

Pharmatose®

milled & sieved lactose.

Productgroup overview.

DMV-Fonterra Excipients
The ingredients of success



DMV-Fonterra Excipients is a leading supplier of excipients for oral solid dose and dry powder inhalation formulations. Continuous investment in leading cGMP standards, excipient technologies and committed personnel, allow us to consistently supply high quality products from our sites around the globe. With more than 100 years of experience in excipient manufacturing and with a broad portfolio of products, we are committed to building trust with our customers through Quality, Reliability and Expertise.

Milled & sieved lactose

Lactose is a natural, safe, excipient with high inertness and neutral taste. Its chemical, physical and microbiological stability, together with its ease of use has always made lactose one of the first choices in solid dosage formulation.

Pharmatose®

Pharmatose milled and sieved lactose products are the most widely used pharmaceutical excipients worldwide. Pharmatose is the industry standard for pharmaceutical grade lactose, with long history of production and expertise, which customers can trust for consistently high quality.

Pharmatose is available in both milled and sieved grades with a wide selection of particle size distributions suitable for many applications.

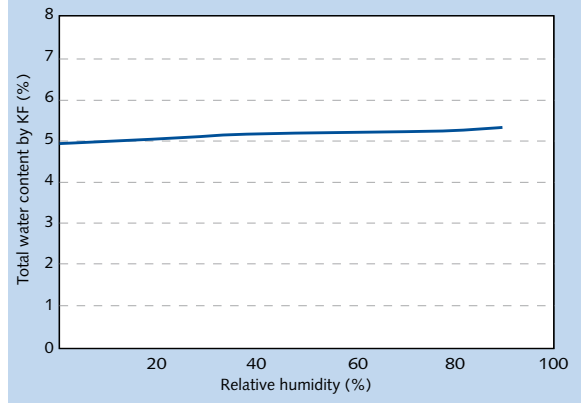
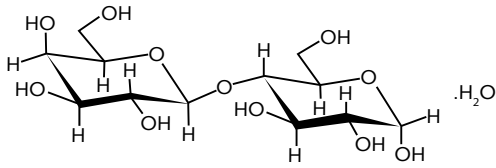
Dual-Sourcing

Pharmatose® 200M is available from our manufacturing sites located in different continents. The Dual-Sourcing products are produced according to the same quality standards, the same documentation support and equivalent performance in formulations.

For more information

Visit www.dmv-fonterra-excipients.com or contact one of our global sales representatives.

Structure of α -lactose monohydrate



Moisture sorption isotherm of α -lactose monohydrate at 20°C.

Product overview & applications

		Wet granulation	Dry granulation	Direct compression	Capsules sachets	Powder blends	Triturations	Pellets
Sieved lactose								
Pharmatose	50M			•	•	•		
	60M			•	•	•		
	70M			•	•	•		
	80M		•	•	•	•	•	•
	90M		•	•	•	•	•	•
	100M		•	•	•	•	•	•
	110M		•	•	•	•	•	•
	125M	•	•	•	•	•	•	•
Milled lactose								
Pharmatose	130M	•	•		•			•
	150M	•	•					•
	200M	•	•					•
	350M	•						•
	450M	•						•

Pharmacopoeia

Pharmatose complies with the latest editions of the USP-NF, Ph.Eur., JP.

Packaging

Pharmatose is available in various packaging forms such as bags, drums and big-bags or in bulk.

Pharmatose sieved lactose

Description

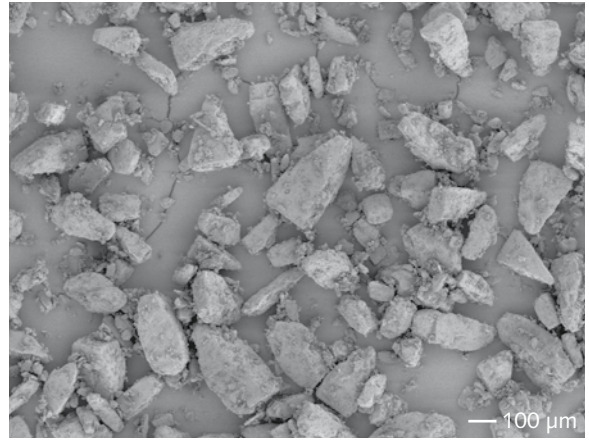
Lactose monohydrate USP-NF, Ph.Eur., JP
White, odourless, free flowing, crystalline powder.

Main benefits

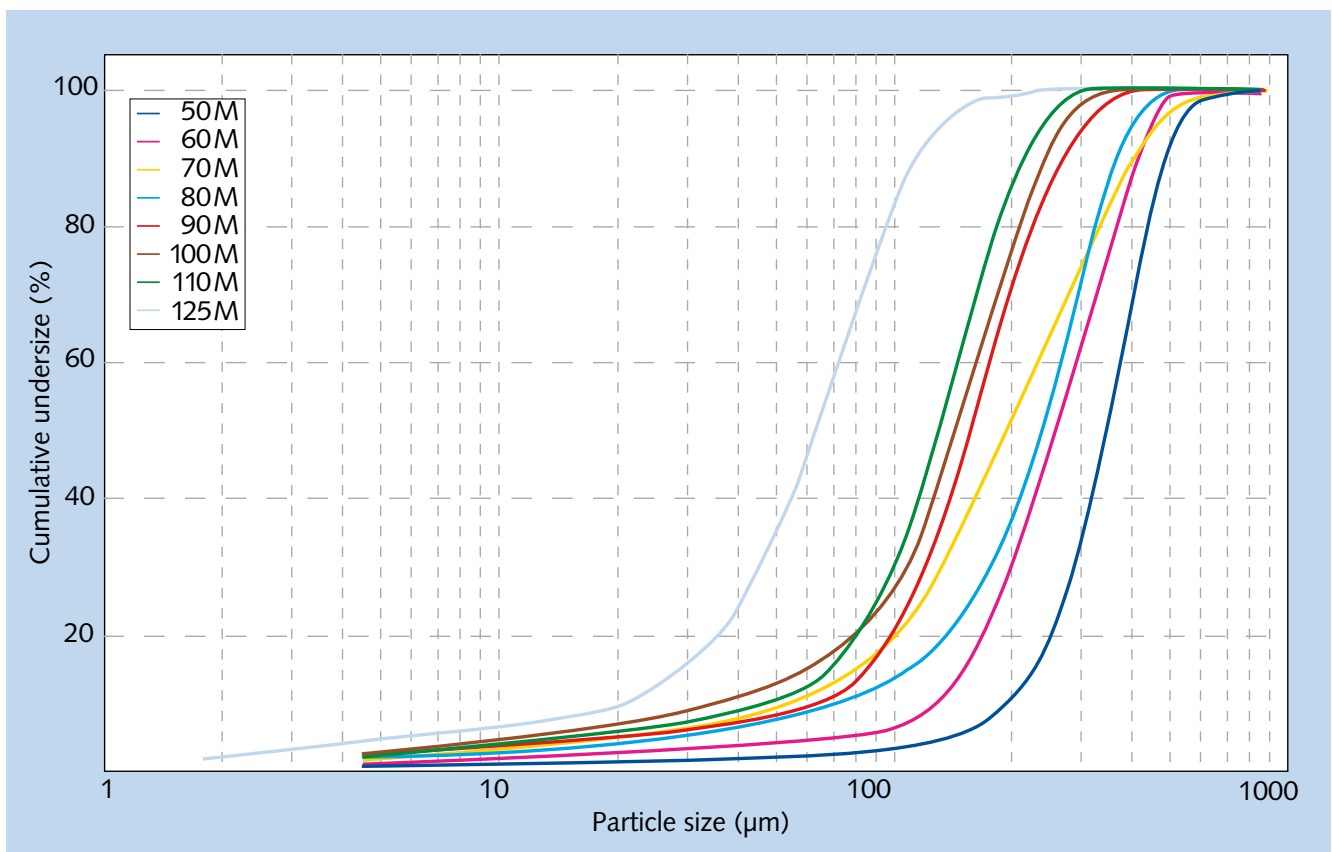
- Size distribution, particle shape and morphology provide good flowability and mixing characteristics
- Wide selection of particle size distribution available for all applications
- Customisation of particle size distribution possible

Application

Various grades are available for use as fillers in wet or dry granulation, direct compression formulations, capsules and as diluents in sachets, or other solid dosage applications.



SEM of Pharmatose 100M.



Particle size distribution of Pharmatose grades as measured by dry powder laser diffraction. These graphs are indicative and should only be used for informational purposes.

Particle size specifications

manufacturing site The Netherlands*

manufacturing site New Zealand**

Pharmatose	sieve aperture (µm)	% passing	sieve aperture (µm)	% passing
50M	200	≤20		
	400	≥80		
60M			75	≤5
			150	10-20
			250	40-65
			600	≥98
70M			75	5-13
			150	25-45
			250	60-80
			600	≥98
80M	100	≤20		
	250	70-90		
	315	≥95		
90M	63	≤15		
	100	15-30		
	150	55-90		
	315	100		
100M	63	≤15		
	150	60-80		
	250	≥99		
110M	63	≤20		
	100	30-60		
	150	75-90		
	315	100		
125M	45	≤40		
	63	40-70		
	100	≥90		
	150	≥97		

*Specification for Pharmatose product on Alpine Air Jet Sieve. **Specification for Pharmatose product on ATM Sonic Sifter.

Bulk density and derived properties

Pharmatose	Typical poured density ^(a) (g/ml)	Typical tapped density ^(b) (g/ml)	Typical Hausner Ratio (-)	Typical Carr's Compressibility Index (%)
50M	0.70	0.82	1.17	14
60M	0.80	0.98	1.22	18
70M	0.81	1.02	1.26	20
80M	0.75	0.92	1.23	18
90M	0.72	0.90	1.25	20
100M	0.73	0.88	1.20	17
110M	0.72	0.88	1.22	18
125M	0.68	0.85	1.25	20

(a) measured on 250 ml volume (b) density after 1250 taps

Pharmatose milled lactose

Description

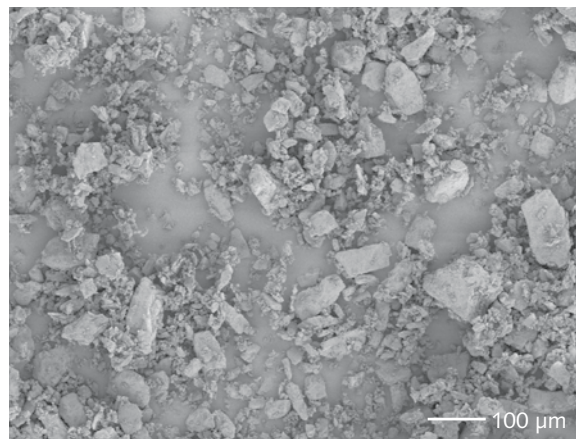
Lactose monohydrate USP-NF, Ph.Eur., JP
White, odourless, crystalline powder.

Main benefits

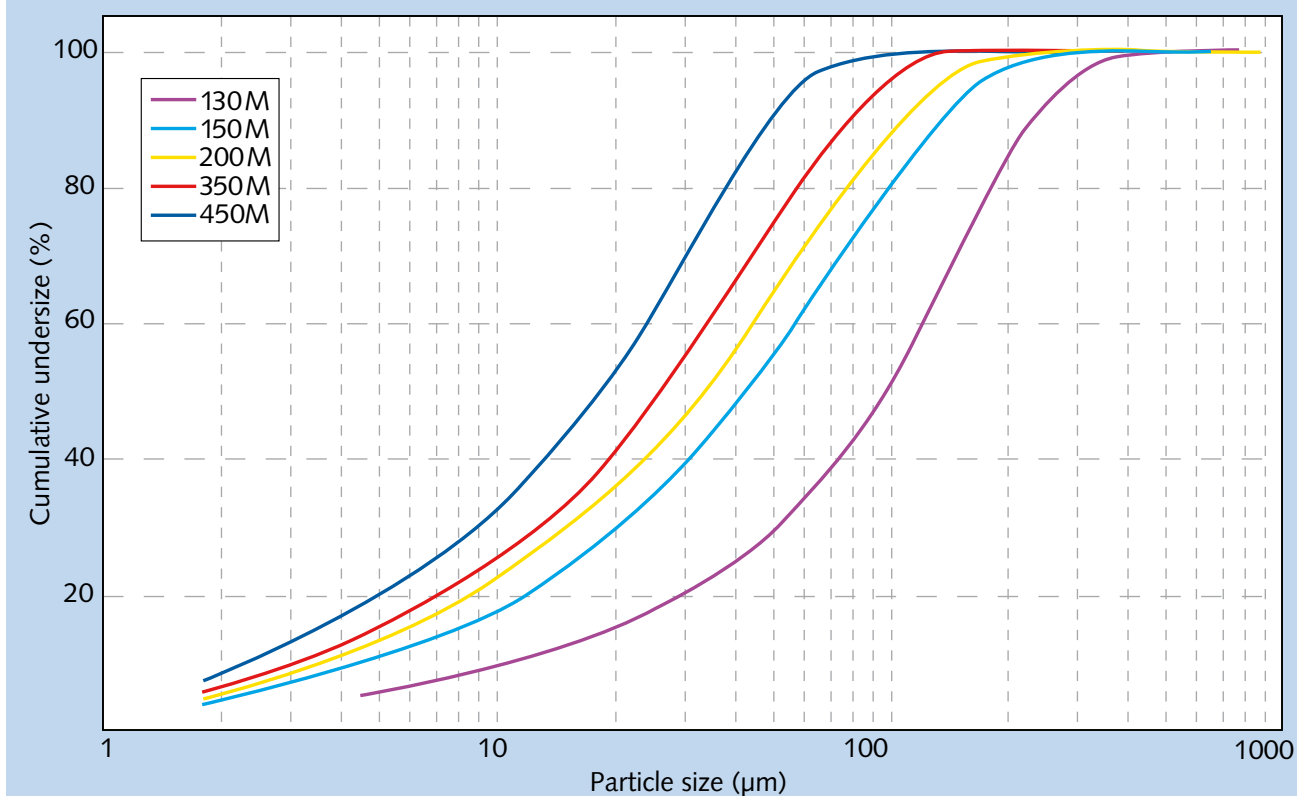
- Most popularly used filler in tablet production
- Wide range of particle sizes for all applications
- Small particles and high surface area for good wettability and compactibility

Application

Various grades are available for use as fillers in wet or dry granulation, capsules and other solid dosage applications.



SEM of Pharmatose 200M.



Particle size distribution of Pharmatose milled grades as measured by dry powder laser diffraction. These graphs are indicative and should only be used for informational purposes.

Particle size specifications

manufacturing site The Netherlands*

manufacturing site New Zealand**

Pharmatose	sieve aperture (μm)	% passing	sieve aperture (μm)	% passing
130M			75 180	≤ 50 80-90
150M	45 100 150 315	≤ 50 ≥ 70 ≥ 85 100		
200M	45 100 150 250	50-65 ≥ 90 ≥ 96 ≥ 99	75 180	78-86 ≥ 98
350M	45 100 250	≥ 60 ≥ 96 100		
450M	45 63 150	≥ 90 ≥ 98 100		

*Specification for Pharmatose product on Alpine Air Jet Sieve. **Specification for Pharmatose product on ATM Sonic Sifter.

Bulk density and derived properties

Pharmatose	Typical poured density ^(a) (g/ml)	Typical tapped density ^(b) (g/ml)	Typical Hausner Ratio (-)	Typical Carr's Compressibility Index (%)
130M	0.65	0.96	1.48	32
150M	0.62	0.90	1.45	31
200M	0.57	0.84	1.47	32
350M	0.54	0.80	1.49	33
450M	0.48	0.74	1.54	35

(a) measured on 250 ml volume (b) density after 1250 taps

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