

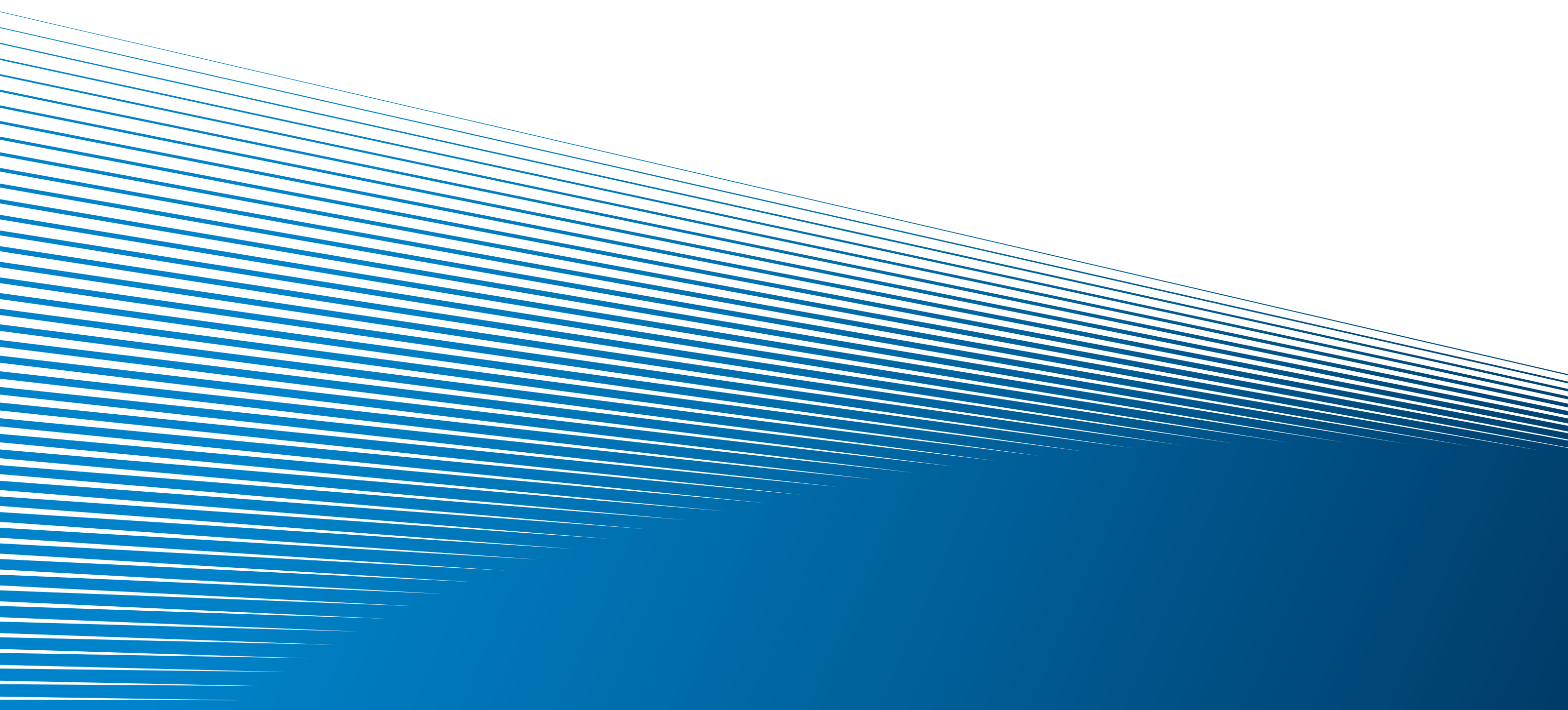
# *MICROCHEM*

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*Micronization Services*

Your performance,  
our goal





## History and vision

It is a story that started a long time ago, around the mid-sixties, when the micronization of active ingredients in pharmaceuticals was more or less unheard of.

In those days, fluid jet micronization was being used, in practice, more often in other sectors, for example in mineral, herbicide and antiparasitic products.

By following this principle and adapting it over the course of time to the increasing demands of the chemical and pharmaceutical industry, micronization started to take its first steps.

At first, the orders came from small and medium-sized companies that found it difficult to set up key departments solely for their micronization requirements, but then, in time, the first “blue chips” joined in.

With the consolidation of MICROCHEM in 1978, and also at the Italian level, micronisation became fundamental. At that time Italy was the number one world market for the production of APIs and even today, it remains in third place, headed only by India and China.

Instilled in the company is the DNA of complementary skills held by its founder engineer, Alberto Martinoli: the art of designing and specifying micronization equipment and machinery and, on the other hand, the art of simply raising service levels to an absolute maximum.

It is quality and service that are the focal points at MICROCHEM: quality assurance, quality controls and careful laboratory analysis constitute the three pillars on which MICROCHEM bases all of its micronization activities.

By service we mean the capacity to adapt the micronization specifications to the needs of the client, the constant presence of our staff and the flexible and dynamic approach that typifies the company culture at MICROCHEM.



## Micronization activities

The micronization activities take place within the recently built cleanrooms. These cleanrooms are qualified to manage processes independently from one another; they are designed to work in safety and there is a net separation between the rooms dedicated to steroid products and those for non-steroid products. Every cleanroom is equipped with an independent filtration system.

At MICROCHEM, the micronization process is performed in various fluid jet mills (MC Jetmill®) which do not require mechanical machine components. Fluid jet mills use the operating principle of planned acceleration and particle-to-particle impact. The fluid jet milling process eliminates concerns relating to frictional heat from mechanical actions and associated mechanical movement concerns.

With fluid jet milling, the particle size reduction of an API is achieved through acceleration of the individual particles using a fluid stream of qualified compressed air or pure nitrogen. With this method, we create a controlled environment to achieve particle size reduction. The fluid gases are filtered before use and after exiting the fluid jet mill.

The plant at MICROCHEM consists of various sizes of mill enabling small as well as large batches to be processed; this is the ideal arrangement to support the research and development activities of clients.

These mills are also designed to obtain high process yields (>99%) and high performance with respect to particle size reduction (<2 microns).

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

There is complete traceability of the batch to be micronized (from entry, right up to return to the client) and batch recording of all the activities connected with the micronization of the batch and its movement within the company.

All the specifications required by the client, such as the type of packaging for the micronized product, can be discussed with our technicians.



## Quality assurance and certifications

MICROCHEM has on-site laboratory support for process operations. Our qualified QC staff perform all in-process and final product particle size analyses to support micronization processes. The laboratory operations are governed by SOP, instrument calibrations and controls.

Our laboratory is fully equipped to perform:

- Laser particle size analysis with the capability to validate the analytical method
- Microscopic analysis in support of the laser analysis, with the capability to take digital pictures of crystals
- Identity test by means of IR
- Cleaning performance analysis with validation of the analytical method
- Environmental microbiological analysis
- Particle size analysis on behalf of third parties with development and validation of the analytical method

MICROCHEM is inspected regularly and has been authorised for the micronization of APIs by the Italian Medicines Agency (AIFA) and undergone several inspections by the FDA for cGMP, as well as successful pre-approval inspections. Our facility has been accepted by the FDA as compliant for the micronization of APIs.

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.



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