



Stability, flowability, dissolution rate and bioavailability (BA) are all critical performance parameters impacted by the size distribution of particles. As part of our integrated product development services, Lonza Pharma & Biotech 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.

### 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 premier 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 BA 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 properties 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)

## Research & Development

Feasibility trials

Process & analytical development

Analytical validation

Robustness studies

DoE in GMP or non GMP environment

Process optimization

## Commercial Micronization

Micronization services

Process & analytical validation

Quality control

Regulatory support

# Particle Size Engineering Through Micronization

## Centers of Excellence for Micronization

Lonza has two Centers of Excellence providing 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 2000 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.



### Quakertown, PA (USA)

|                         |                  |
|-------------------------|------------------|
| Capacity                | > 1000 MT / year |
| Suites                  | 11               |
| Jet Mills               | 25               |
| Pin / Hammer Mills      | 6                |
| High containment        | ✓                |
| Phase-appropriate Mills | ✓                |

### Regulatory Registrations / Inspections

|   |
|---|
| US FDA  |
| Swiss Medic — Agency for Therapeutic Products |

### High Potency Compounds

Lonza's extensive high capabilities support particle size reduction of highly potent and cytotoxic compounds. A range of mechanical and jet milling capabilities are available within an isolator designed to meet containment levels down to 1 µg/m<sup>3</sup> at scales from 2-100 kg batch sizes. The isolator provides a negative pressure nitrogen environment, double HEPA filtration, RTP transfer ports and CIP capability.

|   |
|---|
| Demonstrated containment down to <10 ng/m <sup>3</sup>      |
| Capable of multiple mills 2", 4" or 10" jet mills           |
| Continuous processing via RTP ports and interlocked Airlock |

# Lonza

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### Molinazzo, Switzerland

|                         |                 |
|-------------------------|-----------------|
| Capacity                | >1000 MT / year |
| Suites                  | 19              |
| Jet Mills               | 35              |
| Pin / Hammer Mills      | 2               |
| High containment        | ✓               |
| Phase-appropriate Mills | ✓               |

|   |
|---|
| Japan Ministry of Health, Labor and Welfare       |
| Korea FDA   |
| Australian DOH — Therapeutic Goods Administration |

### Nano-Milling

The Netzsch Delta Vita media mill, a nanoparticle milling solution, 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 BA enhancement suite of technologies. This allows for ample milling energies (or tip speeds) to generate sub 1 µm particles and stabilize them into a suitably formulated solution.

### Cryogenic Micronization

Lonza has cryogenic micronization capability in place to accommodate the use of liquid nitrogen gas for chilled jet milling at extremely low temperatures (to -30C). Cryogenic milling produces a more friable powder and facilitates lower 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.**