



JETPHARMA
Micronization Expertise



Flexibility

is a modus operandi

In response to the increased demand for new high profile services from the global market, JETPHARMA addressed to customers just like a close partner, as if it were a spin-off of the client company.

As a result of such a strategy our company achieved:

- customer loyalty
- continuous development in expertise, both in R&D and commercial quantities
- ever-increasing micronization yields
- ever-decreasing particle sizes
- fast operations and quick lead times
- quality by design approach
- flexible appeal to any non-standard request
- worldwide presence.





Safety first

our most important motto

Jetpharma performs an accurate analysis of the risks connected with the micronization of the different products that the Company is charged to micronize also through an assessment of the exposure level to comply to, in order to guarantee the safety of its staff.

Safety measures are constantly improved through:

- assessment of exposure level on any product
- proper level of containment defined to guarantee safety through every stage of product handling
- in-house safety procedures
- constant training of our production team
- several audits performed by expert customers
- periodical environmental monitoring
- Glovebox and Half Suit Box Isolator for handling highly potent drugs
- measurement of the containment level of our isolators (below 25 ng/m³ - 3rd party verified)
- analyses, dispensing, packaging under inert environment, all in total containment.





Secure micronization

is the key of our success

Micronization is performed by our spiral jet mills, mechanical milling by pin mills, impact mills and hammer mills, and our services are offered for APIs, steroids, cytotoxics and cytostatics, HPAs, antibiotics (excluding Beta-lactams), psychotropic substances.

Besides, micronization provides the following advantages:

- precise scalability in order to reproduce the micronization process on each scale, from few grams up to tons
- no batch size limit
- yields higher than 99%
- very fine and precise particle size distribution with only a single micronization passage
- thanks to the isothermal feature of our jetmills, we can micronize any pharmaceutical ingredients, 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 products and processes.





R&D

redefine & design

Jetpharma offers its experience and expertise in particle reduction to support customers' Research & Development programs, to micronize very small quantities; such systems employ the same micronization technology used for larger clinical and commercial quantities.

Through the usual procedures, but also thanks to a Quality by Design approach, Jetpharma makes available to its customer its experience to:

- conduct a risk assessment
- identify the Critical Process Parameters
- design the experiment and fix the extreme parameters to investigate the process robustness
- find the best solution to meet the customer's Critical Quality Attributes
- let the client directly participate before, during and after the practical implementation of micronization
- share the main experimental aspects
- develop an adequate Analytical Method for the particle size determination
- finalize the reporting activity of results in order to make the investigation process possible.





Trust and Commit

two key words

JP maintains and continuously seeks to improve its integrated Quality, Safety and Environment Management System for its micronization services.

Our successful inspection track record speaks for itself:

- routinely inspected by FDA since 1995
- routinely inspected by Swissmedic, the domestic Authority
- inspected by MFDS (K-FDA)
- accredited as a Foreign Manufacturer in Japan since 2007 by PMDA
- over 50 customer cGMP & HSE audits per year; our Quality level is, in this way, constantly monitored
- Integrated Quality, Safety and Environment Management System for its micronization services.





A Wide Scope of Services

at your complete disposal

Equipped with safety cabins CLEAN ROOM ISO 8 (Class 100,000), we offer our clients a very large range of services concerning the Particle Size Distribution, among which:

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



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