipients in the formulations. Sucrose can generally be considered as suitable in most cases, unless constrained by a low-pH formulation. BioHale® Sucrose can be used in various administration forms, such as for parenteral, oral or ophthalmic route.

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).

ASK AN EXPERT
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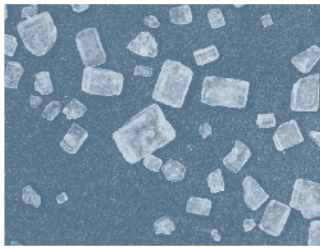
BioHale® **Sucrose**



Benefits

Stabilizing agent

BioHale® Sucrose is a non-reducing sugar and does not react with amino acids or proteins, inhibiting the Maillard reaction. The high stabilization effect of Sucrose is mainly attributed to two theories: The vitrification theory (kinetic stability) and the water replacement theory (thermodynamic stability). The vitrification theory refers to immobilisation of biologics in a matrix of amorphous Sucrose, whereas the water replacement theory refers to the formation of hydrogen bonds between the hydroxyl group of the Sucrose and the polar groups of the biologic drug.

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.

Facts

Product data

- 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: C12H22O11
- Molecular Weight: 342.30 g/mol
- CAS Number: 57-50-1
- T_g: ~61°C

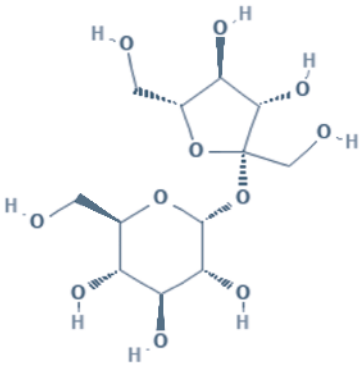


Figure 1: Structural formula of Sucrose
The utility and function are driven by its unique chemical and physical properties, especially in aqueous solutions. It provides tonicity, stabilisation, cryo-preservation and protection during lyophilisation.

Product specification

Endotoxin	≤ 0.25 EU/g
Heavy Metals	≤ 5 ppm
Elemental Impurities	Complies with ICH Q_3D
Total Impurities	≤ 2.0%
Reducing sugars	≤ 0.07%

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 (HPDE drum) with PE inner liner

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