

POWDER PREPARATIONS

SIEVED LACTOSE

Technical brochure

General information

Crystalline alpha-lactose monohydrate grades have a long tradition in pharmaceutical applications due to their chemical and physical stability, in oral, parenteral and inhalative pharmaceutical applications, versatile binder-filler properties, and global availability [1]. Fractionating crystalline lactose by sieving offers multiple opportunities to tailor its physical characteristics and functional performance by adjusting the particle size distribution.

In early stages of formulation development and preparation of clinical trial material, capsules are the ideal choice. When the preservation and long term integrity of the gelatin capsule is needed, lactose is the RIGHT choice! Lactose has limited interaction with gelatin capsules and is the ideal capsule filler for formulators around the world. This clearly has not changed for Hydroxypropylmethylcellulose (HPMC) capsules, which have gained a lot of popularity.

Capsules are of special interest for early stage developments and clinical trials medication, where on a final formulation has not been decided yet.

MEGGLE addresses these formulation needs by offering a range of lactose grades with distinct particle size distributions and bulk densities. Both parameters are critical for successful formulation development, enabling the selection of an excipient grade that supports reliable powder flow, efficient processing, and content uniformity.

Narrow fractionation of crystalline lactose produces coarse, sieved grades with well-defined particle size distributions. Their flow properties are governed by particle size and shape, supporting efficient processing and higher production speeds.

MEGGLE's sieved lactose grades are produced through a well-defined manufacturing process, resulting in tightly controlled particle size distributions and reliable flowability.

Product description

MEGGLE's sieved lactose monohydrate grades are developed specifically for powder applications such as capsule and sachet filling. They feature good flow properties, a narrow particle size distribution, and outstanding batch-to-batch consistency, supporting efficient processing and uniform dosing.

Capsules and sachets are gaining importance – especially in early-stage development, clinical trials, and for patient groups with swallowing difficulties such as children and the elderly. MEGGLE's sieved lactose grades are the ideal choice for these powder preparations, offering excellent compatibility with both gelatin and HPMC capsules. The following table provides an overview of the recommended areas of application and its individual benefits to support optimal product selection.

APPLICATION

Sieved lactose

- Capsule filling
- Sachet filling
- Premixes, dry blends
- Triturations (carrier)

BENEFITS

Sieved lactose

- Very good flowability
- Narrow particle size distribution
- Good blending properties
- High storage stability
- High batch-to-batch consistency

Regulatory & quality information

MEGGLE's sieved (PrismaLac® 40, CapsuLac® 60, Sachelac® 80, SpheroLac® 100) alpha-lactose monohydrate grades comply with the current harmonized Ph. Eur., USP-NF, JP and ChP monographs. Specifications and regulatory documents can be downloaded from www.megggle-excipients.com.

Our pharma-dedicated production facility in Wasserburg am Inn, Germany, is certified according to DIN EN ISO 9001 and has implemented GMP according to the Joint IPEC-PQG (Good Manufacturing Practices Guide for Pharmaceutical Excipients) and USP-NF General Chapter <1078> GOOD MANUFACTURING PRACTICES FOR BULK PHARMACEUTICAL EXCIPIENTS. MEGGLE has been an EXCiPACT™-certified excipient manufacturer and supplier since 2014.

The Wasserburg facility demonstrates MEGGLE's complete lactose production capability range, including sieving, milling, agglomeration, spray-drying, and co-processing. Additionally MEGGLE is a member of IPEC (International Pharmaceutical Excipients Council).

MEGGLE invests considerably in the sustainability of raw material sourcing, production standards, and efficiency. We are actively engaged in environmental protection. In order to guarantee the quality of our products, our commitment and adherence to established pharmaceutical standards is our highest priority.



Particle Size Distribution (PSD)

MEGGLE's crystalline alpha-lactose monohydrate grades are available in various PSDs according to the diversified needs of our customers. **Figure 1** shows typical laser diffraction particle size distribution data for MEGGLE's sieved lactose grades.

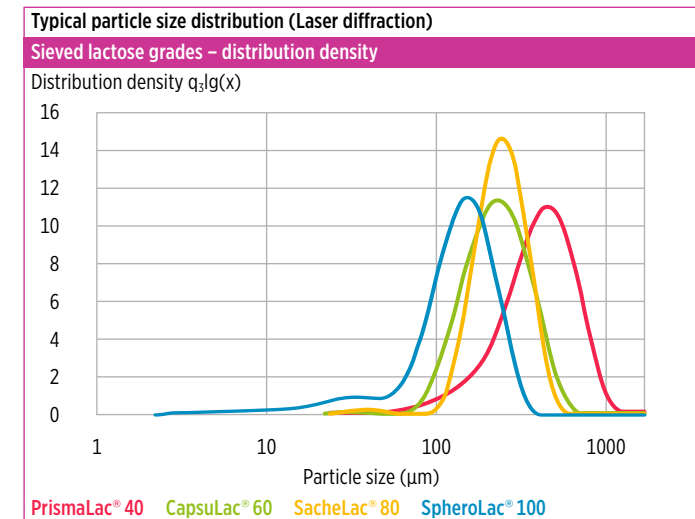
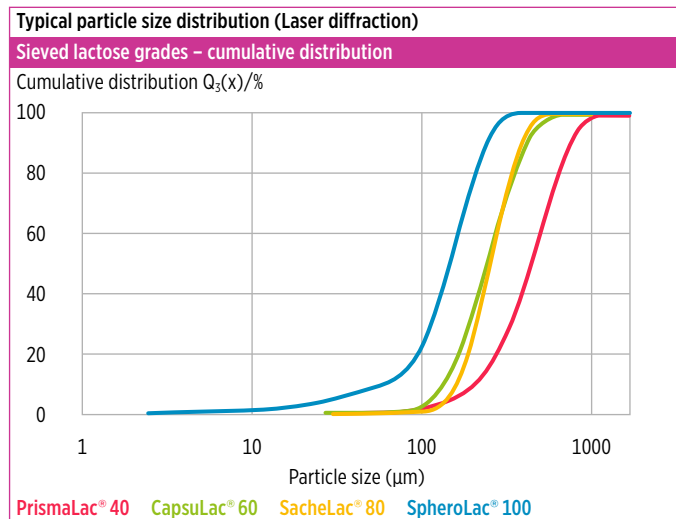


Figure 1: Typical cumulative PSD and distribution density of MEGGLE's sieved lactose grades PrismaLac® 40, CapsuLac® 60, SacherLac® 80 and SpheroLac® 100. Analyzed by Sympatec®/Helos & Rodos particle size analyzer.

Particle Size Distribution (PSD) & Morphology (SEM)

Figure 2 depicts the specified PSD range and typical average values for MEGGLE's sieved grades, and their typical Scanning Electron Microscope (SEM) images. These parameters are constantly monitored through in-process control (IPC) testing and are part of MEGGLE lactose grades' PSD specification obtained using mechanical sieving.

Sieved lactose grades show different morphology as it can be seen in the different SEM pictures. Sieved products are mainly defined by coarse tomahawk-shaped monocrystals and, to a minor extent, agglomerated particles.

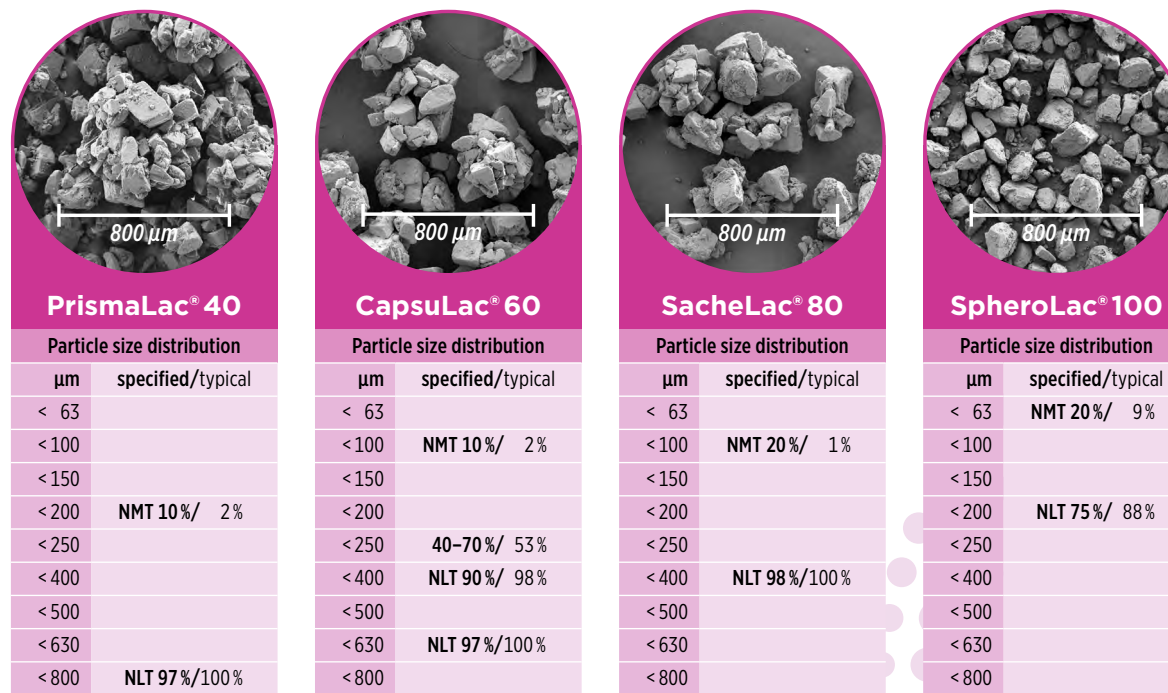


Figure 2: Specified PSD ranges for MEGGLE's sieved lactose grades by mechanical sieving in bold letters. Typical values obtained from a permanent in-process control are shown for orientation. SEM images of all sieved MEGGLE lactose grades by ZEISS Ultra 55 FESEM (U = 5 kV; Au/Pd sputtered).

Functional related characteristics

Powder flow

Powder flow is an important functional characteristic in formulation development and product manufacturing. Differences in morphology and PSD of sieved lactose grades maintain discrete flow performances: Sieved lactose grades exhibit good to fair flowability. According to Ph. Eur. there are different gradiations to define flow property of a powder (Figure 3).

Classification of powder flow according to Ph. Eur.			
Flow property	Carr's Index (%)	Angle of Repose (°)	Hausner ratio
Excellent	1 – 10	25 – 30	1.00 – 1.11
Good	11 – 15	31 – 35	1.12 – 1.18
Fair	16 – 20	36 – 40	1.19 – 1.25
Passable	21 – 25	41 – 45	1.26 – 1.34
Poor	26 – 31	46 – 55	1.35 – 1.45
Very poor	32 – 37	56 – 65	1.46 – 1.59
Very, very poor	> 38	> 66	> 1.60

Figure 3: Calculation of the CI, the Angle of Repose (AoR) and the Hausner ratio. Classification according to Ph. Eur. 2.9.36. A CI below 11, a AoR of 25 – 30 and a Hausner Ratio below 1.12 implies excellent flow property of the material. A value between 21 – 25 (CI), 41 – 45 (AoR) and 1.26 – 1.34 (Hausner Ratio) implies passable flow property.

$$\text{Carr's Index (CI)} = \left(\frac{\rho_{\text{tapped}} - \rho_{\text{bulk}}}{\rho_{\text{tapped}}} \right) \times 100$$

$$\text{Angle of Repose (°)} = \left(\frac{\text{height of the cone}}{\frac{1}{2} \text{ fixed base}} \right)$$

$$\text{Hausner ratio} = \left(\frac{\rho_{\text{tapped}}}{\rho_{\text{untapped}}} \right)$$

Figure 4 shows typical flowability indices for MEGGLE's sieved lactose grades. All sieved lactose grades show a good to fair flowability, with CI values between 13 – 17 %, angle of repose values between 32 – 35° and a Hausner ratio between 1.15 and 1.20.

Flowability					
Sieved lactose					
	Carr's Index (%)	Angle of Repose (°)	Hausner ratio	Density bulk (g/l)	Density tapped (g/l)
PrismaLac® 40	13	35	1.15	512	588
CapsuLac® 60	16	32	1.19	624	740
SacheLac® 80	15	32	1.18	621	732
SpheroLac® 100	17	35	1.20	725	874

Figure 4: Typical technological values, describing powder flowability, shown for sieved MEGGLE lactose grades.

Figure 5 shows the CI of sieved grade lactose. Due to its coarser PSD, PrismaLac® 40 shows better flowability compared to the finer SpheroLac® 100.

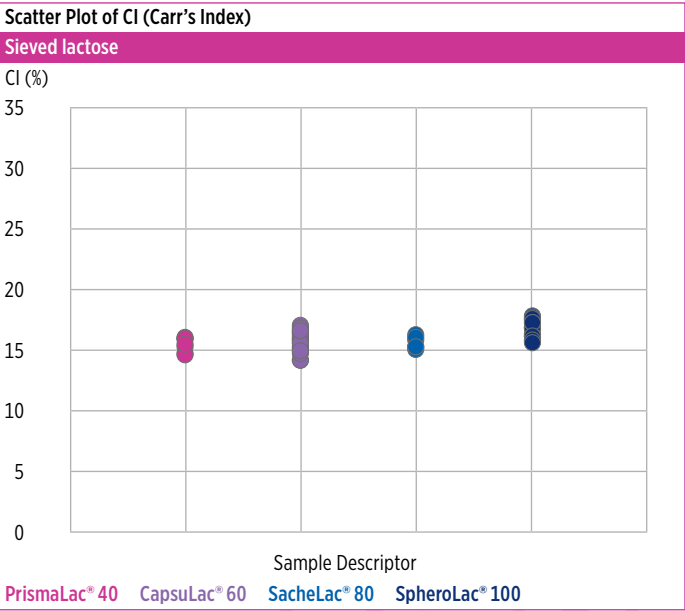


Figure 5: Carr's Index of MEGGLE's sieved lactose grades.

Batch-to-batch consistency

Batch-to-batch consistency for all lactose products can be attributed to MEGGLE’s long history and experience in lactose manufacturing, and broad technical expertise. Constant in-process and final product testing ensures consistency and quality. For detailed information: www.meggle-excipients.com.

Isotherm

MEGGLE’s sieved alpha-lactose monohydrate products do not adsorb significant amounts of water below 90 % relative humidity (25 °C). **Figure 6** shows sorption and desorption isotherm for SacheLac® 80.

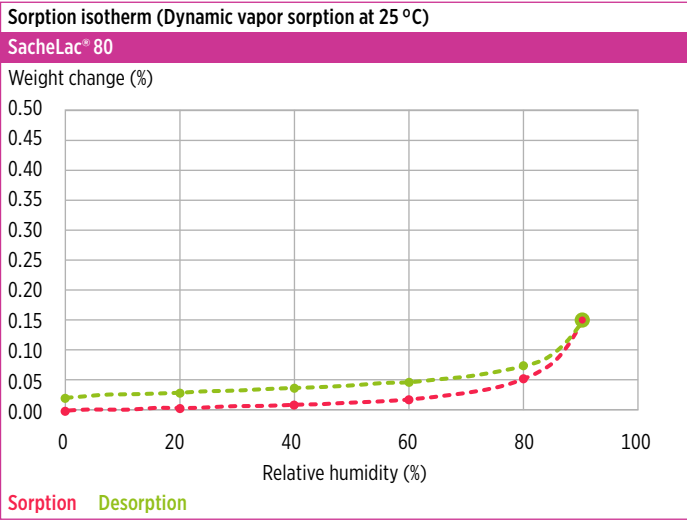


Figure 6: Sorption-desorption isotherms (25 °C) of alpha-lactose monohydrate, using SacheLac® 80 as an example. Analysis performed with SPSx-1µ Advance (proUmid GmbH & Co. KG, Ulm, Germany).

Packaging and shelf life

Packaging material complies with Regulation (EC) No.1935/2004 and 21 CFR 174, 175, 176, 177 and 178. Stability tests have been performed according to ICH guidelines and an ongoing stability program is implemented. **Figure 7** provides an overview about packaging size and material, and product shelf life.

Packaging and shelf life			
Sieved lactose			
	Size	Material	Shelf life
PrismaLac® 40	20 kg	Paper bag with PE-EVOH-PE inliner	36 Months
CapsuLac® 60	25 kg		
SacheLac® 80			
SpheroLac® 100			

Figure 7: Packaging and shelf life of MEGGLE’s sieved lactose grades.

Literature

- [1] Armstrong, N. A. (2007) Tablet manufacture. Encyclopedia of Pharmaceutical Technology, Ed. Swarbrick J., Informa healthcare, New York, London: 3653.

Case study

MEGGLE's sieved lactose grades for capsule and sachet filling: MEGGLE provides detailed information on their sieved lactose grades, emphasizing their suitability for oral dosage forms. The sieved grades are inherently free-flowing due to their low Carr's Index and flowability index. They are recommended for applications such as capsule filling, sachet filling, and powder triturates. The grades discussed include PrismaLac® 40, CapsuLac® 60, SacheLac® 80, and SpheroLac® 100.

Pharmaceutical Networking. (2020, April 30). MEGGLE sieved lactose for powder preparations.
pharmaceutical-networking.com

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