JETPHARMA

Micronization Expertise

YOUR PROBLEM SOLVER

IN MICRONIZATION

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Dynamic Competence

a forward-looking and proactive attitude

When managing the micronization of an API true added value lies in experience. At JETPHARMA our in-depth knowledge acquired over many years in the field with a wide variety of compounds and an extensive range of customers means we can address different issues and turn them into opportunities to refine specific skills. Whether dealing with research products or industrial quantities, fine or coarse particle size, customer needs are becoming increasingly varied and complex, thus the ability to solve different technical and management problems can make all the difference.

Guided by this vision, today JETPHARMA has become a leader global market player, focused on:

- fast operations and quick lead times
- a customer centred approach
- an open project management model, that translates into fast and efficient feedback
- a flexible approach at whatever level
- team involvement and cooperation in process control
- reporting on progress status.

JETPHARMA

Safety first
our most important commitment

For each and every product JETPHARMA is contracted for, we offer a thorough analysis of the risks involved in the micronization process, including an assessment of exposure levels so as to guarantee the safety of the product and ensure the safety of the staff engaged and the environment.

Safety measures are constantly improved through:

- the assessment of exposure level on every product
- the proper level of containment defined to guarantee safety at every stage of handling
- in-house safety procedures
- regular training of our production team
- regular audits carried out by expert customers
- periodic environmental monitoring
- Glove Box and Half Suit Box Isolators for highly potent drugs
- measurement of the containment level of our isolators (below 25 ng/m^3 - 3rd party verified)
- analyses, dispensing and packaging under inert atmosphere, all in total containment.

JETPHARMA

Cutting-edge Micronization

the key to your success

At JETPHARMA we employ a wide variety of micronization techniques using spiral jet mills, mechanical milling by pin mills, impact mills and hammer mills, treating APIs including steroids, cytotoxics and cytostatics, HPAIs, antibiotics (excluding Beta-lactams) and psychotropic substances.

Moreover, micronization provides the following advantages:

- improved bioavailability
- precise scalability, whereby the micronization process can be replicated on every scale, from a few grammes up to several tonnes
- no batch size limit
- yields higher than 99%
- very fine and extremely precise particle size distribution even with one micronization passage
- thanks to the isothermal feature, our jetmills can micronize any pharmaceutical ingredient, even those with a very low melting point (30-40°C)
- qualified solutions for micronization of Highly Potent Active Ingredients, Cytotoxic and Cytostatic compounds, Inhalation Products, R&D compounds, Generics
- excellent level of segregation of compounds and processes.

JETPHARMA

R&D
redefine & design

Our experience and expertise in particle reduction is also available to support customers' Research & Development programs, for the micronization of very small quantities; these systems employ the very same micronization technology used for larger clinical and commercial quantities.

JETPHARMA's know-how is available to customers in order to:

- conduct specific risk assessments
- identify Critical Process Parameters
- design experiments and establish the extreme parameters to investigate process robustness (DoE studies and/or PAR trials)
- find the optimum solution to meet the customer's Critical Quality Attributes
- allow clients to participate directly before, during and after the actual micronization process
- share the main lines of experimentation (Quality by design approach)
- develop a suitable Analytical Method to determine particle size
- finalize a report on the experimental results to guarantee traceability.

JETPHARMA

Trust and Commitment
indispensable prerequisites

Quality can no longer be defined as an added value: quality is an essential component which is central to the micronization process.
However, a partner with an aptitude for Quality is something different: long experience in audits by Agencies and, above all, by customers has afforded us the opportunity to develop a strong inclination towards quality, a “genetic” predisposition towards improvement.

At JETPHARMA our quality can be clearly seen in our impressive inspection record:

- routine FDA inspections since 1995
- routine inspections by Swissmedic, the domestic Authority
- inspected by MFDS (K-FDA)
- accredited Foreign Manufacturer in Japan since 2007 by PMDA
- over 50 customers cGMP & HSE audits each year means that our quality level is constantly monitored
- our micronization services have their own Integrated Quality, Safety and Environment Management System.

JETPHARMA

Evolving range of services
always a step ahead

JETPHARMA is not just a mere supplier, clients need to be completely sure that active ingredients are under the control of someone they can communicate with, someone who responds to their needs and requests, an expert partner in every respect who is both professional and discreet.

Equipped with safety cabins CLEAN ROOM ISO 8 (Class 100,000), we offer our clients an extensive range of services:

- Jet milling
- Pin milling
- Impact milling
- Hammer milling
- Co-micronization
- DOE Studies
- Risk Assessment
- Sieving
- Blending and homogenization
- De-lumping
- Cryogenic Micronization
- Micronization Technical Trials
- Validation of the micronization process
- PSD Analysis and Analytical method development and validation.

JETPHARMA

High-end Technology
for custom-made solutions

JETPHARMA's philosophy and mission is to provide customers with micronization which, simply, sets the standard. As the owners and developers of their technology JETPHARMA fully understand the specifics of micronization processes anticipating the potential of new and emerging technologies.

JETPHARMA clients can rely on:

- plant design technology that can be adapted to both compounds and objectives
- the most suitable isolators to guarantee safety, whether for R&D or commercial volumes
- robust scale up process spanning the smallest and largest plant models in the development of active pharmaceutical ingredients
- continuous development in expertise, both in R&D and commercial projects
- ever-increasing micronization yields
- ever-decreasing particle sizes.

ASK FOR MORE, WE GIVE YOU MORE

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