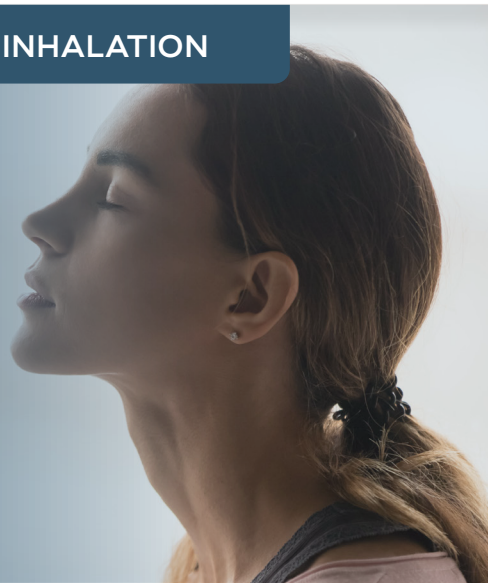
DFE pharma

INHALATION



YOUR SOLUTION FOR Inhalation

As a leader in the field of Inhalation, DFE Pharma offers the pharmaceutical industry the optimal solution for the development of their Dry Powder Inhaler (DPI) drug products.

DFE Pharma has been a partner for companies developing drugs for pulmonary delivery for many years, with a wide range of specialty Inhalation grades of lactose and the option to customize to fit any formulation requirement. Our expertise and three dedicated Inhalation production sites provide a unique starting point for any advanced pharmaceutical inhaled application.

Scan the QR code to know more about our Inhalation portfolio or log on to:

www.dfepharma.com

We are DFE Pharma
A global leader in excipient solutions

We develop, manufacture and supply high quality excipients for use in the pharmaceutical and biopharmaceutical industries. Our products are used for respiratory, oral solid dose, ophthalmic and parenteral formulations. We work closely with pharmaceutical companies around the world by collaborating in original research and supporting their go-to-market strategies.

We are recognized as a true partner to the pharmaceutical industry in helping people around the world live healthier lives. With more than a century of heritage, we strive for customer satisfaction from formulation development support to excipient supply. We provide our customers with comprehensive technical expertise and support to efficiently navigate any regulatory space. Our portfolio consists of filler/binders for oral solid dose, stabilizers for biopharma applications, as well as carriers and stabilizers for Inhalation.

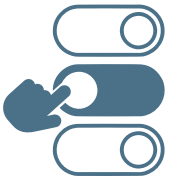
We are DFE Pharma: a global leader in excipient solutions.

Your medicines, our solutions. Moving to a healthier world.

Your solution for Inhalation
by DFE Pharma

DFE Pharma, your trusted partner in DPI formulation development today and tomorrow.

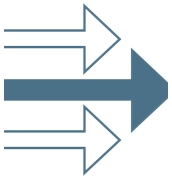
Our Support



Customization

In order to achieve your desired end product performance, a specific particle size distribution (PSD) of your carrier (lactose) is essential. DFE Pharma has unique processing capabilities, resulting in enhanced flexibility to achieve your required PSD parameters consistently.

Find out more on page 4



Pushing the frontiers

An increasing interest is seen in delivering biologics through the respiratory tract to treat pulmonary as well as non-pulmonary diseases. As a consequence new technologies and excipient needs arise for which DFE pharma has offerings available.

Find out more on page 5



Expert Service

Given the complexity of developing DPI formulation and the increasing importance of speed to market, a trend towards outsourcing is observed. DFE Pharma has entered the service industry by leveraging on its extensive Inhalation expertise.

Find out more on page 6

Customized Inhalation solutions

Developing DPI formulations is a complex process. It entails a strong interplay between different parameters: type of drug, device, blending, filling platform, required drug release, etc. The properties of Inhalation grade lactose like flow and fine particles are chosen based upon these parameters. In practice, this means that a specific PSD of an Inhalation grade lactose is likely to be essential to achieve the desired performance of a formulation, particularly for high regulated markets.

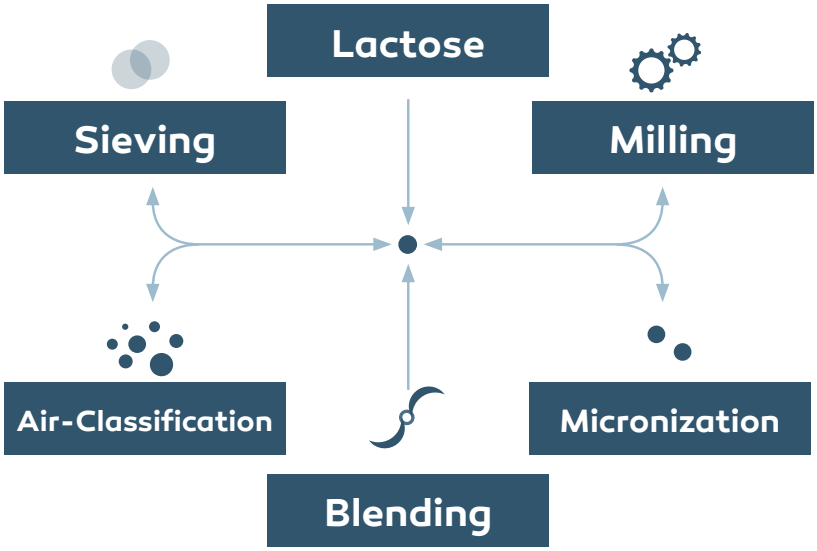


Figure 1. Technologies to obtain different lactose profiles for the inhaled formulation

DFE Pharma

- Four decades of pioneering in the field of Inhalation
- Proven track record in successful formulation development
- Unique and highly flexible production set-up (figure 1)

Offerings

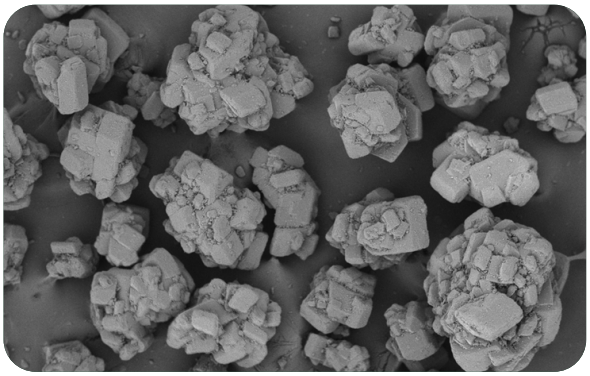
- Enhanced capability to offer
  - Highly controlled PSD
  - Great flexibility in PSD
- Supporting first-time-right, robust inhaled formulations

Pushing the frontiers

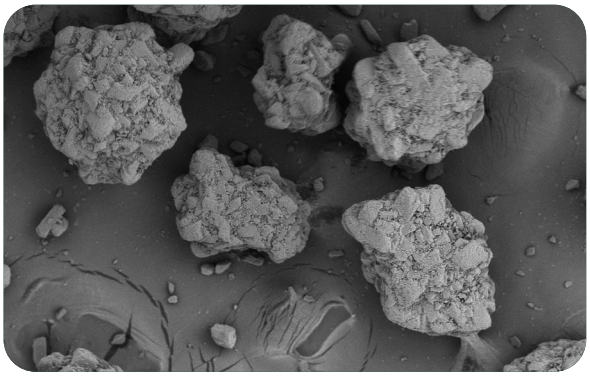
Pulmonary delivery is a non-invasive, patient-friendly route of drug administration. Inhaled medications have shown significant advantages in specific disease treatments outside of asthma and COPD. This combined with the increasing interest in the use of biologics has raised the preference for inhaled therapies.

With the addition of the BioHale® portfolio, DFE Pharma now has an offering for the design of carrier-free DPI formulations and therewith has further enhanced its relevance in the field of Inhalation. BioHale® grades by DFE Pharma can be incorporated in carrier-free formulations to modify the physical properties of the resulting powder.

BioHale®
Because stability matters



BioHale® Sucrose



BioHale® Trehalose Dihydrate

- Approved in parenteral an non parenteral pharmaceutical formulations
- Well established stabilization effect
- Excellent compatibility as it is a non-reducing sugar
- Excellent safety profile, high-purity and low endotoxin
- USP-NF, Ph. Eur, and JPE compliant
- GRAS listed
- Supplied in 1kg and 20 kg drum

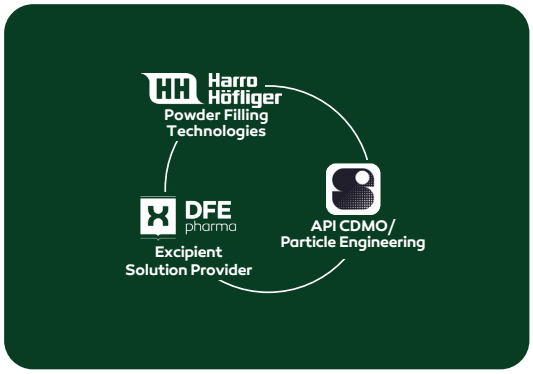
Formulation development services

The respiratory market is continuously evolving. The support needed by pharmaceutical companies has changed, due to a surge in generic medication, a shift in focus of innovators, and increasing importance of speed to market. R&D services and knowledge about DPI formulations have become more important. DFE Pharma, as pioneer in the field of Inhalation, has gained a high level of expertise and has established a proven track record. By leveraging on this expertise and experience, the following services are made available to support your DPI formulation development.

Inhalation Together (INTO)
Accelerating Inhalation Development

From proof of concept studies up to ready for submission formulation development by:

- Overarching formulation expertise with our INTO alliance partners
- Reducing complexity, offering one touch point
- Offering flexible and tailored support



DPI Analytical Services at our state-of-the-art laboratory

- Analytical Method Development
- RLD characterization
- Stability Studies
- IVIVC techniques



Excipient expertise

First hand excipient expertise for inhaled delivery:

- Continuous knowledge building through close co-operation with scientific institutions
- Right technical advice based on latest scientific developments



Inhalation product overview

At DFE Pharma, our brands Lactohale® and Respitose® offer a wide range of milled (irregular shaped particles) and sieved (tomahawk-shaped particles) Inhalation grades of lactose. Both product ranges provide highly consistent Inhalation grades of lactose with an excellent control of particle size during the production, supporting Quality by Design (QbD) studies and robust formulation development. Varying degrees of particle sizes are available allowing our customers to choose the best grade fitting their formulation need.

Three production sites for a secured supply

Respitose® and Lactohale® are produced under GMP conditions at dedicated Inhalation lactose production sites in Veghel (NL), or Borculo (NL) and Kapuni (NZ) respectively. Our plants are designed to meet the strict quality requirements demanded by the FDA and support commercialized end-products in regulated markets. In order to secure supply, DFE Pharma is the only excipient supplier with three production sites on two different continents for Inhalation-grade lactose, providing our customers a secured supply.

Grade	Type	x10 (µm)	x50 (µm)	x90 (µm)	Bulk density (g/L)	Tapped density (g/L)	Carr's Index (-)	Re-test date	Packaging size (kg)	
Lactohale® 100	Sieved	58	132	214	840	960	12	3 years	Cardboard box	20
Lactohale® 200	Milled	9	72	149	650	940	>25	3 years		20
Lactohale® 206	Milled	33	83	154	720	870	17	3 years		20
Lactohale® 230	Milled	1.4	8	23	310	500	>25	3 years		10
Lactohale® 220	Milled	2.5	13	34	370	660	>25	3 years		15
Lactohale® 210	Milled	2.7	16	41	400	680	>25	3 years		15
Lactohale® 201	Milled	3.3	22	56	500	700	>25	3 years		20
Lactohale® 300	Micron-ized		≤ 5	≤ 10	260	520	>25	12 months		12, 5
Lactohale® 400	Anhy-drous	6	102	272	650	920	>25	12 months		20
Respitose® ML001	Milled	4.7	48	147	570	880	>25	3 years	HDPE drum	50
Respitose® ML003	Milled	3.7	38	112	560	850	>25	3 years		40
Respitose® SV001	Sieved	139	226	312	700	810	14	3 years		50
Respitose® SV003	Sieved	31	61	95	630	780	19	3 years		50
Respitose® SV010	Sieved	51	109	178	690	830	17	3 years		50
Respitose® SV014	Sieved	245	365	545	720	810	12	3 years		50

Table 1. Standard offerings of Lactohale® and Respitose® are listed. For customization possibilities, please reach out to us.

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Your medicines, our solutions.
Moving to a healthier world.

DFE Pharma GmbH & Co. KG
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