

TECNOLOGIA MECCANICA

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The J-20 J-25 J-30 Fluid Jet Micronizers



Introduction

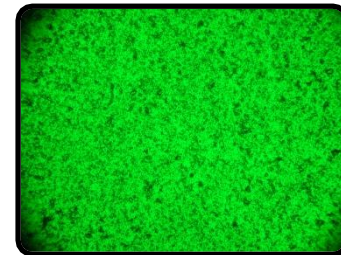
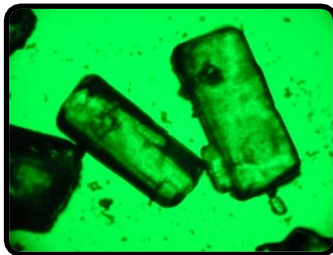
Tecnologia Meccanica is focused on two synergetic activities:

- ▣ Prototypes for R&D
- ▣ Micronization Technology

Our engineering team has prepared in the following pages an overview of the most important characteristics of our Fluid Jet Micronizers designed for Pilot or Small Production purposes.

For presentation of the newest technology, the complete range of our products and engineering performance, and last but not least to go into a more detailed discussion concerning your project and your requirements, we would be pleased to have the opportunity to introduce ourselves to you in our workshop.

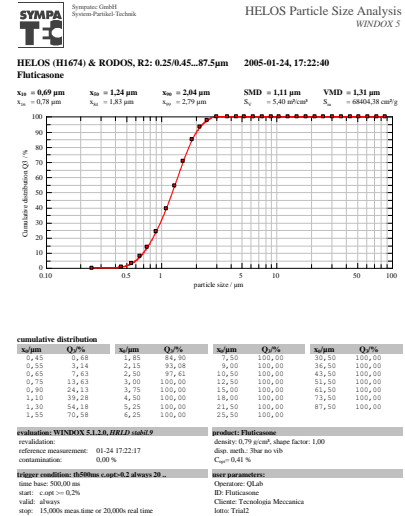
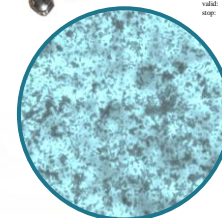
If you are interested in purchasing a micronization system, you will have the chance to perform trials at our testing center and to personally ascertain the performance of our technology.





The Micronization Process

- With the term micronization it is indicated a method of reduction of the dimensions that results in powders under 10 µm in size.
- This technology is extremely important in different industrial fields, in particular in the druggist field where the reduction of the active principles (the so-called API and HPAI) to such dimensions increases exponentially the characteristics of Bioavailability, of Bioequivalence, and the surface area available of the product.
- Tecnologia Meccanica J-20 J-25 J-30 fluid jet micronizers are able to obtain an extremely narrow tight particle size distribution curve of $d_{100} < 5 \mu\text{m}$ (100% below 5 µm) and $d_{99} < 3 \mu\text{m}$ (99% below 3 µm) or even less depending on the nature of the product.





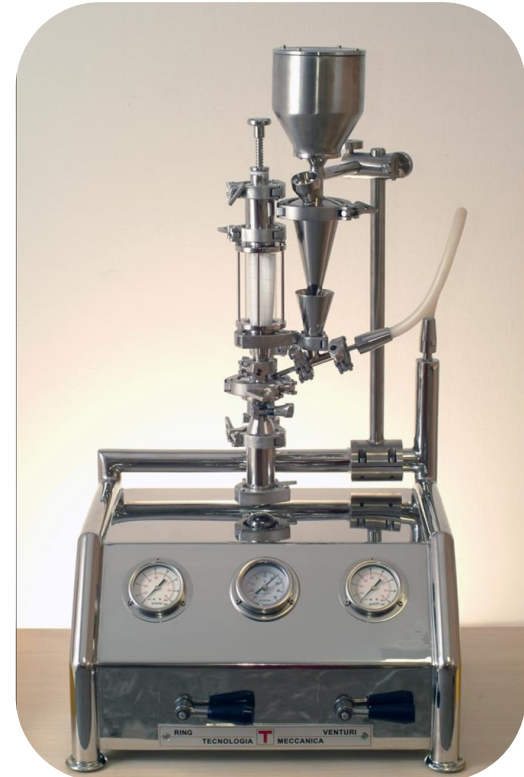
Working Principle

The original principles of jet milling are simple. The powder particles are fed into the milling chamber tangentially through a Venturi system by pressurized process gas, generally air or nitrogen.

The particles are accelerated in a spiral movement inside the milling chamber by a number of nozzles placed around the periphery of the milling chamber.

The micronizing effect takes place by the collision between the slower incoming particles and those already accelerated in the spiral stream. Centrifugal forces retain the larger particles at the periphery of the milling chamber, while the smaller particles exit with the exhaust gas from the center of the chamber by means of a static classifier and are recovered in a collecting container just beneath the jet mill.

The PSD (particle size distribution) is controlled by adjusting two parameters: Pressure and Feed rate.



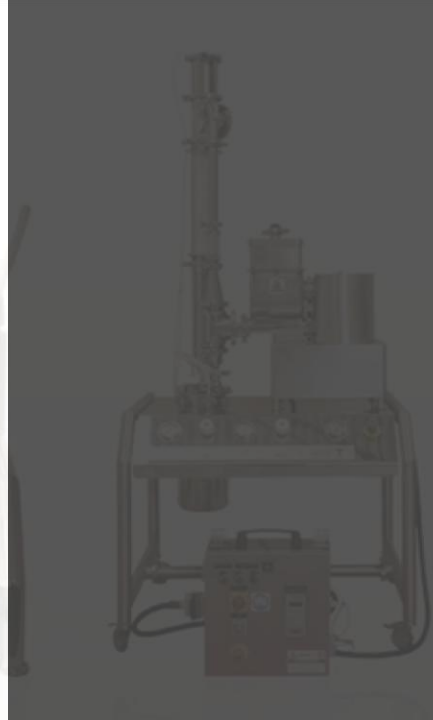


The Machine

- ❑ Versatile and flexible, this modular design makes possible unlimited expanded configurations starting from batches of 0.1 gram up to 400 grams batches on the same machine, assuring better than 99% of product yield.
- ❑ Smart pressure technology which allows higher pressure to the perimeter jet nozzles and lower pressure to the Venturi creates energy savings and a narrow tight psd.
- ❑ A wide range of options for the geometric variation of the milling chamber and of the jet nozzles.
- ❑ High pressure technology with capability for particles size distribution below 1 micrometer.



Fluid Jet Mill designed for r&d.



Technical Specification

T General Provisions

Working environment

Our micronization unit can be installed in ambient conditions without explosion risks (non classified zones). The unit is also built to be easily assembled, disassembled and easily cleaned. Furthermore it offers a very high degree of resistance from powder penetration.

Principles of design

The unit has been designed to mainly work with several types of food and pharmaceutical products. The machine is not planned to work with flammable products or products that can generate explosive atmospheres. It is conceived in order to avoid product contamination, considering both normal use and in the case of a malfunction. The unit can be cleaned with most common detergents, solvents and alcohols.

Applied standards

The unit has been designed and constructed in compliance with the following standards:

- Machinery Directive (2006/42/EC) and any relevant provisions.
- Electromagnetic Compatibility (89/336/EEC) and Low Voltage Directives (73/23/EEC) and subsequent amendments.
- cGMP guidelines.

Ergonomics

The unit is mounted on a mobile supporting table on which an easy to read control system is provided, with the positioning of the components designed to easily allow the cleaning, assembly/disassembly and charging/discharging operations.



Equipment Specifications

Jet Mill

The completely accessible fluid jet mill is composed of a milling chamber in three main parts, an open manifold, a static classifier and a Venturi product induction line. All these components are easily assembled and disassembled using tri-clamp connections with no tools. This fluid jet mill family has been designed to exchange a big part of its components between the different milling chambers, since this money saving configuration makes it possible to upsize or downsize very easily.

Collecting container

The product is collected directly beneath the fluid jet mill in a stainless steel product container, which is easily disassembled by means of fast opening sanitary clamps.

Filtering unit

One filter sleeve is placed inside a stainless steel pipe with an in line sight glass (360°) and a manual shaking system. The pipe as well as the sight glass are easily disassembled by means of fast opening tri-clamps.

Table and manifold

The whole unit is mounted on a stainless steel supporting console. On the console the following instruments and controls are built in:

- two pressure gauges (1-16 bar)
- one thermometer (-30°C +50°C)
- two ball valves for process gas
- one main process gas inlet (1½" tri-clamp)



Technical Data

■ Milling Chamber: J-20

Process gas at 7 bar = 0.08 m³/min (2.82 CFM)

Process gas at 12 bar = 0.20 m³/min (7.06 CFM)

Estimated capacity = from 0.50 to 100.00 g/hour

■ Milling Chamber: J-25

Process gas at 7 bar = 0.14 m³/min (4.94 CFM)

Process gas at 12 bar = 0.24 m³/min (8.47 CFM)

Estimated capacity = from 5.00 to 300.00 g/hour

■ Milling Chamber: J-30

Process gas at 7 bar = 0.17 m³/min (6.00 CFM)

Process gas at 12 bar = 0.28 m³/min (9.89 CFM)

Estimated capacity = from 5.00 to 600.00 g/hour

Design pressure

The fluid jet mill is designed for a working pressure of 12 bar (tested at 18 bar).

Gas design temperature

The mill is designed to work with a gas temperature between 0°C and 50°C.

Environment design temperature

The mill is designed to work in an environment between 0°C and 40°C.



Manufacturing Materials & Finishes

- All metallic parts coming into contact with the product are made in Aisi 316L (EN 1.4404) stainless steel, all other metallic parts are made in Aisi 304L (EN 1.4307) stainless steel.
- The anti-static filtering sleeve is made in Polyester with stainless steel wire.
- Sight glass contact part is in borosilicate.
- Gaskets in contact with the product are manufactured with silicone, ptfе or kaflon. Other gaskets are manufactured in epdm or ptfе.
- All surfaces in contact with the product are mirror polished ($Ra \leq 0.25 \mu\text{m}$), surfaces not in contact with the product are satin or mirror polished 220 grit ($Ra \leq 0.8 \mu\text{m}$).
- Feeders, motor and gear-reducer are in aluminium (non contact parts).
- Feeder control panel in Aisi 304 (EN 1.4301) stainless steel, satin finished.
- Characteristics of materials and finishes not corresponding to the above mentioned description are indicated in the technical specification.



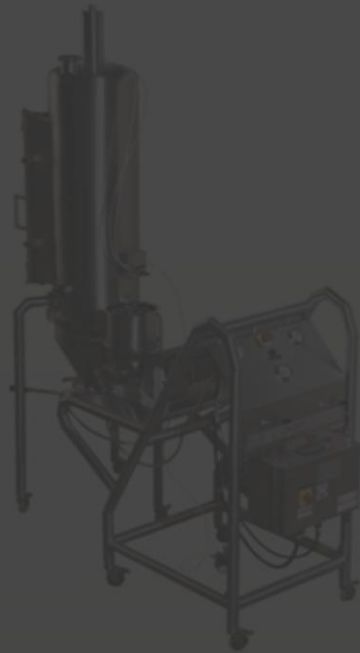
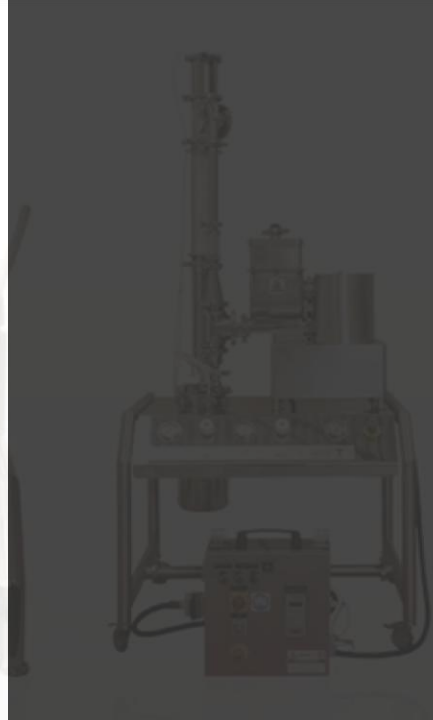
Documentation

Project Book

- CE declaration of conformity
- Use and maintenance manual with product guarantee, instrument calibration certificates, and general assembly drawings
- Spare parts manual
- Manufacturing book including
 - hydraulic test certificate
 - dye penetrant certificate
 - roughness test certificate
 - dimensional inspection certificate
 - material certificate 3.1 as per Uni En 10204 for metallic contact parts
- FAT report

Additional documentation

- Additional copies of the project book
- PED certificate for pressurized vessels
- IQ/OQ protocols
- FAT/SAT
- Micronization protocol
- Training note



Options



Milling Chamber

- Adjustable nozzle angles

Sets of different nozzle angles are available to achieve the required fineness value in which case the complete nozzle ring must be exchanged.

- Elliptical milling chamber

This option makes it possible to keep the fluid jet flow totally contained into an elliptic field of forces, making it possible to achieve extremely narrow particle size distributions.

- Static classifier

Multipurpose - Reverse vortex effect - Unclogging effect, depending by product nature, the specific classifier enhances product flow and productivity.

Technical details are described in the machine Data Sheet.



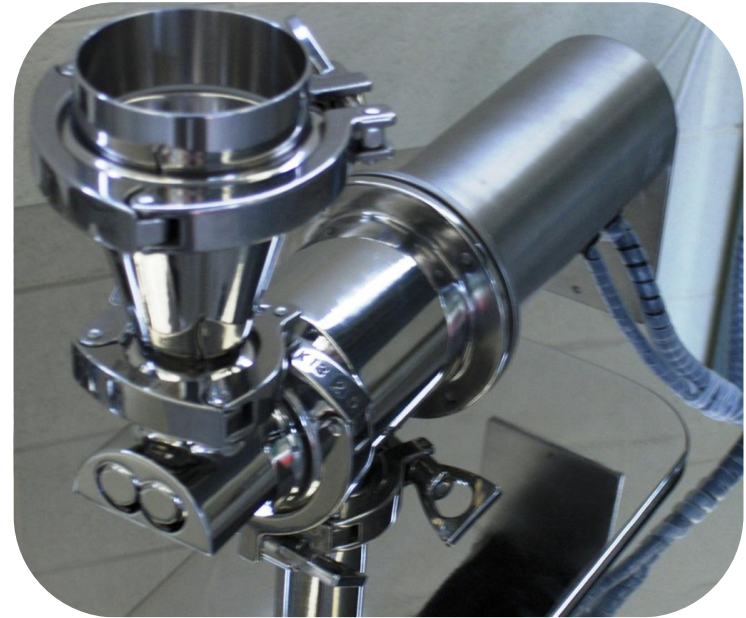


Feeders

Product feed rate is one of the most important micronization parameters, consequently a wide choice of feeders is a must.

- Custom Feeders:
 - DS20
- Retsch Feeders:
 - DR100

Complemented by a wide choice in size of hoppers and hermetically sealed hopper lids.



Technical details are described in the machine Data Sheet.

T Collecting Containers

- ▣ product collecting bin, 0.010 liters, stainless steel
- ▣ product collecting bin, 0.200 liters, stainless steel
- ▣ product collecting bin, 0.400 liters, stainless steel

Technical details are described in the machine Data Sheet.





Milligram Kit

This kit permits the process of preliminary micronization trials on New Chemical Entities, assuring high safety conditions since the overall dimension of the milling chamber is less than 2.5 cm³:

- minimum batch 10 mg
- initial granulometry <500 micrometer
- final granulometry d100<5 micrometer
- feed rate 5 g/h
- max process gas pressure 12 bar

This option turns your equipment into a complete perfect laboratory scale-up pilot unit, able to follow the complete development process of a micronized drug from laboratory until its production stage.

Technical details are described in the machine Data Sheet.





Balance Line

This option provides hermetic sealing of the whole unit so that the product is in contact only with the process gas. It is comprised of:

- T connection seal for the twin screw
- Tee-connection at process gas outlet
- Silicone piping

Balance line could be also supplied in stainless steel for micronization with cold process gas.



Technical details are described in the machine Data Sheet.



Filtering Unit

A properly engineered filtering unit is fundamental to the micronization process, to the product yield and to the productivity. Three different filtering units are available:

- ▣ 75 cm² Single bag sleeve
- ▣ 135 cm² Single bag sleeve
- ▣ External mini Cyclone Filter

in combination with three different filtering media:

- ▣ P65
- ▣ P100
- ▣ P200

All are supplied with a mechanical pneumatic up-down shaking system.

Technical details are described in the machine Data Sheet.



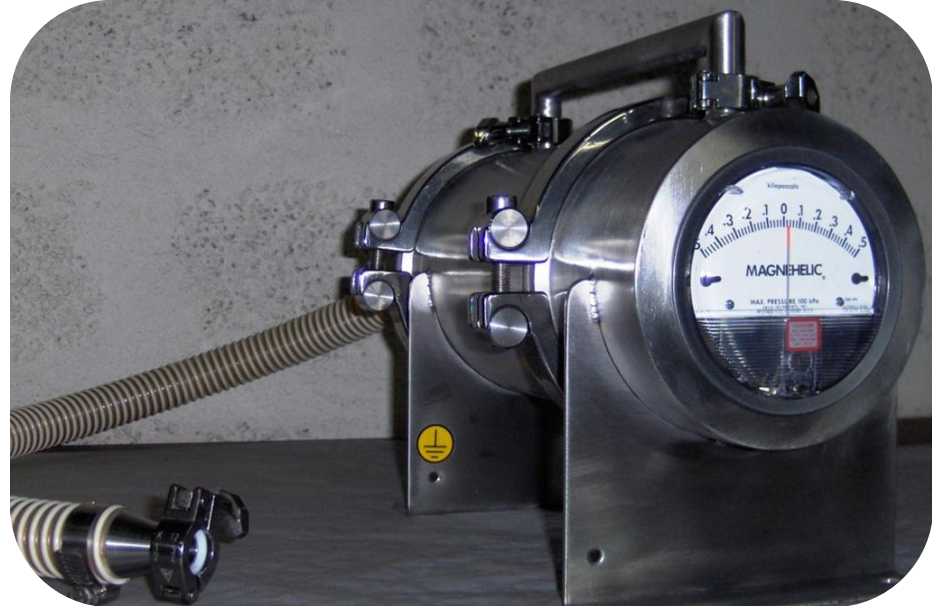


Final Filtering Unit

Hepa final filter to recover the very ultra fine particles that pass through the filtering sleeve, comprising:

- Hepa push-push filter H13 (MPPS) EN 1822
- Flexible pipe in PUR or in Stainless Steel to connect the Hepa filter housing to the expulsion TEE
- 3/4" tri-clamp for the exhaust gas outlet

Technical details are described in the machine Data Sheet.



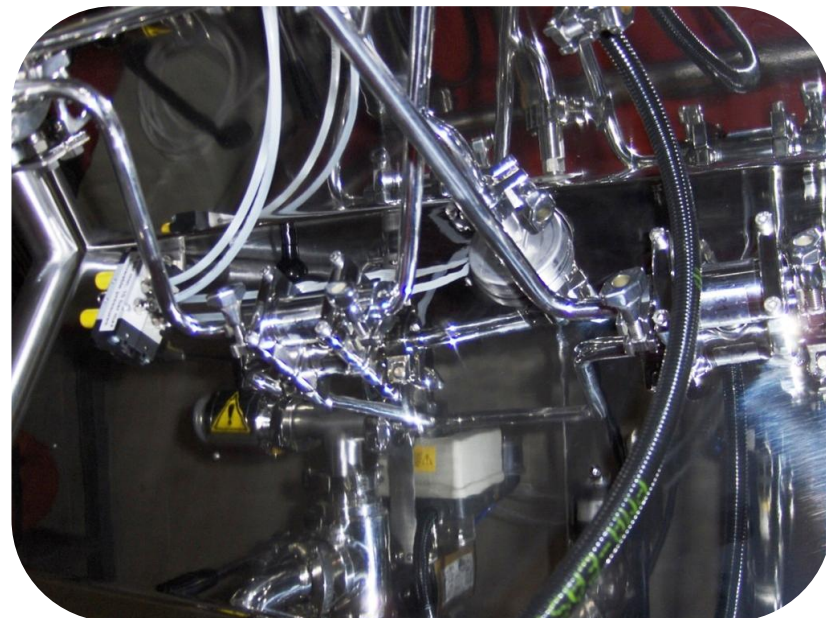


Explosion Proof

Many pharmaceutical products are potentially explosive in their fine dry powder state. The technique of explosion protection to be used for a particular application will very much depend on the explosive nature of the product and also the location of the equipment. We can supply three different methods of explosion protection:

- ▣ Containment
- ▣ Inert gas blanketing
- ▣ Venting

Our micronizing systems could be supplied entirely or partly in Atex version.



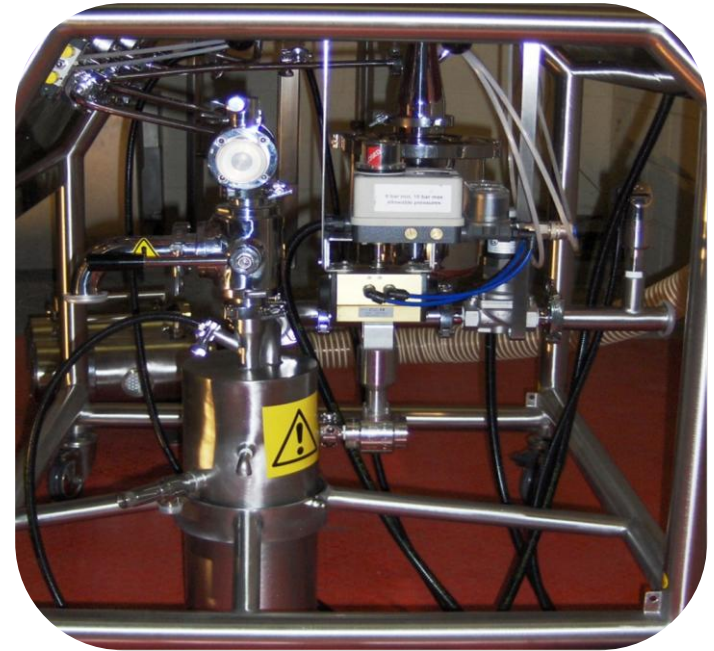
Technical details are described in the machine Data Sheet.



Cold / Cryogenic Execution

The complete micronizing line can be supplied with a special execution suitable for working with cold process gas, generally cryogenic nitrogen.

Depending on the sophistication of the micronizing line, many components are completely reengineered in order to guarantee proper function according to the process gas temperature and pressure.



Technical details are described in the machine Data Sheet.



Process Gas Generator

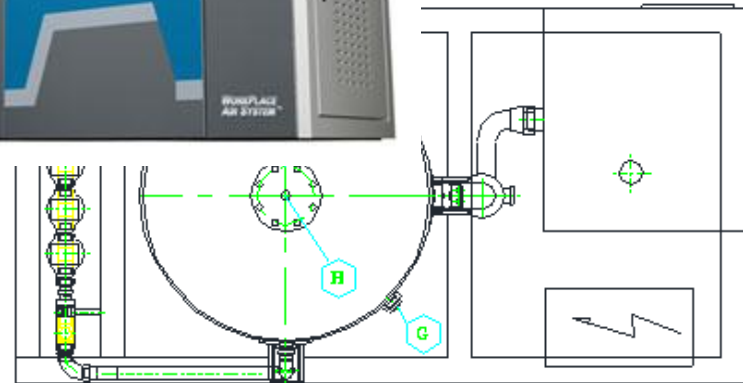
Skid mounted system for feeding treated process gas to the jet mill, this system could be supplied in many different versions. Custom designed according to the client's requests, for many different fluid media such as air, nitrogen, with cryogenic system etc...

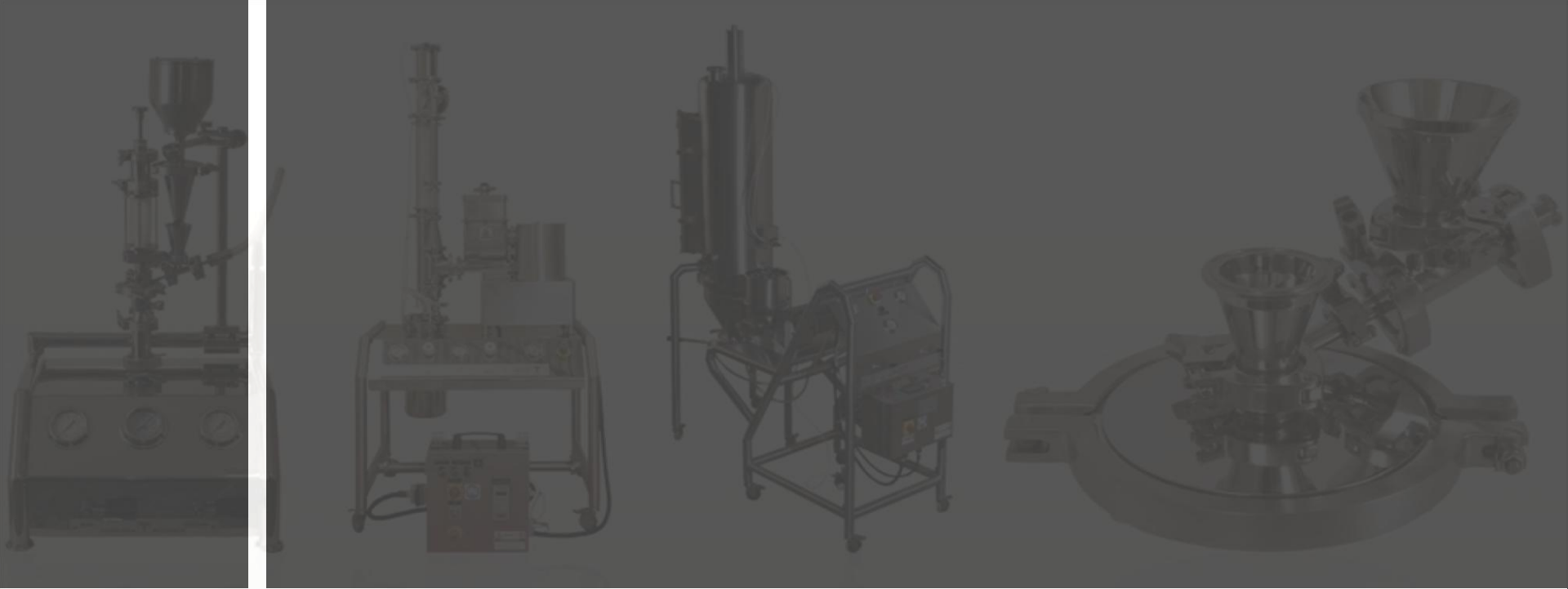
The system is made up by the following components:

- ❑ Compressor (screw or oil-free, 10 to 15 kW)
- ❑ Dryer
- ❑ Pressure vessel (storage tank)
- ❑ Reducing valve
- ❑ 5 μm cartridge filter, 1 μm cartridge filter, 0.01 μm cartridge filter, Active carbon cartridge filter
- ❑ On-Off main valve



Technical details are described in the machine Data Sheet.





Commercial Conditions



Guarantee

- Tecnologia Meccanica Srl guarantees all the supply against failure due to faulty design and/or workmanship for a period of 12 months from the date of start-up, but in any case for not more than 18 months from the date of delivery of all materials.
- Tecnologia Meccanica Srl considers excluded from the guarantee all the parts subjected to normal wear, to chemical and electro-chemical corrosion due to external agents and to damage caused by customer's lack of care or by the use of incorrect raw or auxiliary materials.
- The above guarantee means that Tecnologia Meccanica Srl will modify, repair and eventually replace the defective parts as soon as possible and at its charge, excluding expenses for removal, installation, transport and packing of the original parts and the replaced ones.
- Warranties cannot be called upon, if mechanical commissioning on site is not performed by our technicians.
- Any other obligation or liability for direct or indirect damages is not included, except for the repairs or replacement of defective parts as mentioned above.



Partners

Tecnologia Meccanica works worldwide in cooperation with:



for process gas technology and process gas supply