microsize

Particle Size Reduction Specialists

Particle Engineering and Solubility Optimization Experts

Microsize was created out of a growing demand for solubility and bioavailability enhancements utilizing technologies that can accelerate speed-to-market

Microsize is the largest, **independent**, US-based CDMO specializing in cGMP micronization and particle size control

350+
APIs Processed

10,000+
Production Campaigns

100,000sf
Largest US Micronization Footprint

30+
Years of Experience

25+
Years of Successful FDA Inspections

Located in Quakertown, PA USA	Serving the global community from the heart of the Philadelphia pharma hub
100,000 ft2 of cGMP Facilities Processing over 600MT Annually	Scale & capacity to handle your requirements now and into the future for milling, micronization, sieving and blending applications with ample controlled room temperature (CRT) warehousing
11+ cGMP Processing Suites 2 Process Development Suites	Support your process from early phase development to full commercial cGMP scale (custom dedicated suites available) with electronic batch record (eBR) tracking and management
HPAPIs, DEA Controlled Substance (I-V), and Cryogenic*	Ability to handle your most demanding compounds under the strictest requirements in a safe, secure environment
APIs, Excipients and Other Pharma-Related Specialty Materials	Years of experience handling a wide variety of cGMP materials: “we’ve micronized every layer of the pill”
Subject Matter Expertise Across all Areas of Milling, Co-Milling, Micronization and Blending	Microsize has the experience, expertise and domain knowledge to understand your specific process (CPPs) and optimize it to meet your critical quality attributes (CQAs)
Design and Manufacture own Jet Mills and Critical Infrastructure	We can customize micronization and milling solutions to augment our inventory of jet mills (1” – 30”), turbo screen air classifiers, vibratory/micro feeders and continuous blending technology

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1994

Microsize was founded in 1994 as Powdersize. The newly formed company occupied a 20,000 sf facility and began building jet millsand providing micronization services

PowderSize

1994-2009

1995-present: Capabilities expanded to full commercial scale with design/ build of micronization mills to accommodate seamless scale up from grams to tons

2005: Facilities expanded with a second 20,000 sq ft building

2009: First high potency isolator added

2014-2015

2014: Second manufacturing facility added

2015: Solumatrix dry nano milling added – pilot through commercial

2015

2015: Acquisition of Powdersize by Capsugel/Lonza

Lonza

2015-2021

2015: Additional warehousing added, expanding footprint to >100,000 sq ft

2016: Continued investment in HPAPI containment solutions

2017: Digitization of all QMS systems

2021: Analytical characterization expanded to include solid state characterization

2022

2022: Microsize launched as a spin out from Lonza

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Regulatory Compliance

- 21 CFR 211 cGMP for finished dosage forms
- ICH Q7 Guidelines for API manufacture
- FDA – last inspection July 2023, no findings
- DEA – last inspection 2020
- Global regulatory approvals including Pmda, Health Canada, TGA, MHRA and EMA

FDA

BARDA

U.S. Justice Department Drug Enforcement Administration

Pmda

Medicines & Healthcare products Regulatory Agency

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Health Canada

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Solubility Characterization & Optimization

Microsize is developing an on-site ecosystem of solubility characterization and optimization technologies, in addition to milling & micronization, under one roof to support our clients API & drug product development requirements

Solubility | SPA™ Method

AUSTINPx™ PHARMACEUTICS / MANUFACTURING | KinetiSol™ Technology

SoluMatrix™ | Fine Particle Technology

Analytical Capabilities

cGMP QA/QC
- FTIR Chemical Identification
- HPLC Cleaning Validation
- Loss on Drying (LoD)
- Karl Fischer Titration (KF)
- Particle Size (Malvern & Microtrac)
- Bulk &Tapped Density

Solid State Characterization
- X-ray Powder Diffraction (XPRD)
- Differential Scanning Calo. (DSC)
- Thermogravimetric Analysis (TGA)
- Dynamic Vapor Sorption (DVS)

Imaging and Particle Size
- Scanning Electron Microscope (SEM) Image Analysis
- Polarized Light Particle Size Analysis (Nikon)
- Particle Size (Malvern & Microtrac)

Powder Flow Assessment
- FT4 Powder Rheometer
- Bulk & Tapped Density
- Angle of Repose

Design of Experiment (DOE)
- Design Expert™ by Stat-Ease
- Pairing statistics with science to drive decisions on process parameters (CPPs)
- Building central composite response surface models to predict PSD

Short Term Stability Testing
- 1 – 4 weeks
- Ambient and elevated conditions
- Solid-state characterization and PSD determination

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