

Particle Size Engineering Through Micronization

Over six decades of experience and >1000 drug compounds



Stability, flowability, dissolution rate and bioavailability are all critical performance parameters impacted by the size distribution of particles.

As part of our integrated product development services, Lonza Small Molecules offers premier particle engineering capability through micronization, from early stage design through scale-up and commercial quantities. We are well versed in particle size reduction to low-micron or sub-micron levels, which plays an important role in effective drug delivery.

Research and development

Feasibility trials
Process and analytical development
Analytical validation
Robustness studies
DoE in GMP or non-GMP environment
Process optimization

Commercial micronization

Micronization services
Process and analytical validation
Quality control
Regulatory support

Full service micronization services

Particle size reduction through micronization is a core capability of Lonza. Decades of jet milling experience with more than 1000 drug compounds has led to substantial capabilities and expertise in micronization and particle classification. Specialized and phase-appropriate jet mills and labs are in place to support early stage development studies. Clinical and commercial scale production leverages the processing and process validation from early stage studies.

Wide-ranging applications

Micronization and nano-milling are used routinely in many applications in solid oral and other dosage forms.

- Enhance bioavailability through dissolution optimization for oral drugs
- Help solubilize and stabilize poorly soluble compounds in the development of multiparticulate systems, as well as drug emulsions and suspensions
- Improve the palatability of a compound
- Generate particles fine enough to be properly delivered to the lungs (for inhalation product development)
- Help ensure absorption of a drug across the skin (in the development of transdermal products)

European Center of Excellence for particle engineering

Lonza's Center of Excellence in Monteggio, Switzerland, provides full services for particle size reduction and control technologies, tailored to our customers' exact needs. With more than 65 years' experience in milling and an excellent inspection history, we have a proven track record for developing robust processes for R&D, pilot and commercial scale. Multiple cGMP production suites and more than 1000 MT capacity/year provide security of supply. Our micronization range includes isolation for highly potent active ingredients, multiple approaches to particle size classification, and specialized nano-milling and cryogenic capabilities.

Monteggio, Switzerland

Capacity	>1000 MT/year
Suites	19
Jet mills	34
Pin/hammer mills	1
High containment	●
Phase-appropriate mills	●

Regulatory registrations/inspections

- US FDA
- Swiss Medic – Agency for Therapeutic Products
- Japan Ministry of Health, Labor and Welfare
- Korea FDA
- Australian DOH – Therapeutic Goods Administration

High potency compounds

Lonza's extensive high capabilities support the particle size reduction of highly potent and cytotoxic compounds. A range of jet milling capabilities are available within an isolator designed to meet containment levels down to 50 ng/m³ at scales for batches of 2 – 100 kg. The isolator provides a negative pressure nitrogen environment, double HEPA filtration, continuous liner with crimp and cut system and CIP capability.

- Demonstrated containment down to <10 ng/m³
- Multiple contained mills, including 2", 4" and 10" jet mills
- Continuous processing via continuous liner with crimp and cut system and interlocked airlock

Nano-milling

The Netzsch Delta Vita media mill, a nanoparticle mill, provides additional size reduction to nano-scale particles for development and production quantities. The Delta Vita is used for wet grinding of batches ranging from 15 mL to approximately 60 L, complementing our bioavailability enhancement suite of technologies. This allows for ample milling energies (or tip speeds) to generate sub-1 µm particles and stabilize them into a suitable formulation.

Cryogenic micronization

Lonza has cryogenic micronization capability in place to accommodate the use of a liquid nitrogen heat exchanger for chilled jet milling at extremely low temperatures (ie -30°C). Cryogenic milling produces a more friable powder, and facilitates greater particle size reduction of elastic/semi-solid compounds than is possible with ambient milling conditions.

Learn more about how Lonza's micronization capabilities can support your development programs and commercial-scale production needs.

Contact us

Get in touch with the Small Molecules team to learn more. We work as one.



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