

New from MEGGLE: Lactose LE – Lactose Monohydrate Low Endotoxin



Lactose is a well known excipient as bulking agent in freeze-dried parenteral products*

Lactose LE is MEGGLE's protective sieved product, which is not specified in PSD, but in microbiological quality and endotoxins. Due to the characteristics of the product, **Lactose LE** is suitable for use in inhalation and parenteral applications. It is therefore a good starting material if you want to perform your own milling or fractionation to achieve a certain PSD.



Benefits:

- High purity grade
- Low bioburden, low endotoxin
- Q3D statement for parenteral **and** inhalation applications
- Conforms to Ph. Eur., USP-NF, JP and ChP
- Listed in FDA inactive ingredient database for inhalation **and** parenteral applications
- High glass transition temperature, usage for stabilization/cryoprotectant

Applications:

- DPI formulations
- Parenteral/Injectables
- (Thin-film) freeze-drying and spray-drying (high dose formulations and sensitive APIs)

Additionally, product characteristics have been also proven to be advantageous for other applications. In that respect the cryoprotective properties and the possibility of using lactose as a bulking agent are particularly popular.

Excipients which are suitable to stabilize products during lyophilization, and which are approved by regulatory agencies for parenteral formulations are highly limited. The FDA regulatory requirements for parenteral formulations are quite strict: they must be proven safe, non-toxic, sterile, pyrogen-free, and particle-free. Notable, lactose is listed in the FDA Inactive Ingredient Database (IID) for parenteral and ophthalmic applications. β -Lactoglobulin (BLG) is monitored as marker allergen/milk protein, levels are below LOQ (0.010 ppm). Due to crucial design of production processes and sourcing of raw material **Lactose LE** shows very low bioburden. It is therefore well suited for the manufacturing of parenteral final dosage forms. Notably, the market authorization holder (MAH) is obliged to ensure sterility in its final dosage form.

Contact our specialist team for support and a comprehensive information package and required documentations.

Sugars for Cryoprotection

Cryoprotectants are substances that protect biological materials from damage caused by freezing and thawing. Remarkably, whilst lactose is a reducing sugar and the risk of the Maillard reaction should be taken into account for certain molecules, there is a multitude of applications.

Lactose may work as a cryoprotectant via different effects, amongst the most prominent are water replacement, forming a glass-like amorphous structure during freezing or provide osmotic protection. Additionally, lactose molecules can engage in hydrogen bonding interactions with water molecules. This eventually can inhibit the formation of large, damaging ice crystals.

For judgement of two possible protective excipients the glass transition temperature (Tg) next commercial aspects should be considered. The sugar with the higher Tg should be selected. Tg of lactose is with 102°C comparable high, only the higher priced trehalose shows higher values with 107–120°C. Mannitol on the other hand has much lower values with 93°C.

| Microbiology | |
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| Lactose LE | |
| Parameters | Specified |
| Total aerobic microbial count (TAMC) | NMT 10 cfu/g |
| Total combined yeasts and molds count (TYMC) | NMT 10 cfu/g |
| Bile tolerant gramnegative bacteria | absence/10 g |
| <i>Escherichia coli</i> | absence/10 g |
| <i>Pseudomonas aeruginosa</i> | absence/10 g |
| <i>Staphylococcus aureus</i> | absence/10 g |
| <i>Salmonella spp.</i> | absence/10 g |
| <i>Burkholderia cepacia</i> | absence/10 g |
| Bacterial endotoxins | < 5 EU/g |