DRY POWDER INHALER →
SIEVED/MILLED/FINE MILLED
LACTOSE

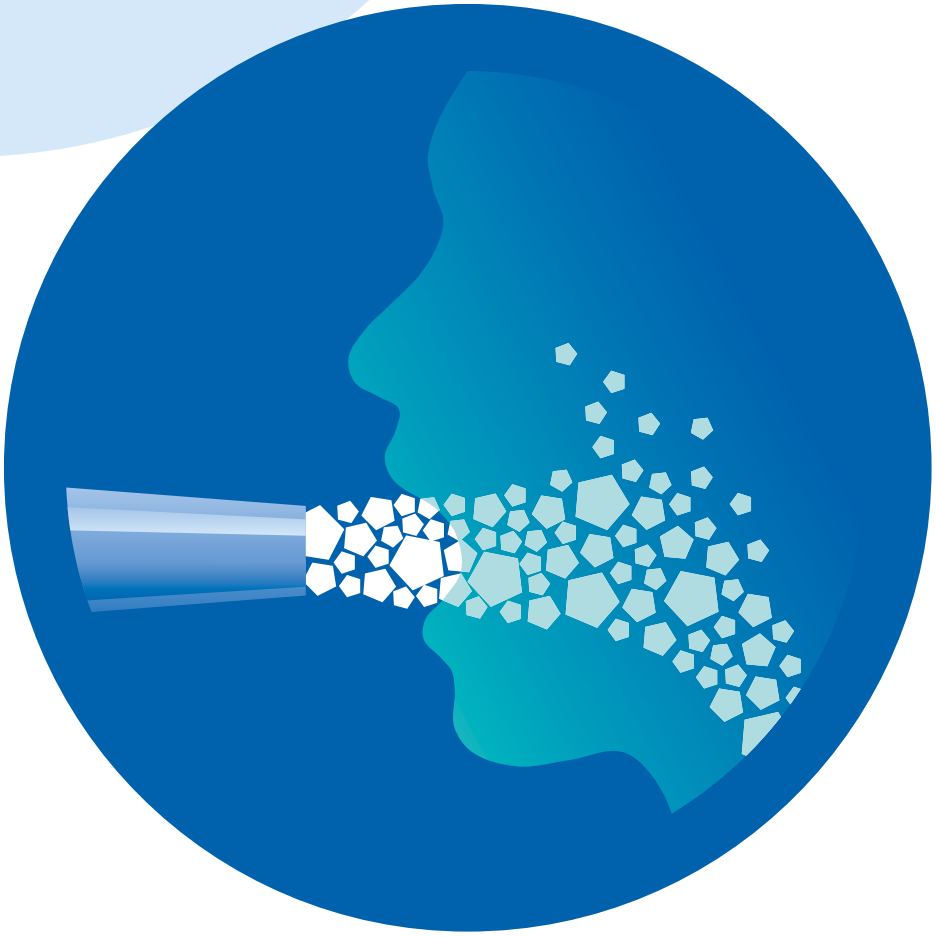
Technical brochure
InhaLac®

MEGGLE's sieved, milled and fine milled alpha-lactose monyhydrate for dry powder inhalation: InhaLac®

MEGGLE's beyond suppling of lactose

MEGGLE dry powder inhaler has a long-standing and trustworthy partnership with leading formulators for dry powder inhalation (DPI). With years of experience and expertise, MEGGLE guarantees the production of high-quality lactose for pharmaceutical applications. MEGGLE is a partner to its global customers, providing them with not only high-quality products but also formulation services and ideas.

MEGGLE is known to collaborate with various pharmaceutical companies covering the entire pipeline of DPI development and commercialization. MEGGLE is committed to support its customers based on their needs. Thanks to its own globally distributed laboratories MEGGLE is able to generate valuable application data rapidly.



General information

The delivery of active pharmaceutical ingredients (APIs) via the lung is becoming increasingly important as more patients worldwide suffer from chronic respiratory diseases [1]. Additionally, the use of the respiratory tract for systemic application is gaining more attention than in the past.

MEGGLE benefits:

- Customization and tailored solutions
- Leading manufacturer of DPI lactose
- Comprehensive and constantly expanding portfolio
- Broad spectrum of tightly controlled particle sizes
- DPI grades available for all types of devices
- Individualized service with quick response time
- Expertise and support in the development of DPI formulations
- Global application laboratories to optimize new and existing formulations
- Collaboration with leading industrial partners and scientific institutes
- Lactose for parenteral or ophthalmic application available

DPIs are widely used in pulmonary drug delivery. This is because of their advantages like ease of use, small size, portability, and lack of breath-actuation coordination requirement [2]. **They are also environmentally friendly as they are propellant-free** and comparatively stable as solid-particle formulations [3].

Typically, this dosage form comprises a device, one or more APIs, and excipients. The main function of the excipient lactose is to act as carrier. Carriers are used to help deposit the active ingredient in the lung and may have a secondary role in diluting the active to ensure that dosages can be properly metered. Other excipients, like lactose fines or force control agents, may be used to further modify drug detachment.

Lactose has a long tradition in inhalative dosage forms and is proven to be safe. Therefore, lactose is the excipient of choice in pulmonary drug delivery. MEGGLE's InhaLac® product family is highly specialized and produced using a dedicated and well-documented process.

Regulatory & quality information

MEGGLE's InhaLac® grades comply with the current USP-NF, Ph. Eur., JP and ChP monographs. In order to meet the special requirements for pulmonary drug delivery, additional and in some cases even stricter specification limits are in place for all InhaLac® grades. For many InhaLac® grades a drug master file (DMF) is available for drug product submission review and approval in the US or China. Specifications and regulatory documents can be downloaded from www.meggle-excipients.com.

MEGGLE's pharma-dedicated production facility in Wasserburg, Germany is certified according to DIN 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. All InhaLac® products are manufactured on product lines exclusively dedicated to inhalation lactose. 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 and is actively engaged in environmental protection. In order to guarantee the quality of the products, commitment and adherence to established pharmaceutical standards is the highest priority.

InhaLac® portfolio overview

MEGGLE offers a wide range of sieved, milled, and fine milled inhalation grades of lactose monohydrate – the InhaLac® types. All of them have excellent physico-chemical characteristics and conform to the highest compendial requirements. The broad MEGGLE portfolio allows to meet any formulator's expectations.

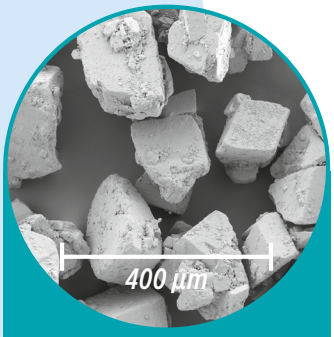
InhaLac® grades are produced through crystallization, followed by sieving or milling, using a dedicated production line. The optimized and standardized production process consistently ensures the highest quality production, made in Germany.

Lactose is usually used in a DPI formulation as a coarse carrier to help deposit the active ingredient in the lung and may have a secondary role in diluting the active to ensure that dosages can be properly metered. Moreover, finely milled lactose is often used to improve the performance (detachment of API). Formulation requirements vary depending on the API's target concentration and characteristics, like particle size and shape hydrophilicity/lipophilicity, as well as on the device. Additionally, downstream processes like blending and filling are also important to consider.

The different requirements have to be considered during development to ensure a high and repeatable delivery of the API to the lungs as well as a robust production process. Carrier properties are herby significantly determining the product performance.

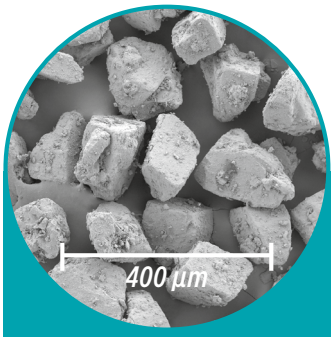
Therefore, MEGGLEs InhaLac® portfolio offers a variety of both sieved (tomahawk-shaped particles) and milled (irregular shaped) grades with distinct and highly controlled particle sizes as carriers, as well as fine milled grades for DPI performance fine tuning.

Sieved



InhaLac® 70

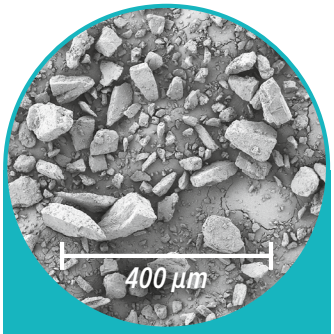
Particle size distribution	
x_{10}	110 – 160 µm
x_{50}	180 – 250 µm
x_{90}	270 – 340 µm



InhaLac® 120

Particle size distribution	
x_{10}	70 – 105 µm
x_{50}	110 – 155 µm
x_{90}	160 – 215 µm

Milled



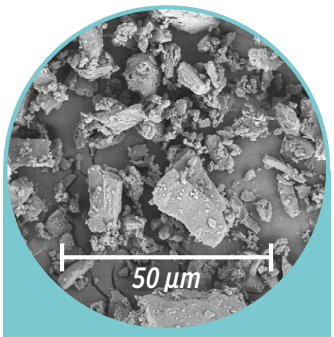
InhaLac® 140

Particle size distribution	
x_{10}	3 – 7 µm
x_{50}	37 – 61 µm
x_{90}	120 – 190 µm

InhaLac® 145

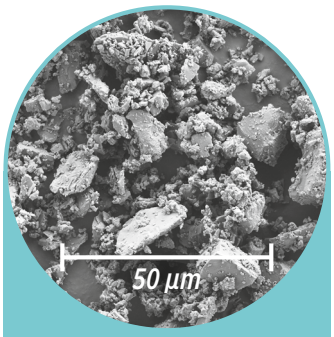
Particle size distribution	
x_{10}	1 – 6 µm
x_{50}	20 – 50 µm
x_{90}	65 – 140 µm

Fine milled



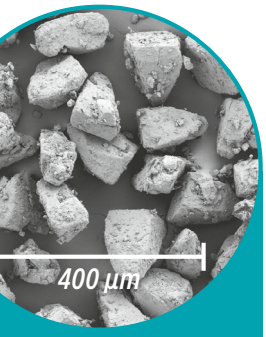
InhaLac® 300

Particle size distribution	
x_{10}	2.0 – 3.5 µm
x_{50}	14.0 – 19.0 µm
x_{90}	40.0 – 56.0 µm



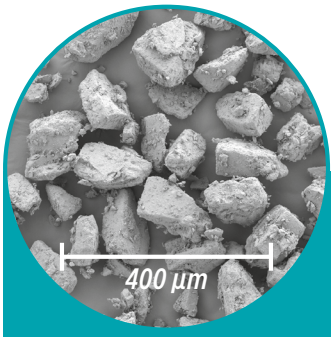
InhaLac® 400

Particle size distribution	
x_{10}	0.8 – 1.6 µm
x_{50}	4.0 – 11.0 µm
x_{90}	15.0 – 35.0 µm



nhaLac® 160

Particle size distribution	
x_{10}	55 – 85 µm
x_{50}	90 – 120 µm
x_{90}	125 – 165 µm

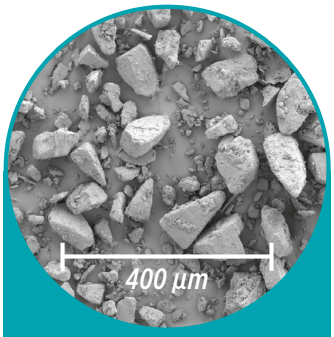


InhaLac® 230

Particle size distribution	
x_{10}	30 – 60 µm
x_{50}	70 – 110 µm
x_{90}	110 – 150 µm

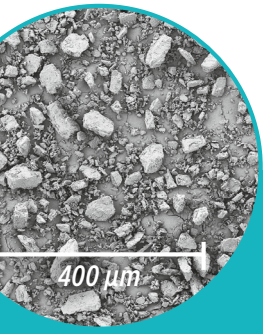
InhaLac® 240

Particle size distribution	
x_{10}	20 – 40 µm
x_{50}	55 – 70 µm
x_{90}	85 – 110 µm



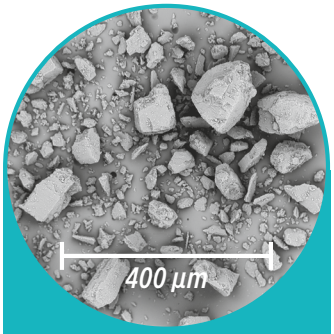
InhaLac® 251

Particle size distribution	
x_{10}	7 – 22 µm
x_{50}	40 – 70 µm
x_{90}	80 – 120 µm



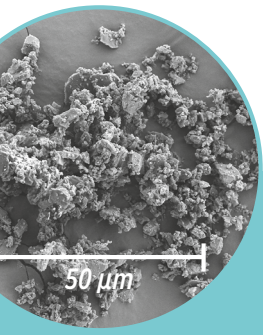
nhaLac® 150

Particle size distribution	
x_{10}	1 – 5 µm
x_{50}	18 – 30 µm
x_{90}	65 – 95 µm



InhaLac® 180

Particle size distribution	
x_{10}	1 – 15 µm
x_{50}	50 – 100 µm
x_{90}	120 – 160 µm



nhaLac® 500

Particle size distribution	
x_{10}	–
x_{50}	NMT 5 µm
x_{90}	NMT 10 µm

Beyond that, a highly experienced team of specialists is waiting to support you in any matter.

DPI Selection Guide

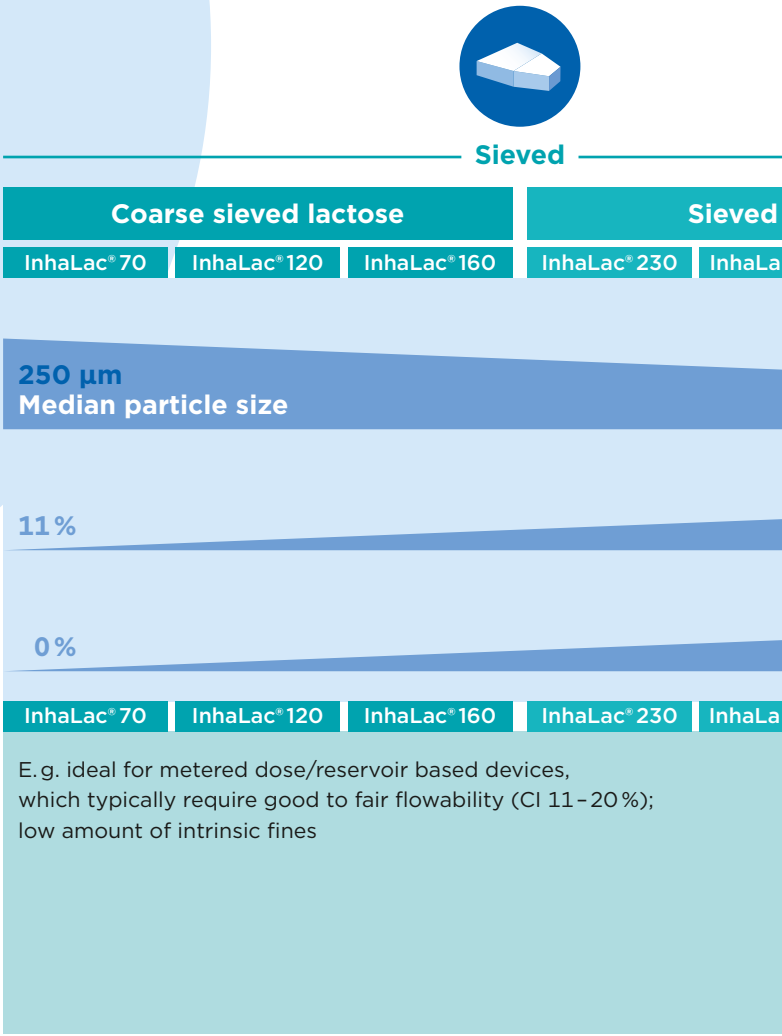
InhaLac® is suitable for use in pulmonary and nasal drug delivery.

Development of a DPI is determined by many aspects **(figure 1)**. MEGGLE offers for each application the right lactose grade, but there is no one fits all solution. The **figure 2** gives some examples for selection of suitable DPI grade lactose. Please contact the MEGGLE experts for further help to choose **your** InhaLac®.

The many different available InhaLac® grades offer you a high flexibility ("tool-box") to achieve the desired product performance.

Benefits:

- Highly controlled powder characteristics
- Low microbial burden including endotoxines
- Customized grades



E. g. ideal for metered dose/reservoir based devices, which typically require good to fair flowability (CI 11 – 20 %); low amount of intrinsic fines

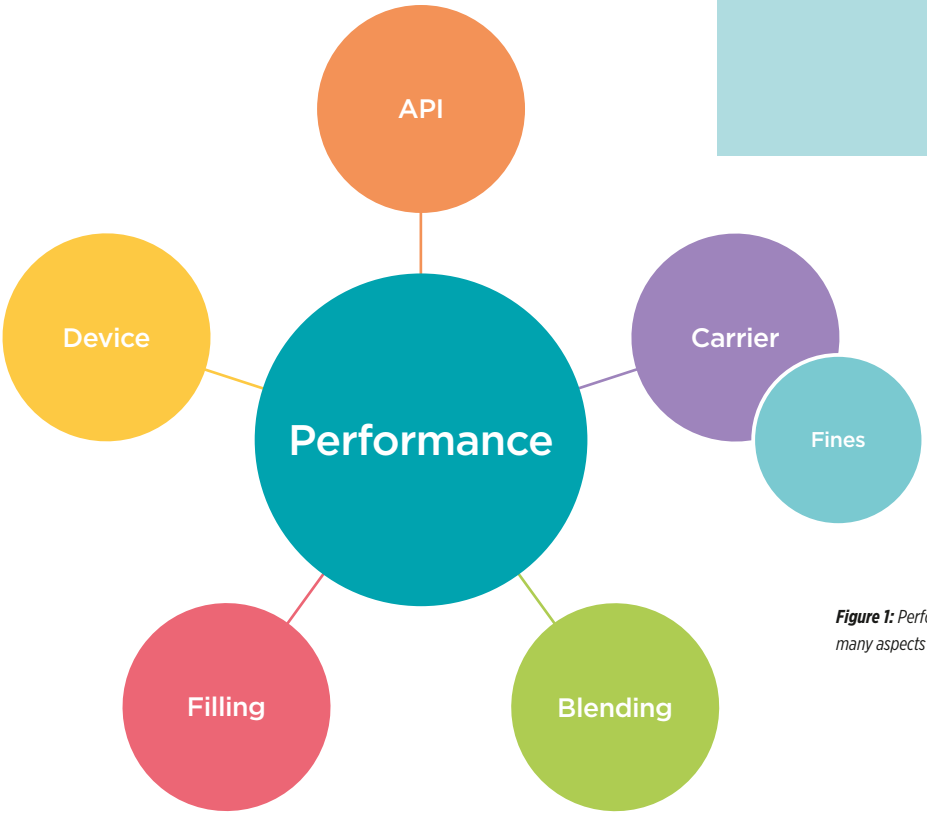


Figure 1: *Performance of a DPI is influenced by many aspects as schematically shown above*

Milled

lactose

Milled lactose

Fine milled lactose

c® 240 | InhaLac® 251 | InhaLac® 180 | InhaLac® 140 | InhaLac® 145 | InhaLac® 150 | InhaLac® 300 | InhaLac® 400 | InhaLac® 500

The difference in particle morphology between sieved and milled should be also considered for selection.

40 %
Compressibility/Carr's index

75 %
Amount of intrinsic fines < 5 µm

c® 240 | InhaLac® 251 | InhaLac® 180 | InhaLac® 140 | InhaLac® 145 | InhaLac® 150 | InhaLac® 300 | InhaLac® 400 | InhaLac® 500

E. g. typcially used for capsule & blister based formulations, for which some cohesivity is required; upper limit depends on the dosing principle and filling volume:

– Dosator principle and drum dosing are both suitable for micro-dosing of a varitie of differnet powders; with durm dosing even very cohesive powders (CI > 38 %) can be filled precicsly
– Dosing disc system might have some limitations regarding micro-dosing precision and powder cohesivitiy (typically CI 20 – 31 %)

E. g. typically used to fine tune DPI performance (typically addition of 2 – 20 %) or for soft pellet formulations

Figure 2: *Filling and selection of device is essential for DPI development, form most common filling principals and devices beneficial powder characteristics are given*

Sieved lactose for inhalation

Sieved inhalation lactose grades consist of single or agglomerated crystals, mostly typically refered to as tomahawk-shaped. Coarser material exhibits a higher share of agglomerate particles.

Sieved InhaLac® grades with good flowability – most suitable for reservoir formulations

InhaLac® 70, the coarsest, sieved product, has a typical median particle size of approximately 215 µm, is virtually free of fines (particles < 5 µm). It shows a narrow PSD and is best suited to cyclone-based inhalation devices. Inhalac® 70 has additionally an agglomerated structure and poses certain pockets and cavities, which makes it very suitable for higher drug loading applications.

InhaLac® 120 (typical median particle size: ~130 µm) and InhaLac® 160 (median particle size: ~110 µm) are also a coarse sieved grade, but finer compared to InhaLac® 70. They have good to excellent flowability (Carr's index ≤15 %) and are well suitable for application focusing e.g. on reservoir devices.

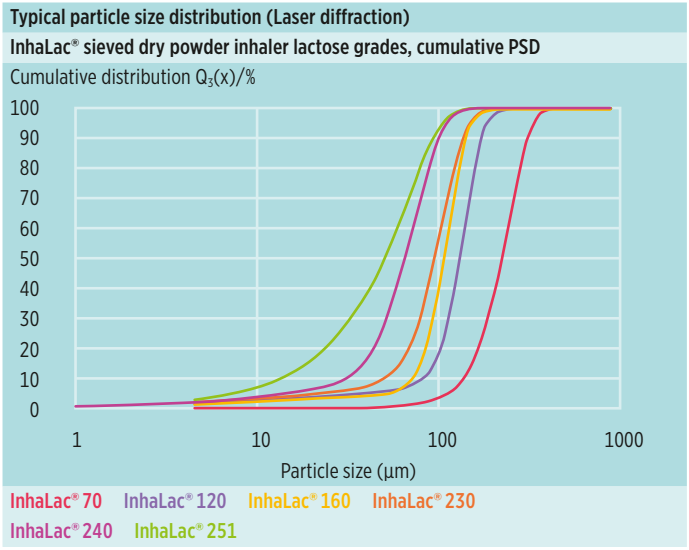
Sieved InhaLac® grades – ideal for capsules or blisters

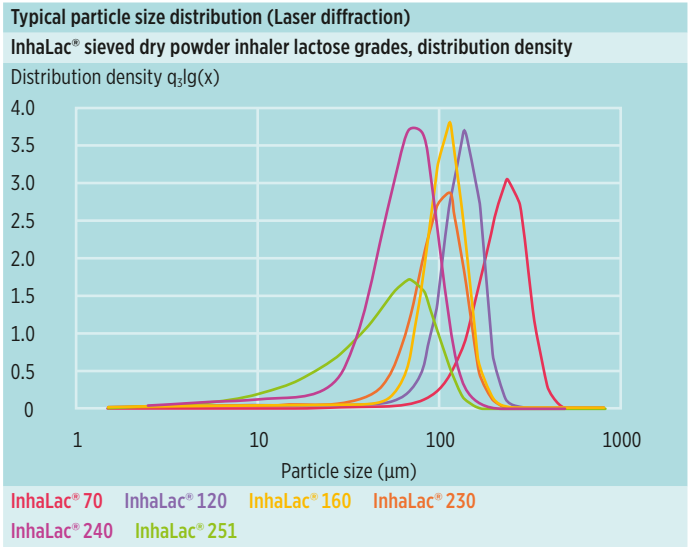
InhaLac® 230 (median particle size: ~100 µm) and a fines content between 3 – 5 %.

Inhalac® 240 is a sieved grade with a fine median particle size (~65µm), but still fair flowability characteristics (Carr's index ≤20 %).

InhaLac® 251, the finest sieved lactose grade, has a median particle size of approximately 50 µm. The product is characterized by a higher fines content. The compressibility/flowability is more comparable to milled grades.

Stay tuned for regularly published application studies and white papers: www.meggle-excipients.com





Figures 3–4: *Typical cumulative particle size and density distribution of MEGGLE's sieved inhalation lactose grades InhaLac® 70, InhaLac® 120, InhaLac® 160, InhaLac® 230, InhaLac® 240 and InhaLac® 251. Analyzed by Sympatec®/Helos & Rodos particle size analyzer.*

Sieved InhaLac® grades							
	Lactose type	**InhaLac® 70**	**InhaLac® 120**	**InhaLac® 160**	**InhaLac® 230**	**InhaLac® 240**	**InhaLac® 251**
		typical	typical	typical	typical	typical	typical
Particle size distribution	x_{10}	140 µm	97 µm	75 µm	50 µm	30 µm	15 µm
	x_{50}	215 µm	137 µm	111 µm	96 µm	63 µm	52 µm
Laser diffraction	x_{90}	295 µm	178 µm	152 µm	144 µm	101 µm	92 µm
	Span $[(x_{90}-x_{10})/x_{50}]$	0.7	0.6	0.7	1.0	1.1	1.5
	% fines < 5 µm	0	1	2	2	3	3

Figure 5: *Specified PSD for MEGGLE's inhalation lactose grades by laser diffraction (in bold letters). Typical values are shown solely for reference.*

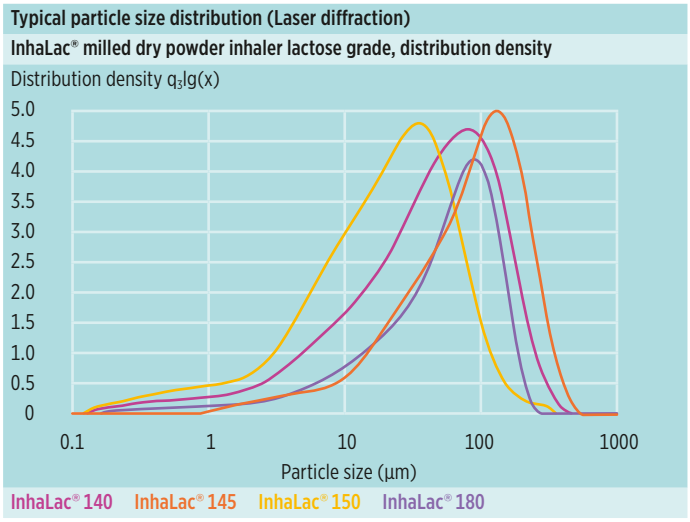
Milled lactose for inhalation

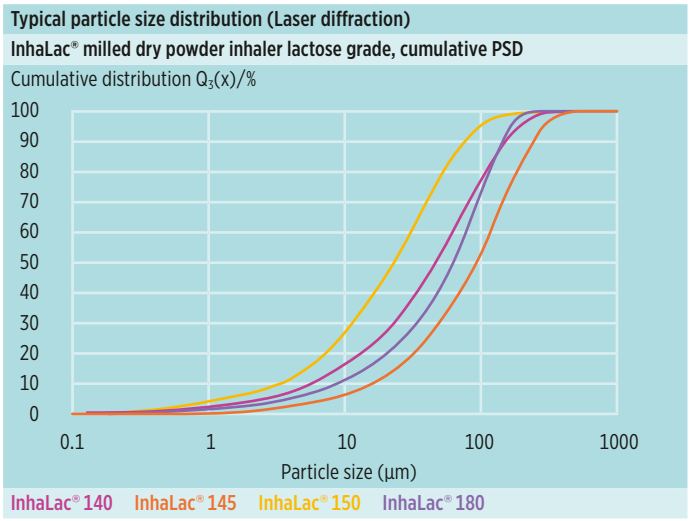
Milled InhaLac® for superior performance during blister and capsule filling

In contrast to the sieved grades, milled and fine milled grades consist of lactose particles that are finer, more irregular and sharp-edged due to the manufacturing by milling. Milled lactose typically has a broader particle size distribution and a smaller mean compared to sieved grades. Therefore, cohesiveness is typically higher (Carr's index ≥ 31%). milled grades are carriers for capsule and blister based formulations with intrinsic amount of fines.

MEGGLE's current portfolio contains four milled carrier grades, for which the PSD characteristics are highly controlled. InhaLac®145 is a middle sized carrier with a mean particle size of 35 µm and approximately 11% of particles below 5 µm. In comparison InhaLac®140 shows a mean of 50 µm and InhaLac®150 has with 24 µm the smallest mean particle size. The possibility to choose between the variety of milled grades allows the formulator to evaluate the design space.

The portfolio is completed by the blockbuster product InhaLac®180. It features the frequently requested particle sizes of x_{10} = 5 – 25 µm, x_{50} = 50 – 100 µm and x_{90} = 120 – 160 µm. InhaLac®180 could be described as a broad lactose suitable for many applications. It contains approximately 6% of intrinsic fine particles below 5 µm.





Figures 6–7: *Typical cumulative PSD and distribution density of MEGGLE's milled inhalation lactose grades, InhaLac® 140, InhaLac® 145, InhaLac® 150, and InhaLac® 180. Analyzed by Malvern Mastersizer 3000 laser diffraction system.*

Milled InhaLac® grades

	Lactose type	InhaLac® 140	InhaLac® 145	InhaLac® 150	InhaLac® 180
		typical	typical	typical	typical
Particle size distribution Laser diffraction	x_{10}	5 µm	4 µm	4 µm	9 µm
	x_{50}	45 µm	34 µm	25 µm	65 µm
	x_{90}	135 µm	102 µm	80 µm	143 µm
	Span $[(x_{90}-x_{10})/x_{50}]$	2.9	2.9	3.0	2.1
	% fines < 5 µm	10	11	14	6

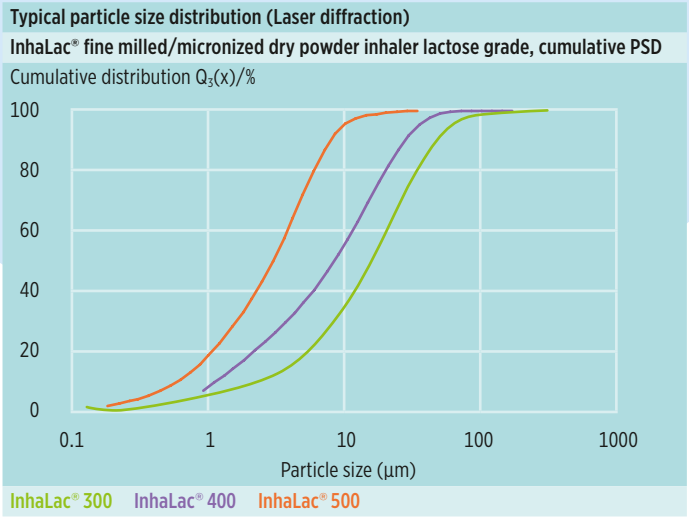
Figure 8: *InhaLac® milled dry powder inhaler lactose grade, distribution density*

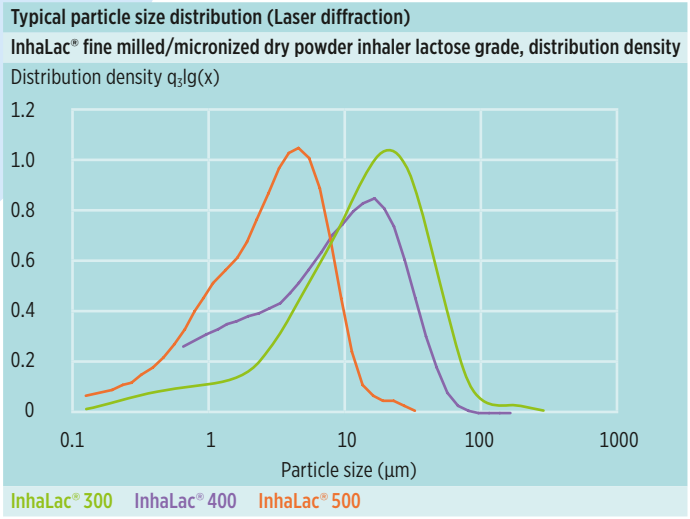
Check out MEGGLE's latest application studies for blockbuster formulations using milled InhaLac® grades: www.meggle-excipients.com

Fine milled lactose for inhalation

A well-balanced proportion of finely milled or micronized lactose in the DPI blend is often important to achieve the required performance of the DPI formulation. This is because fines can advance the deposition via various mechanisms like enhanced aerolidsation/dispergation. However, different quantities and qualities of lactose fines can not only influence the deposition performance of the API, but they may also impact the flowability and further downstream processing of the material.

MEGGLE offers three grades of fines with different characteristics and particle size distribution. This allows the formulator to choose according to requirements and to evaluate the design space. For each formulation, a compromise must be found between the titration of active sites, the adjustment of the performance parameters and the flow behavior of the powder bulk.





Figures 9–10: *Typical cumulative PSD and distribution density of MEGGLE's fine milled inhalation lactose grades, InhaLac® 300, InhaLac® 400 and InhaLac® 500. Analyzed by Sympatec®/Helos & Rodos particle size analyzer.*

Fine milled/micronized InhaLac® grades				
	Lactose type	**InhaLac® 300**	**InhaLac® 400**	**InhaLac® 500**
		typical	typical	typical
Particle size distribution Laser diffraction	x_{10}	2.5 µm	1.2 µm	–
	x_{50}	16.0 µm	8.0 µm	3.1 µm
	x_{90}	50.0 µm	25.0 µm	7.9 µm
	Span $[(x_{90}-x_{10})/x_{50}]$	3.0	3.0	2.5
	% fines < 5 µm	18	38	75

Figure 11: *Specified PSD for MEGGLE's milled and fine milled inhalation lactose grades by laser diffraction (in bold letters). Typical values are shown solely for reference.*

InhaLac® 300 – coarsest fine quality

InhaLac® 300 contains 90 % of particles below 35 – 50 µm (Sympatec) and 40 – 56 µm (Malvern). The reason to add this grade is to modulate the cohesiveness of the powder rather than to adjust the deposition of the API. Cohesiveness is particularly important during encapsulation.

InhaLac® 400 – "the multitalent"
InhaLac® 500 – "the micronized"

MEGGLE's finest grades are used to tune DPI performance in tertiary blends. The addition of fines usually improves aerosolisation performance by enhancing the API detachment or co-agglomeration. InhaLac® 400 and InhaLac® 500 are both fine lactose grades produced under different milling conditions to achieve the desired particle size distribution (PSD). InhaLac® 500 is finer, with 90 % of particles smaller than ≤ 10 µm. InhaLac® 400 is slightly coarser with a typical median particle size of x_{50} = 8 µm.

Typical concentrations of fines ranges from a few percent up to 20 % for InhaLac® 400 and up to 10 % for InhaLac® 500. If the fine content is too high, flowability and further processing may be impaired.

InhaLac® 500 is also an excellent choice for soft pellets. Soft pellets typically consist onyl of API and fines.

InhaLac® characterization

MEGGLE ensures highest quality for critical properties. MEGGLE monitors FRC (functional related characteristics) and supports customers with their expertise. MEGGLE's sophisticated knowledge management allows fast and easy answering of customer questions.

Functional related characteristics

Typical powder technological values

Figure 12 provides additional information on the other functional characteristics of the inhalation lactose grades.

Typical powder technological values					
InhaLac®					
	BET surface (m^2/g)	Density bulk (g/ml)	Density tapped (g/ml)	Hausner ratio	Carr's index (%)
Sieved					
InhaLac® 70	0.2[1]	0.66	0.77	1.17	14
InhaLac® 120	0.3[1]	0.73	0.83	1.14	12
InhaLac® 160	0.3[1]	0.71	0.83	1.17	14
InhaLac® 230	0.3[1]	0.73	0.87	1.19	16
InhaLac® 240	0.3[1]	0.71	0.87	1.23	18
InhaLac® 251	0.4[1]	0.62	0.87	1.40	29
Milled					
InhaLac® 140	0.9[1]	0.58	0.90	1.55	35
InhaLac® 145	1.3[1]	0.54	0.87	1.61	38
InhaLac® 150	1.3[1]	0.51	0.84	1.65	39
InhaLac® 180	0.4[1]	0.63	0.91	1.44	31
Fine milled					
InhaLac® 300	1.5[1]	0.44	0.72	1.67	39
InhaLac® 400	2.2[2]	0.35	0.58	1.66	40
InhaLac® 500	5.3[2]	0.21	0.32	1.52	34

Figure 12: *Typical technological powder values of MEGGLE's inhalation lactose grades (Quantachrome Autosorb-3, Krypton adsorption[1]/Nitrogen adsorption[2]).*

Microbiology

All of MEGGLE's InhaLac® grades have stricter or additional microbial limits compared to the current monographs of the Pharmacopoeia. This guarantees the highest safety in the use of InhaLac® grades in DPI formulations. All microbiological parameters listed in **figure 13** are part of the product specification. MEGGLE has a validated production process with respect to bacterial endotoxines.

Microbiology	
InhaLac®	
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
Escherichia coli	absence/10 g
Pseudomonas aeruginosa	absence/10 g
Staphylococcus aureus	absence/10 g
Salmonella spp.	absence/10 g
Burkholderia cepacia	absence/10 g
Bacterial endotoxins	< 5 EU/g

Figure 13: *Specified microbiological parameters of MEGGLE's inhalation 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.

Packaging and Stability

Packaging material complies with Regulation (EC) No. 1935/2004 and 21 CFR 174, 175, 176, 177 and 178. Stability tests were performed according to ICH guidelines and an ongoing stability program is in place. **Figure 14** provides information on packaging size, material, and shelf life.

Packaging and Stability			
InhaLac®			
	Size	Material	Retest
Sieved			
InhaLac® 70	25 kg	Carton box with PE-EVOH-PE double inliner	24 Months
InhaLac® 120			
InhaLac® 160			
InhaLac® 230		Carton box with aluminium laminated and PE-EVOH-PE inliner	
InhaLac® 240			
InhaLac® 251			
Milled			
InhaLac® 140	25 kg	Carton box with aluminium laminated and PE-EVOH-PE inliner	24 Months
InhaLac® 145	20 kg		
InhaLac® 150			
InhaLac® 180	25 kg		
Fine milled			
InhaLac® 300	15 kg	Carton box with aluminium laminated and PE-EVOH-PE inliner	24 Months
InhaLac® 400		Carton box with aluminium laminated inliner	
InhaLac® 500	6 kg	Carton box with aluminium laminated and PE-EVOH-PE inliner	18 Months

Figure 14: *Packaging and shelf life of MEGGLE's inhalation lactose grades.*

Customization according to your needs

Tailor-made solutions

Decisive factors for the performance of inhalers are particle size, fine particles and flow characteristics of the selected lactose grade. Therefore, precise control and optimization of the particle size plays a key role in efficacy, dosing accuracy and success of your development.

To provide the best support and to be able to fully meet your specific inhalative lactose needs, MEGGLE offers the possibility of development of tailor-made product solutions. Decades of experience and a flexible production set up make it possible to provide partners with highly controlled customized lactose of desired PSD, and with **quality** made in German standards. A good understanding of your requirements are obligatory for a successful project.

Open communication and close collaboration are fundamental for the development of tailored solutions. After first discussions with MEGGLE's Inhalation Experts, MEGGLE will start working on your project. As the development of a new customized product is a challenging task, a well-structured process **(figure 15)** has been developed and a dedicated project manager will be responsible throughout the entire process.

As a result, MEGGLE obtains a well-characterized product, which will fully comply with your individual needs.

Create your blend

Formulation of DPIs relies on carefully crafted blends to achieve uniformity, stability, and optimal performance. The ratio of coarse and fine particles mainly determine the characteristics of powders and directly impact the powder's flow properties, particle size distribution, and overall suitability for effective inhalation therapy. Through precise blending, pharmaceutical companies can create DPI formulations that meet both regulatory requirements and the therapeutic needs of patients.

If needed, MEGGLE can provide DPI Lactose pre-blends. This saves time and resources.

Development process – stage gate model

Customized lactose products

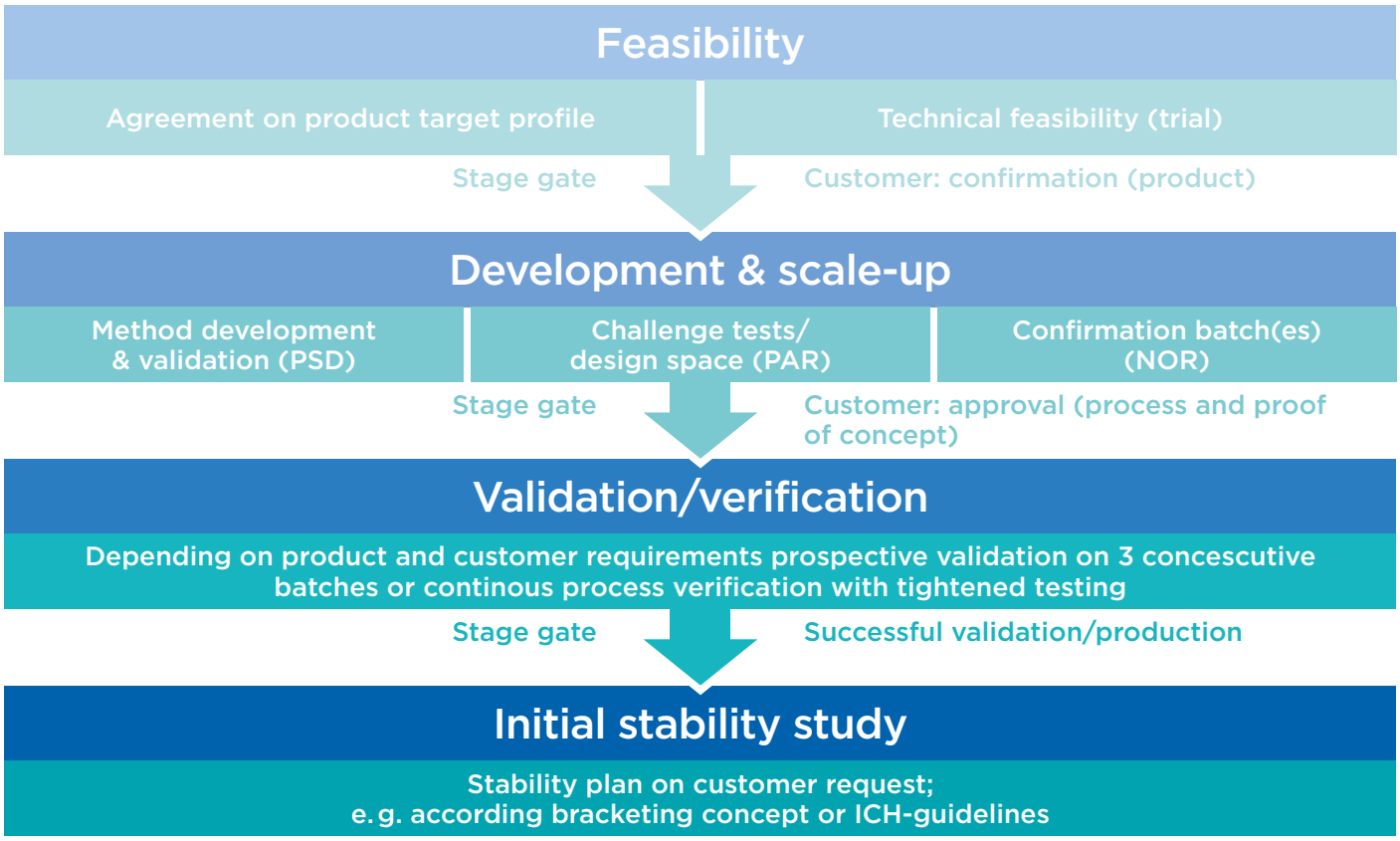


Figure 15: *Stage-Gate-Model for the development process of customized products.*

Experts in dry powder inhalation – technical support

Global service labs, the Innovation & Formulation Campus Munich and partnering with leading research institutions in the field to accelerate your development

With a long history in manufacturing and distribution of excipients for the pharmaceutical industry MEGGLE has a lot of expertise to share. The MEGGLE R&D team works in close collaboration with research institutes and universities all over the world. This provides customers with additional technical and analytical data and support. The capabilities of the MEGGLE experts as well as the product portfolio are continuously being expanded.

MEGGLE can utilize an application lab to cope with any challenge during the development of your DPI formulation.

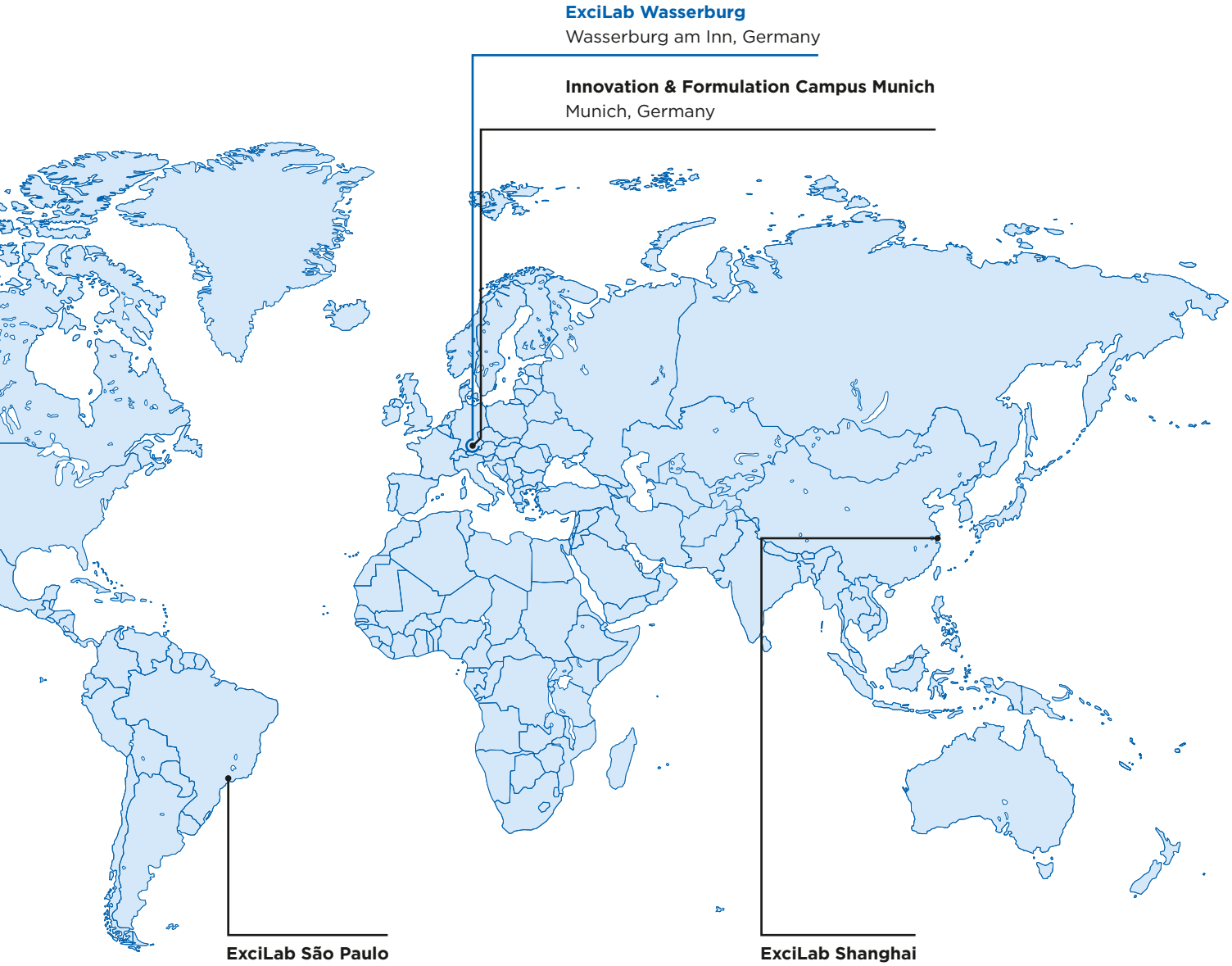
MEGGLE's service and support includes

- Manufacturing of blends
- Advanced powder and blend characterization
- DPI testing (NGI, DUSA)
- Application studies for selected formulations

Why is blending so important and how MEGGLE understands your need

A major challenge is to reach content uniformity for the typically low dose of the API (< 5 % API). In this respect, the current trend towards combining several APIs in one formulation increases the precautions that formulators have to take to ensure blend uniformity. For example, a modern DPI formulation is very often a multi-component system containing 2 or 3 APIS, lactose carriers and lactose fines and additional Force Control Agents such as magnesium stearate. There are several ways to blend these components and a multitude of influencing factors (type of blender, sequence and method of addition of different components, mixing energy), all of which can affect homogeneity and DPI performance.

Therefore, a profound understanding of blends and blending is important. In the fully equipped Innovation & Formulation Campus Munich, the customer's process can be mimicked and helped to elucidate the optimal blending. Reversed engineering and typically analysis like homogeneity, particle size distribution and morphology are suitable as well. The customer is supported in every aspect of formulation development.


ExciLab Wasserburg
Wasserburg am Inn, Germany
Innovation & Formulation Campus Munich
Munich, Germany
ExciLab São Paulo
São Paulo, Brazil
ExciLab Shanghai
Shanghai, China

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Submitted by

MEGGLE GmbH & Co. KG
Business Unit Excipients
Megglestrasse 6–12
83512 Wasserburg
Germany

Phone +49 8071 730
info.excipients@meggle.com
www.meggle-excipients.com

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