



DFE
pharma



Disaccharide **BioHale[®]** for Inhalation

Expanding Inhalation excellence to biologics

With BioHale[®] Sucrose and BioHale[®] Trehalose we offer the highest purity non-reducing sugars for the use in inhalation applications.

Multiple technologies for nasal and pulmonary drug delivery of active pharmaceutical ingredients exist. For the design of carrier-free formulations, spray drying has emerged as the preferred technology. Spray drying can be used to modify the particle surface, shape and density. An advantage of spray drying is that excipients, like the BioHale[®] grades, can be incorporated to modify aerosolization and flow properties.

Ask an



EXPERT

dfepharma.com/inhalation

BioHale® for Inhalation

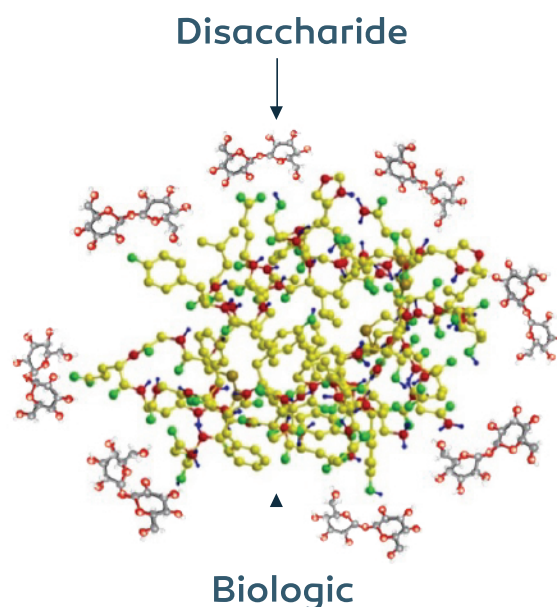
Benefits

BioHale® excipients are high-purity excipients with an excellent safety profile. Trehalose and sucrose are both listed in the USP-NF, Ph. Eur and JP. They are GRAS listed and approved for the use in parenteral and non-parenteral pharmaceutical formulations.

BioHale® Sucrose and BioHale® Trehalose Dihydrate are both non-reducing crystalline disaccharides. Non-reducing sugars provide improved compatibility over reducing sugars with amino acids and proteins, and are not easily hydrolyzed by acid.

An additional advantage of BioHale® excipients is that they can help complex molecules to maintain their native conformation. There are several theories describing the mechanisms behind this stabilization effect. In dry systems, the formation of an amorphous glass is found to be critical in both the vitrification theory and the water replacement theory.

BioHale® excipients can be used in spray drying processes to modify the physical properties of the resulting powder. They are also commonly used in other applications for the lyoprotection and cryoprotection of therapeutics proteins.



Facts

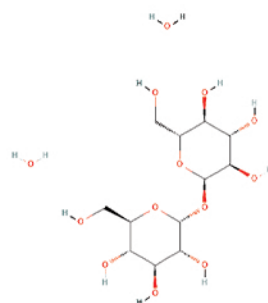
Quality

- High-purity, low endotoxin grades
- Produced in The Netherlands.
- Compliance with Ph. Eur, USP-NF, JP, ChP
- Chinese DMF available

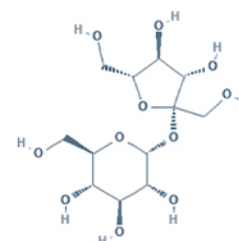
Packaging sizes

- 1kg (HDPE container) with PE inner liner
- 20kg (HDPE drum) with PE inner liner

Trehalose dihydrate
More stable under
low-PH conditions



Sucrose
Stable



Molecular formula	$C_{12}H_{22}O_{11} \cdot 2 H_2O$	$C_{12}H_{22}O_{11}$
Molecular weight	378.33 g/mol	342.30 g/mol
CAS number	6138-23-4	57-50-1
Glass transition temperature	107°C	61°C
Solubility @ 20°C	41 g/mL	67 g/mL
Re-test date	24 months	24 months