

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).

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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

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
- 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

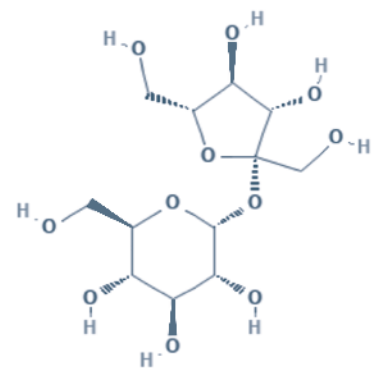


Figure 1: Structural formula of Sucrose

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.

YOUR EXCIPIENTS FOR BIOLOGICS



As a leader in the field of excipients, DFE Pharma offers pharmaceutical industry the most optimal solution for the development of their drug. Being a partner for pharmaceutical companies since many decades, DFE Pharma provides a wide range of functional excipients for oral solid dose, inhalation and biopharmaceutical applications. Together we contribute to the development of efficacious medicine by broadening our excipient excellence to biopharma.

We are DFE Pharma

We are DFE Pharma: the global leader in excipient solutions.

We develop, produce and supply functional excipients for use in biopharmaceutical, inhalation and oral solid dose formulations, but as a supplier of complete solutions we do a lot more than that.

We work closely with pharmaceutical companies around the world, collaborating in original research, supporting their go to market strategies and fine-tuning our products to ensure that their medicines deliver exactly the right outcomes for patients. That makes us more than just a supplier. We are recognized as a true partner to the pharmaceutical industry in helping people around the world live healthier lives.

We have spent more than 100 years in proving that excellence is not just a word but a deep, long-term commitment to our customers and to the millions of patients who use our products every day.

Our customers respect us for product quality, technical expertise and hands-on market support. We work with your future in mind: today, tomorrow and always.

Our portfolio consists of filler/binders (Lactose, Microcrystalline Cellulose and Starches) and superdisintegrants (Croscarmellose Sodium and Sodium Starch Glycolate) for oral solid dose, carriers for inhalation (Lactose) and excipients for biologics (non-reducing sugars).

DFE Pharma, in pursuit of excipient excellence.

Your excipients for biologics

by DFE Pharma

Recent developments in the field of biologics provide unique therapy options for many of the world's most challenging diseases. Biologics offer distinct advantages over small molecules, however are far more complex to develop and manufacture. To collaborate with a reliable excipient partner is crucial to de-risk the formulation challenges as well as development timelines. As a trusted solution provider and development partner, we are committed to support our customers in the formulation process for efficacious delivery of biologics.

Enabling your success with our unique center of excellence

With BioHale®, our new excipient portfolio for biologics, we offer the highest purity excipients to be used in formulation. Beyond our portfolio, customers benefit from our technical solutions. We help our customers to choose the right excipients for stabilization of biologics. In addition, DFE Pharma also ensures a robust supply chain and security in supply to unlock your competitive advantage.



Uncompromised quality with BioHale®

By making use of the best available technologies in state-of-the-art cGMP manufacturing, DFE Pharma ensures highest purity of excipients. Our excipients comply with the global regulatory requirements of the pharmaceutical industry (Ph. Eur., USP-NF, JP, ChP). The BioHale® portfolio consists of a range of non-reducing sugars enabling stable formulations.

Supply Chain security

Valued as a true excipient partner, DFE Pharma is uniquely positioned

in its ability to deliver the best-in-class excipients across the various dosage forms such as for oral solid, inhalation or parenteral application – a comprehensive excipient portfolio available for your convenience. Customers trust us for our long history of providing reliable security of supply.

Technical solution provider

In addition to serving product and service excellence, DFE Pharma provides the full benefits of profound technical know-how and application knowledge for our customers. We are highly rated by

our customers for our technical expertise and formulation support. With the combination of the right BioHale® excipients, we support you to create biological medicine allowing fast time-to-market for your products.

Together we can create best solutions for your therapeutic actives in helping people lead healthier lives.

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DFE Pharma GmbH & Co. KG - Warranty

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