



RESPIRATORY DRUGS (DPI)

Milling, classifying & mixing.



HOSOKAWA MICRON GROUP

Process technologies for tomorrow.

PROCESS SOLUTIONS FOR DPI FORMULATIONS

A guide to select the proper process equipment.

To ensure proper delivery, inhalation products require active pharmaceutical ingredients (APIs) and carriers to be sized precisely and mixed carefully. When selecting processing equipment, it is essential to consider all aspects of the materials involved and the final product

requirements. Those aspects may include, for example, cohesiveness, flow properties, particle size distribution, the amorphous content of the API and property enhancing additives. The Hosokawa Group provides the DPI manufacturing industry with milling, classifying and mixing solutions.

"PARTICLE SIZE IS CONSIDERED TO BE THE SINGLE MOST IMPORTANT DESIGN VARIABLE OF A DPI FORMULATION."
(A.J. HICKEY)

MILLING & CLASSIFYING

Active Pharmaceutical Ingredients (APIs)

The typical fineness requirement for the API is in the range of 1-5 µm. Besides this challenging high fineness, a steep particle size distribution is required. Hosokawa Alpine offers different technologies to achieve this.

The spiral jet mill is the most common jet mill used for micronisation of fine particles in the pharmaceutical industry. Without movable parts or drives, it is easy to inspect and clean.



> Spiral jet mill

The fluidised bed opposed-jet mill is the first choice whenever a sharp top cut and steep particle size distribution are in focus and a wide range of fineness requirements 4-150 µm should be achieved in one machine.



> Opposed-jet mill

For highly potent APIs, Hosokawa Alpine offers containment integrated milling systems.

Carriers

Carrier production often combines milling, classifying and sometimes mixing to avoid fine dust. The typical fineness is in the range of 40-200 µm with a minimum amount of fine particles.

Pin mills are the proven technology for carrier production. When steeper particle size distribution or higher-end fineness is required, an impact mill with an integrated air classifier can be preferable. To eliminate any significant amount of fine dust still left, a second classifying step can further improve the particle size distribution.



> Fine impact mill/classifier mill

MIXING

Mixing formulations for dry-powder inhalers is a delicate matter. Delivering a fully homogeneous blend, without deterioration of the particles is a prerequisite.

To disperse the actives in the carrier, a certain amount of mechanical energy is required to break the cohesive forces between the particles. Applying too much energy however, results in excessive adhesive forces between the carrier and the actives, restricting the separation during inhalation.

Cyclomix high shear impact mixer

Finding the right balance for the required mixing energy calls for a very efficient mixer. Hosokawa Micron's Cyclomix high shear impact mixer has proven to be perfectly suitable for this application.

The Cyclomix combines impact mixing by knife blades and shear mixing by paddles. It has proven to be suitable for other processes as well, such as coating, bonding, rounding and densification.

Custom production scale

Clinical trial batches can be processed in a mixer of 5 litres. These units are built and documented according to cGMP guidelines. Standard sizes on a larger scale are: 1, 5, 15, 50, 100 litres and larger. Larger production scale units are fully custom-built.



➤ Cyclomix, 5 litres



➤ Mini Cyclomix lab mixer

Key features Cyclomix

- Perfect dispersion of fines
- Accurate temperature control with jacketed vessels
- Creates homogeneous mixtures without lumps
- Reproducible processes
- Filling rates between 30-100%
- CIP- and SIP-able designs

Key features Mini Cyclomix

- Compact table top design
- Exchangeable product bowls, available in 0.1, 1 or 2 litres
- Offline filling and discharging (contained)
- Touch panel operation
- Recipe management, data logging and data export



➤ 75 litre Cyclomix system

PLENTY OF REASONS TO GIVE US A CALL



Combined advantage

The Hosokawa Group has several technology centres, each expert in one or more specific powder processing technologies. Combining this knowledge gives you the benefit of having just one supplier and contact.



Vast experience

Hosokawa has decades of experience in providing solutions for respiratory drugs (DPI) applications. We have references all over the world, including the biggest names in the industry.



R&D/test facilities

Hosokawa has extensive research and test facilities in Germany and the Netherlands, perfectly outfitted to assist clients determining what the best system solution is for their specific process.



Worldwide service

Hosokawa has a very responsive and smoothly operating service department. Our Service Team carries out repair and maintenance services onsite or in one of our fully-equipped workshops.

More information

For detailed information and equipment and system specifications, please contact one of our offices below or visit us online.



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Mixing

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