



MICROCHEM

The Micronization since 1978

YOUR PERFORMANCE, OUR GOAL



History and vision

The story began a long time ago, in the mid-sixties, when the micronization of active ingredients in pharmaceuticals was practically unheard of.

In those days, fluid **jet micronization** was employed in other sectors, for example in mineral, herbicidal and anti-parasitic products.

Following this same principle and adapting it over time to the increasing demands of the chemical and pharmaceutical industries, micronization began to take its first steps.

In the wake of Microchem's foundation in 1978, micronization became a fundamental aspect of the pharmaceutical industry in Italy.



The principle of complementary skills, so dear to Alberto Martinoli, Microchem's founding engineer, is instilled in the company's DNA: the art of designing and specifying micronization equipment and machinery on the one hand and the art of bringing levels of service to an absolute maximum, on the other.

Quality and service are focal points at Microchem: quality assurance, quality control and careful laboratory analysis are the three pillars that support all Microchem's micronization activities.

By service we mean our capacity to adapt micronization specifications to the client's needs thanks to our staff's constant presence and a flexible and dynamic approach that typifies company culture at Microchem.

Micronization activities

Micronization processes are carried out in Microchem's recently built cleanrooms which have been designed to maximise safety and are qualified to manage processes independently from one another. Each cleanroom is equipped with an independent filtration system.

At Microchem, **micronization is undertaken using a range of fluid jet mills**, conceived and designed by us, which do not require mechanical machine components. Fluid jet mills apply the principles of planned acceleration and particle-to-particle impact. The process eliminates concerns relating to frictional heat due to mechanical action and associated issues regarding mechanical movement.

In fluid jet milling, particle size reduction of an API is achieved through the acceleration of individual particles using a fluid stream of qualified compressed air or pure nitrogen. Using this method, we create a controlled environment in which particle size reduction is achieved. Fluid gases are filtered before and after use.

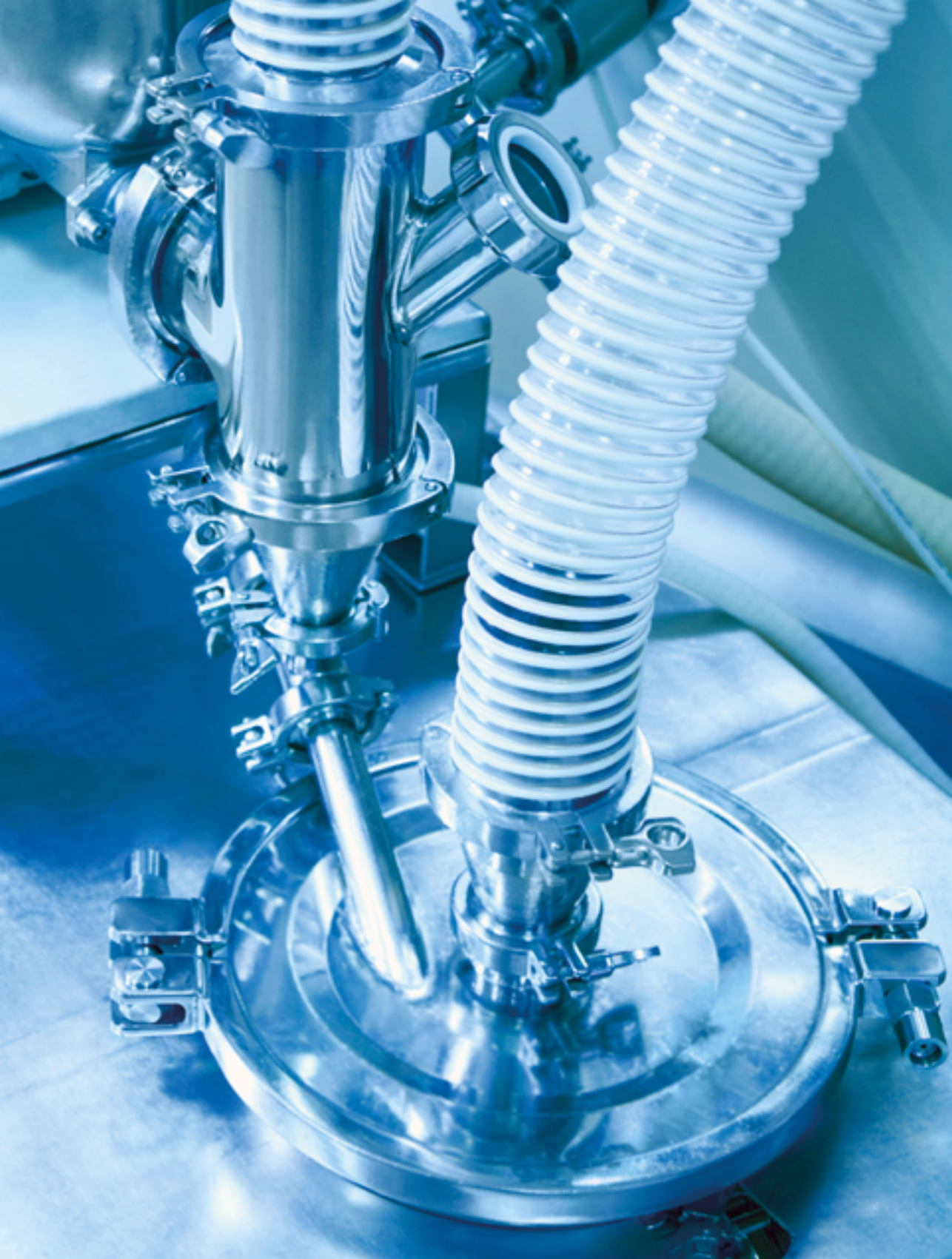


Microchem's plant consists of mills of various sizes enabling the processing of small as well as large batches; this is an ideal arrangement for client's research and development activities. Furthermore, the mills are also designed to obtain high process yields (>99%) and high performance in particle size reduction (<2 micron).

The micronization plants have been designed to guarantee rapid cleaning so as to minimise impact on the micronization times of individual batches; cleaning procedures are also validated.

Complete traceability is ensured for each batch thanks to our batch record registration system: all activities connected with the micronization process and the movements of a batch within the company are recorded.

Any specifications the client requires, such as the type of packaging for the micronized product, can be discussed with our technicians.

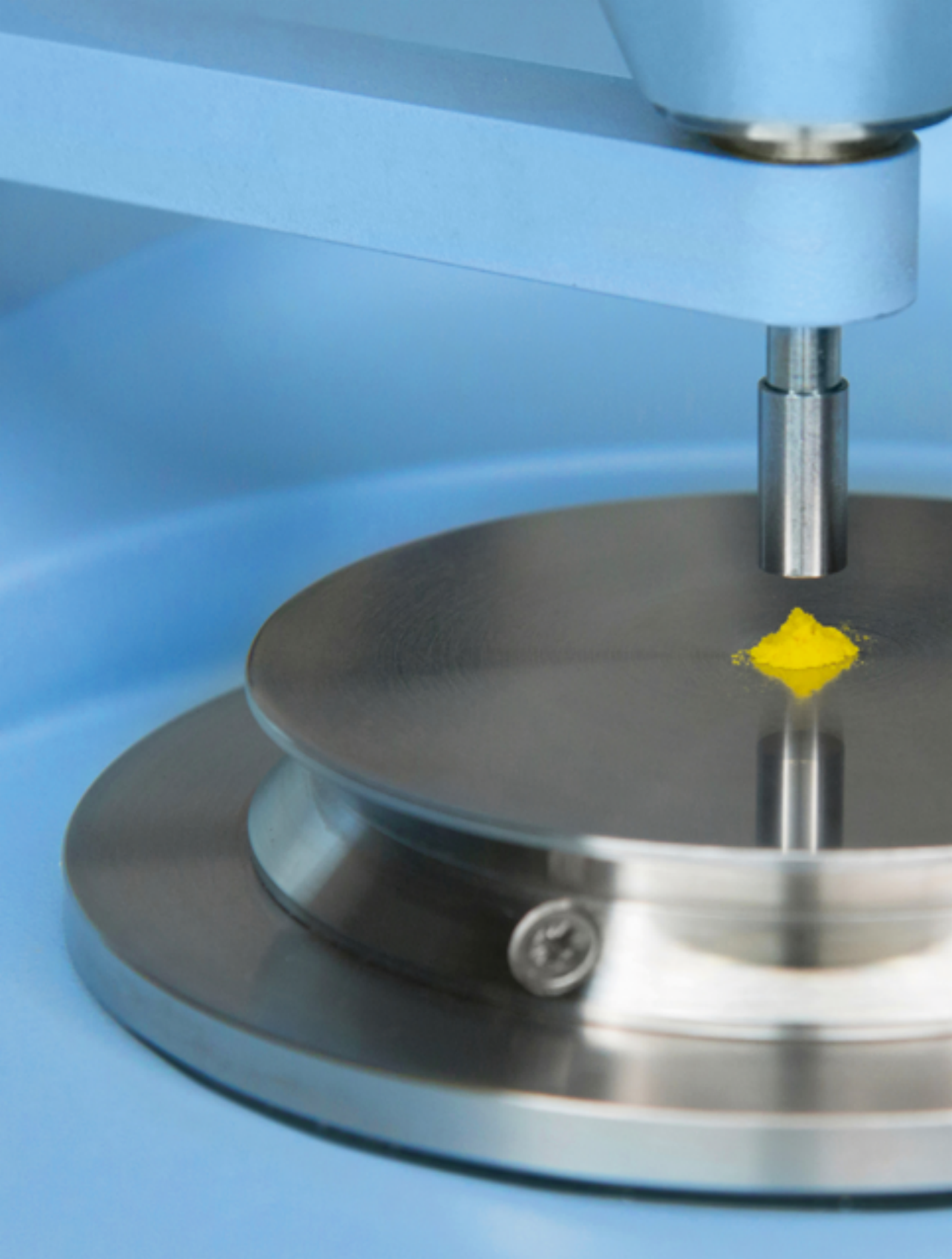


Quality assurance and certifications

Microchem provides on-site laboratory support for process operations. **Our qualified QC staff** can perform all in-process and final product particle size analyses to support micronization processes. Laboratory operations and instrument calibration and control are governed by SOP.

Our laboratory is fully equipped to perform:

- **Laser particle size analysis** with the option to validate the analytical method used
- **Microscopic analysis** in support of the laser analysis, with the capability to take digital photographs of crystals
- **Identity tests**
- **Cleaning performance analysis** and the validation of the analytical method used
- **Environmental microbiological analysis**
- **Particle size analysis** on behalf of third parties including the development and validation of analytical methods.



Microchem undergoes inspections regularly and has been authorised for the micronization of APIs by the Italian Medicines Agency (AIFA). Several inspections have been carried out by the FDA for cGMP, including successful pre-approval inspections. Furthermore, **the FDA has approved numerous products listing Microchem as the contract API micronizer.**

Microchem has obtained accreditation as a foreign manufacturer by the Japanese MHLW and has been inspected by the Korea Food and Drug Administration.

Microchem is ISO 9001 and ISO 14001 certified for quality and environmental management respectively and operates an integrated management system.

ASK FOR MORE, WE GIVE YOU MORE





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MICROCHEM S.R.L.

Via Turati 2
I - 29017 Fiorenzuola d'Arda (PC)

T. +39 0523 98 11 30
F. +39 0523 94 29 35

microchem@microchem.it
www.microchem.it