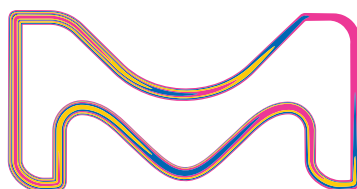


stable success.

High-quality stabilizers
for your biomolecules.



The life science business
of Merck KGaA, Darmstadt,
Germany operates as
MilliporeSigma in the
U.S. and Canada.

SAFC[®]

Pharma & Biopharma Raw
Material Solutions

Trehalose dihydrate

- Multi-compendial, including ChP
- China registration dossier submitted
- Low endotoxin limit (≤ 0.3 I.U./g)
- High-quality grade in a market with limited number of suppliers

Glycine

- Dry-granulated without any additives
- Better handling and processing: reduced caking, improved flowability
- Multi-compendial



More control for your stabilization challenges

Chemicals play an important role in the stabilization of your biologic drug during its manufacturing and formulation process – for instance, by preventing aggregation. Select the right product from our range of high-quality stabilizers to successfully formulate your biomolecules.

Specifically developed for high-risk applications, our sugars, polyols, and amino acids are low in bioburden. They are supported by our Emprove® Program, helping you minimize regulatory and quality-associated risks in your biopharmaceutical manufacturing.

Features:

- Emprove® Expert products addressing high-risk application
- Low endotoxin and microbial limits
- Emprove® program and documentation supporting risk assessment
- Elemental Impurity Information according to ICH Q3D

Sucrose

Sucrose is the most widely used stabilizer for the formulation of biomolecules. Sourcing the appropriate quality of sucrose is key, especially in respect to microbial and endotoxin limits. In addition, it has been discovered that sucrose contains nanoparticulate impurities¹ (range of 100–200 nm) rooting to the sucrose raw material. In addition to disturbing aggregate analytics¹, such nanoparticulate impurities can also negatively influence the stability of biomolecule formulations.²

We developed a new filtration-based manufacturing process leading to a sucrose grade with unique quality characteristics.

In an exclusive partnership with Coriolis Pharma³, we designed the purification process and associated nanoparticle analytics of sucrose.

The resulting highly pure sucrose shows significantly reduced levels of nanoparticles (Graph a) with high batch-to-batch consistency (Graph b).

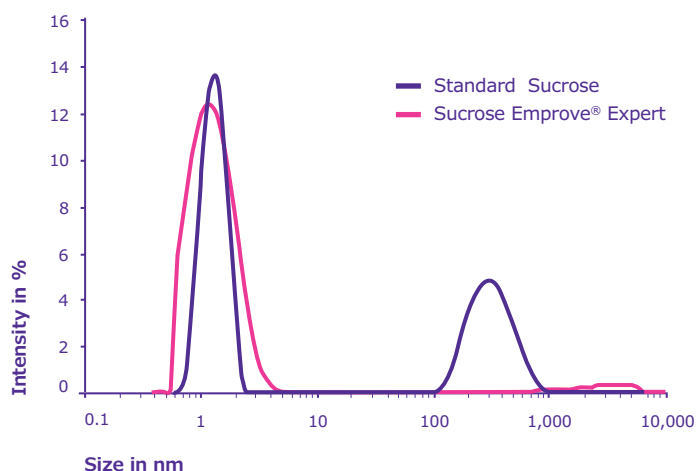
The new product Sucrose Emprove® Expert Ph Eur, ChP, JP, NF will be the right choice for your high-risk applications in the manufacturing and formulation of biomolecules.

Features of our Sucrose

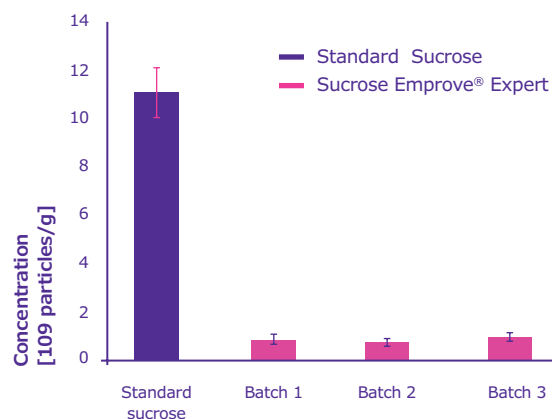
- Multi-compendial, including ChP
- China registration dossier submitted
- Low endotoxin limit (≤ 0.3 I.U./g)
- Addressing nanoparticulate risk with dedicated purification process

Reduction of Nanoparticulate Impurities in Sucrose

Graph a



Graph b



Levels of nanoparticulate impurities were compared between standard pharmaceutical grade sucrose and highly purified sucrose Emprove® Expert. (a) Size distribution of nanoparticles present in sucrose was determined by dynamic light scattering. The nanoparticle peak (size range 100–1,000 nm) was absent in the case of the purified sucrose (Emprove® Expert). (b) The concentration of nanoparticles present in sucrose (particles/g sucrose) was measured by nanoparticle tracking analysis. The concentration in 4 different batches of sucrose Emprove® Expert was significantly lower than the standard sucrose grade and close to the detection limit of the method. For all measurements, 10% sucrose solutions (w/w) were prepared in Milli-Q® water and filtered through a 0.22-µm PVDF membrane before analysis.

¹ Weinbuch et al., Pharm Res (2015) 32:2419-2427

² Weinbuch et al., Pharm Res (2017) 34:2910-2921

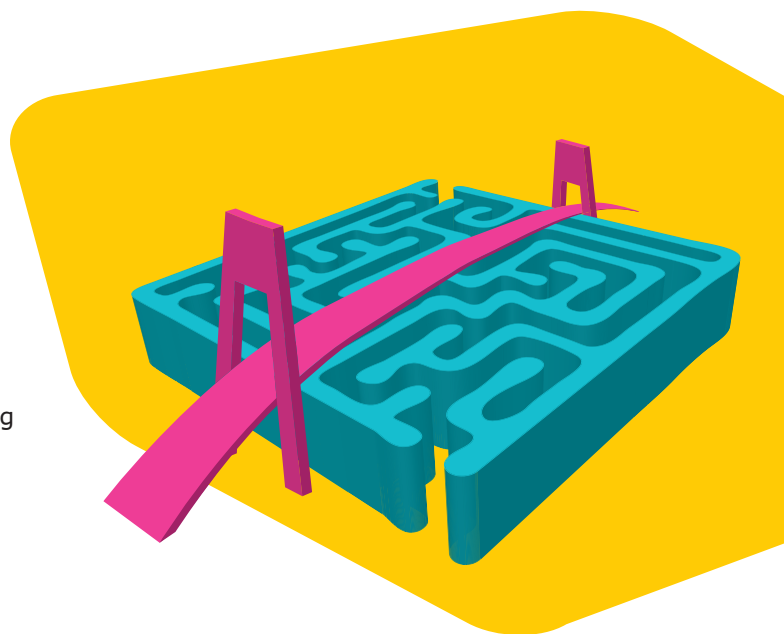
³ Coriolis Pharma, Martinsried, Germany

The Emprove® Program

Your fast track through regulatory challenges.

Ensuring the compliance of your pharmaceutical and bio-pharmaceutical products involves the compilation of a vast amount of data, which can be time and resource intensive. In order to facilitate and accelerate this process, we developed our Emprove® Program. It includes 400 pharmaceutical raw and starting materials and a selection of filtration and single-use products. Each product in the portfolio is complemented with three of dossiers supporting you throughout the different stages of your operations: qualification, risk assessment, and process optimization – all designed to help you accelerating you through the regulatory maze.

For more information, please visit
EMDMillipore.com/emprove



Ordering information

Sugars, polyols

Order No.	Product	Order No.	Product
103789	Sucrose Emprove® Expert Ph Eur, ChP, JP, NF	101544	L-Arginine monohydrochloride Emprove® Expert Ph Eur, BP, JP, USP
111597	Parateck® SI 400 LEX (Sorbitol) , suitable for use as excipient Emprove® Expert Ph Eur, BP, NF, JP	101587	L-Arginine Emprove® Expert Ph Eur, JP, USP
137096	Mannitol Emprove® Expert Ph Eur, BP, USP, JP	100590	Glycine cryst. , Emprove® Expert Ph Eur, BP, JP, USP
102776	Trehalose dihydrate Emprove® Expert Ph Eur, ChP, NF, JP	103669	Glycine granulated Emprove® Expert Ph Eur, BP, JP, USP

Amino acids

Discover our comprehensive portfolio of buffers, salts, and other specialty chemicals suitable for biopharmaceutical manufacturing and formulation.

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The typical technical data above serve to generally characterize the product. These values are not meant as specifications and they do not have binding character. The product specification is available separately at: **EMDMillipore.com**

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