

SUCROSE (LOW ENDOTOXIN)

A critical key material in (bio)pharma
production processes



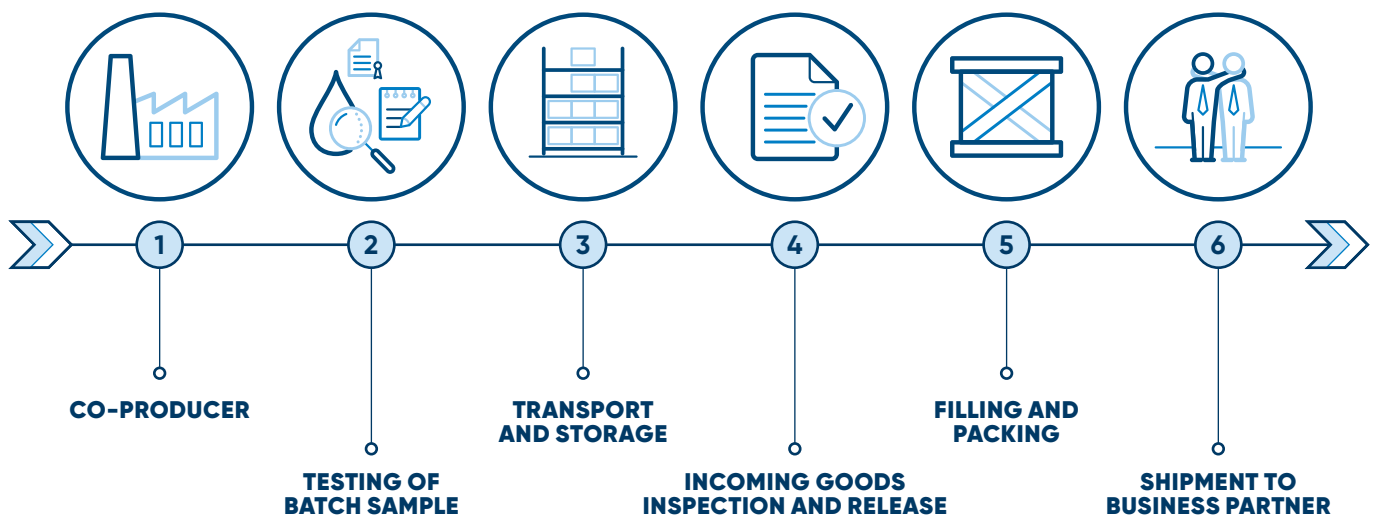
HIGHLIGHTS

EU GMP-certified production facility	Low in endotoxins
IPEC GMP-conform for excipients certified by EXCiPACT standard	Flexible cleanroom-suitable packaging (1 kg - 25 kg)
Packaged in cleanroom class D (ISO 8)	Batch-to-batch consistency
Multi-compendial EP, BP, USP, JP, ChP	Year-round availability through stock management, dedicated warehousing and robust production capacity

Your challenge - Our solution

CUSTOMER IN FOCUS

Our concept: tailored solutions to meet your specific needs



CG PHARMA & BIOTECH QUALITY PROCESS

Co-producer: Qualification of co-producer for sugar (derived from sugar beets), establishment of a purification step for co-producer to ensure high quality of sucrose.

Testing of batch sample: Testing of representative sample from produced sugar campaign to check EP, BP, NF, JP, ChP criteria plus microbiological parameters.

Transport and storage: Transport with own logistics from German sugar plant to qualified CG warehouse.

Incoming goods inspection and release: sampling for microbiological limit testing (endotoxins, TAMC/TYMC) in CG's own lab and partner labs, full testing according to pharmacopoeia (EP, BP, NF, JP, ChP).

Filling and packing: repacking of low endotoxin sucrose (filling line in a controlled environment at CG), storage in CG warehouse (wide range of packaging e.g. 1 kg, 5 kg, 10 kg, 12kg, 20 kg, 25 kg).

SUCROSE

Rooted in quality: rising from beet farm to GMP excellence

Discover sucrose that meets the exacting standards of EP, BP, NF, JP, and ChP. At CG Pharma & Biotech, we're proud to present a sucrose supply concept that's been sensitively designed to not just meet but surpass the stringent requirements of these respected compendia.

- **Proven compendial compliance:** Our multi-compendial sucrose derived from beets is a testament to our dedication to quality.
- With EP, BP, NF, JP and ChP certifications you can trust that your products are built on a foundation of uncompromising quality.
- Every batch is rigorously **analysed**, leaving no room for uncertainty.
- **Low endotoxin levels:** Our multi-compendial sucrose boasts low endotoxin levels, offering an added layer of purity and safety to your products.
- Filling of sucrose into a wide range of packaging (e.g. 1 kg – 25 kg) under cleanroom conditions.
- Ensuring year-round availability through stock management, dedicated ware-housing and robust production capacity.



SUCROSE: APPLICATIONS IN THE (BIO)PHARMACEUTICAL INDUSTRY

Stabilisation of proteins: Sucrose is often used as a stabilising agent in the formulation of protein-based (bio)pharmaceuticals. It helps protect the structural integrity of proteins and peptides during storage and handling, preventing denaturation or aggregation.

Cryopreservation: Sucrose is employed in cryoprotectant solutions for freezing and storing cells, tissues and even certain (bio)pharmaceutical products. It helps prevent ice crystal formation, which can damage cell structures, by acting as a protective barrier.

Lyophilisation (freeze drying): During the lyophilisation process, where water is removed from a product while maintaining its structure, sucrose can be used as a stabilising excipient. It aids in preserving the stability of the product's structure and activity.

Osmotic pressure regulation: In cell culture media and buffer solutions, sucrose is used to control osmotic pressure. This is important for maintaining the health and viability of cells, ensuring they're not subjected to abrupt changes in their environment.

Vaccine formulations: Sucrose can be utilised in vaccine formulations to stabilise the active ingredients, maintain their efficacy, and enhance their shelf life. It helps protect vaccines from temperature fluctuations and other stressors.

Oral dosage forms: In oral dosage forms like tablets and capsules, sucrose can serve as a bulking agent, improving the overall consistency and structure of the product.

Taste masking: For paediatric formulations or patient-friendly dosage forms, sucrose can be used to mask the bitter taste of certain active ingredients, making the medication more palatable.

Parenteral formulations: In injectable formulations, sucrose can act as an osmotic regulator and tonicity-adjusting agent, ensuring that the injection is compatible with the body's physiological conditions.

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