

# 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
- Usage for stabilization and protectant in temperature-sensitive production processes

### 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 protective properties and the possibility of using lactose as a bulking agent are particularly popular.

Excipients which are suitable to stabilize products during freeze-drying (lyophilization) and spray-drying, 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.  $\beta$ -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 protection during drying and as bulking agent

Cryoprotectants/Stabilizers are substances that show a molecular protection for sensitive ingredients regarding damage caused by freezing and spray-drying.

Lactose may work as a protectant 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.

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. It can be used as protection during freeze-drying or spray-drying, similar to other disaccharides, like Sucrose, Trehalose and the sugar alcohol Mannitol.

| Microbiology                                 |              |
|--|--------------|
| 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     |

\*<https://www.pharmaexcipients.com/excipients-for-parenterals/>