



DFE
pharma

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, such as for parenteral or ophthalmic.

Our BioHale[®] promises

- Uncompromised quality
- Security of supply
- Expert support

Ask an

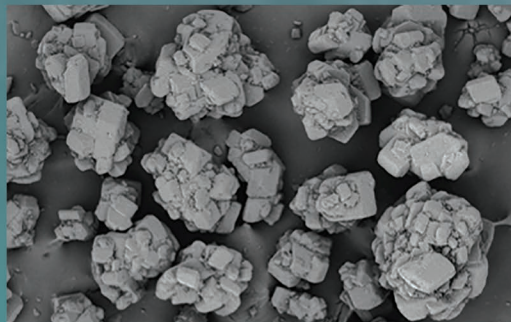


EXPERT

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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. 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.

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

Product specification

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

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

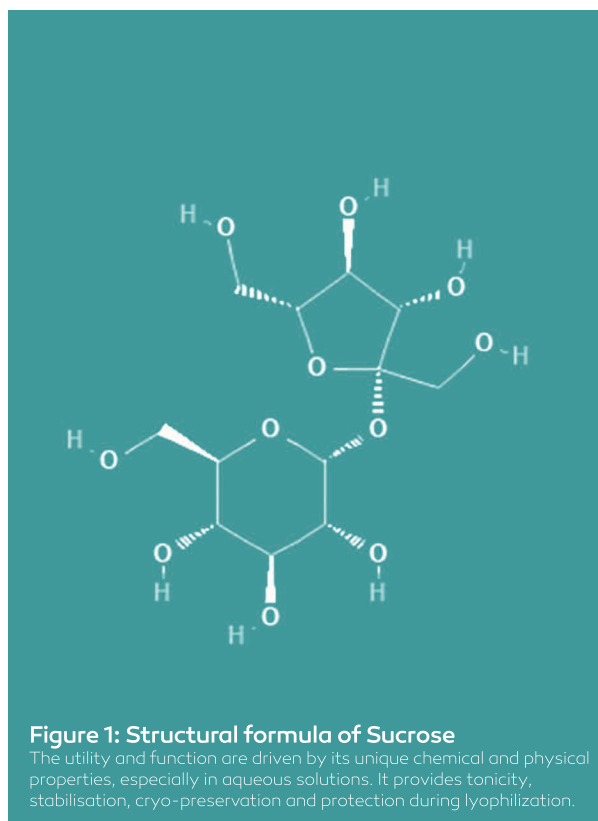


Figure 1: Structural formula of Sucrose

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 lyophilization.