

Merck launches nanoparticle-reduced sucrose for biopharma formulations

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Reduces analytical issues due to interference with common methods of aggregate analysis



Merck has developed a new filtration-based manufacturing process resulting in a new, highly purified sucrose grade with reduced levels of nanoparticle impurities (NPI). The new product, Sucrose EMPIROVE® EXPERT Ph Eur, ChP, JP, NF, is the ideal choice for the high-risk applications of manufacturing and formulating biomolecules.

As a widely used protein stabilizer for biomolecule formulation, the quality of sucrose is crucial. In an exclusive collaboration with Coriolis Pharma, Merck designed the new purification process and associated nanoparticle analytics of sucrose. The result is a highly pure sucrose that offers the following benefits over non-purified sucrose:

- A low level of NPIs on the limit of detection of current technologies, reducing the risk for protein instability
- Less interference with analytical methods
- High batch-to-batch consistency
- Reduced risk of API damage

Sucrose EMPIROVE® EXPERT Ph Eur, ChP, JP, NF is part of Merck's broad portfolio of protein stabilizing excipients including trehalose, mannitol, sorbitol and glycine. The new offering is part of the company's Emprove® Program, which facilitates drug product manufacturers' risk assessment workflows and supplier qualification.