

TECNOLOGIA MECCANICA

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The J-100 J-125 J-150 Fluid Jet Micronizers

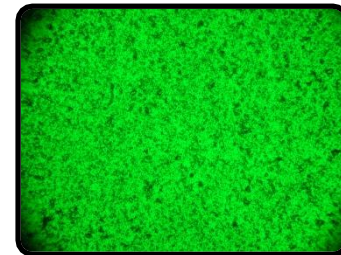
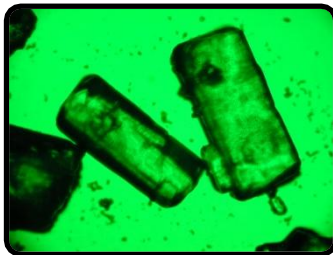


Introduction

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 Small Production purposes.



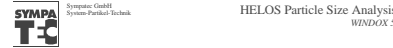
For presentation of the newest technology, the complete range of our products and engineering performance, and last but not least to go into a more detailed discussion concerning your project and your requirements, we would be pleased to have the opportunity to introduce ourselves to you in our workshop.

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.



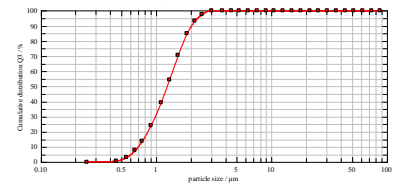
The Micronization Process

- 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-100 J-125 J-150 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.



HELOS (H1674) & RODOS, R2: 0.25/0.45...87.5 μm 2005-01-24, 17:22:40

Fluorescence:
 $N_{90} = 0.69 \mu\text{m}$ $N_{50} = 1.24 \mu\text{m}$ $N_{10} = 2.04 \mu\text{m}$ $SMD = 1.11 \mu\text{m}$ $VMD = 1.31 \mu\text{m}$
 $N_{95} = 0.78 \mu\text{m}$ $N_{55} = 1.43 \mu\text{m}$ $N_{15} = 2.79 \mu\text{m}$ $S_N = 5.40 \text{ m}^2/\text{m}^3$ $S_{90} = 68404.38 \text{ cm}^2/\text{g}$



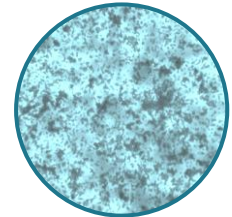
cumulative distribution							
$x/\mu\text{m}$	Q _x %	$x/\mu\text{m}$	Q _x %	$x/\mu\text{m}$	Q _x %	$x/\mu\text{m}$	Q _x %
0,15	0,00	1,15	99,00	2,15	100,00	3,15	100,00
0,55	3,14	2,15	99,08	4,15	100,00	36,50	100,00
0,65	7,63	2,50	97,81	12,50	100,00	43,50	100,00
0,75	13,63	3,00	100,00	12,50	100,00	51,50	100,00
0,90	24,33	3,75	100,00	15,00	100,00	61,50	100,00
1,10	39,28	4,50	100,00	18,00	100,00	73,50	100,00
1,30	54,28	5,25	100,00	21,00	100,00	87,50	100,00
1,55	70,58	6,25	100,00	25,50	100,00		

evaluation: WINDOX 5.1.2.0. (R2)Z2 (04)E9
 evaluation: 01-24 17:22:17
 contamination: 0,00%

filter: conditions: 15000ms cap: R2 always 20...
 time base: 2000,00 ms
 start: c apt => 0,2%
 valid: always
 stop: 15.000ms max time or 20.000ms real time

product: Fluorescence
 density: 0,79 g/cm³ shape factor: 1,00
 disp. meth.: But so vib
 C₉₀ = 0,41 %

user parameters:
 Operator: G.Lab
 EQ: Fluorescence
 Client: Tecnologia Meccanica
 Inno: Tru2





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.



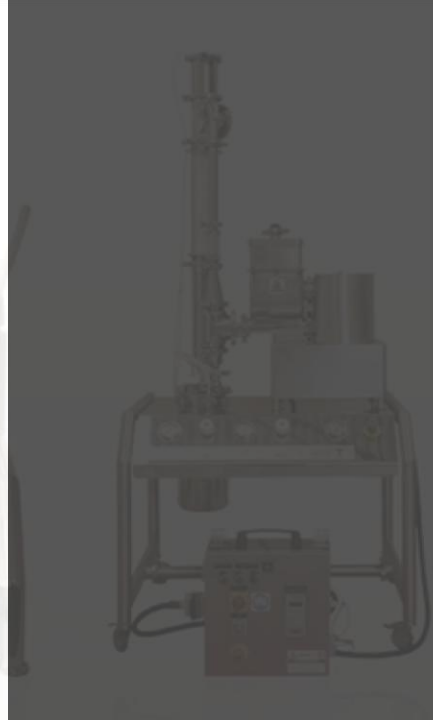


The Machine

- ❑ We call this family of machines Easy-Micronization.
- ❑ It is a complete micronization system for production which has been reengineered and compacted.
- ❑ Estimated working capacity from 0.50 to 30.00 kg/hour with very reduced energy/utility request, 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 Small Production.





Technical Specification



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 frame 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.

Feeder

K-Tron K-MV-KT20 model volumetric type comprising: horizontal double screw for product transportation, product hopper with wide choice of capacity starting from 10 liters, upper safety grill, tee connection and inspection glass.

Product Line

Stainless steel line, single pipe with tri-clamp connections.

Cyclone filter

The cyclone filter allows separation of product from the filtered process gas, it is a closed model supported by lateral legs with revolving wheels. The conical bottom part, together with the filtering sleeves is built to be easily removed from the main body and brought to the washing room.

Lab Ship and manifold

The whole unit is mounted on a stainless steel supporting frame (the Lab Ship) having revolving, antistatic wheels with brakes. On the table the following instruments and controls are built in:

- one emergency ball valve
- 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)
- control system PLC based



Technical Data

■ Milling Chamber: J-100

Process gas at 7 bar = 0.45 m³/min (15.9 CFM)

Process gas at 12 bar = 0.73 m³/min (25.8 CFM)

Estimated capacity = from 0.50 to 7.50 kg/hour

■ Milling Chamber: J-125

Process gas at 7 bar = 0.59 m³/min (20.9 CFM)

Process gas at 12 bar = 1.01 m³/min (35.7 CFM)

Estimated capacity = from 0.50 to 15.0 kg/hour

■ Milling Chamber: J-150

Process gas at 7 bar = 0.73 m³/min (25.8 CFM)

Process gas at 12 bar = 1.25 m³/min (44.2 CFM)

Estimated capacity = from 0.50 to 30.00 kg/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 ($Ra \leq 0.25 \mu m$), surfaces not in contact with the product are satin or mirror polished 220 grit ($Ra \leq 0.8 \mu m$).
- 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.



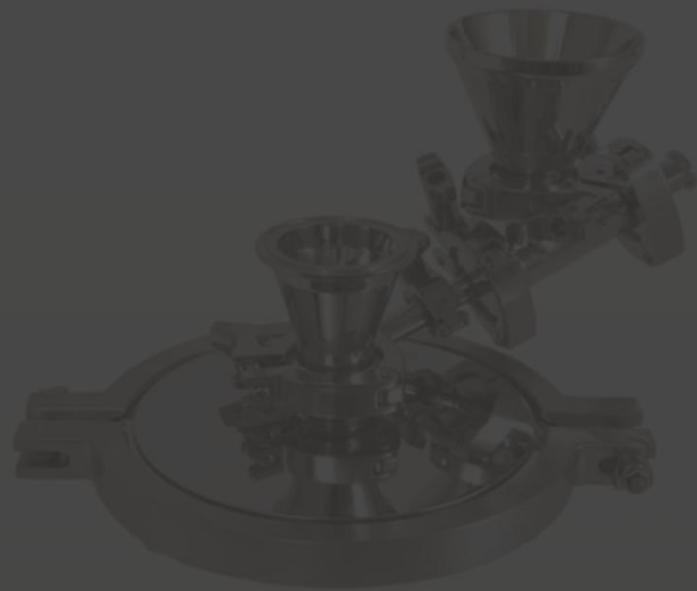
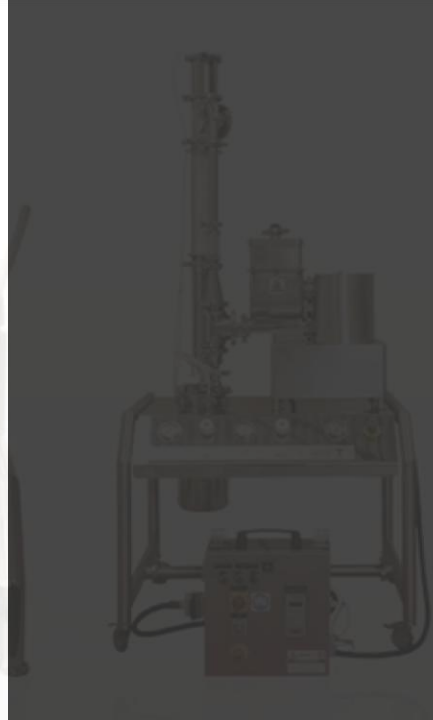
Documentation

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
- ▣ DQ/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:
 - DS25, DS30-PH, Peristaltic
- ❑ K-Tron Feeders:
 - K-MV-KT20/35, K-PH-MV-KT20/35
- ❑ Retsch Feeders:
 - DR100/40

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



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:

- ❑ Tee connection seal for the twin screw
- ❑ Upper balance line with an in line inspection glass (360°)
- ❑ Connection to the Venturi-Hopper



Technical details are described in the machine Data Sheet.



Cyclone Filter

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:

- ▣ D300
- ▣ D350
- ▣ D450

in combination with three different filtering media:

- ▣ P65
- ▣ P100
- ▣ P200

All are supplied with a mechanical pneumatic up-down shaking system, and RIP / WIP systems.



Technical details are described in the machine Data Sheet.





Powder Sampling & Rotary Valve

Powder Sampling Device

Manual system for sampling up to 20 cm³ of powder in-line, without stopping the process, placed at the cyclone filter exit, tri-clamp connections.

Rotary Valve

Our rotary valves are especially developed and optimized for micronized powders. Rotor with 6 blades. Easy assembly/disassembly through tri-clamps, easy cleaning.



Technical details are described in the machine Data Sheet.





Final Filtering Unit

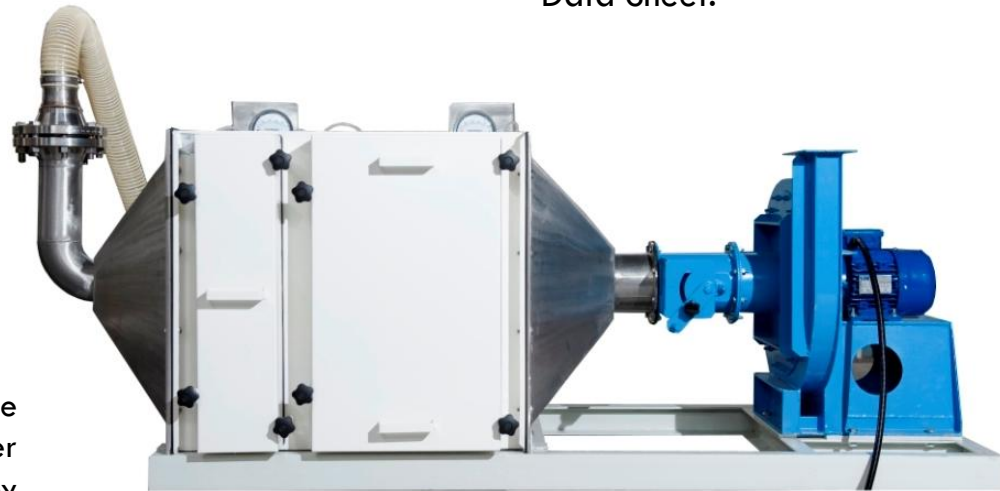
Hepa final filter to recover the very ultra fine particles that pass through the filtering sleeve, in two different configurations:

- G4 + absolute Hepa filter H13 (MPPS)
or
G4 + semi-absolute F6 + Hepa filter H13 (MPPS)
- one inlet conveyor and differential manometers

Pressure control system

If the Filtering Unit is in the scope of the supply, the control of the internal pressure of the cyclone filter takes place by means of a centrifugal fan controlled by an inverter.

Technical details are described in the machine Data Sheet.





Manifold

Diaphragm valves instead of two ball valves

To allow a more precise regulation of the pressure and avoid any contamination risks of the inlet process gas.

Point of use filter

To allow filtration of the process gas which will be injected into the Venturi inlet and into the central ring. This is recommended when the customer's pipeline is not provided with any cartridge filter. In stainless steel with tri-clamp connections and sterilizable cartridge (the cartridge is not sterilizable in place).

Technical details are described in the machine Data Sheet.

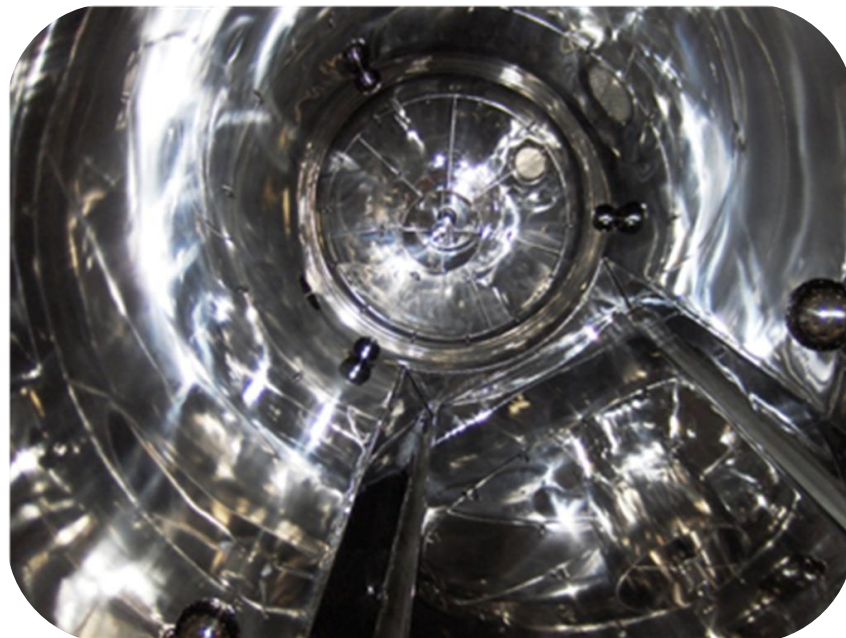




Sterilize in Place

Skid mounted SIP system based on hydrogen peroxide solution, this solution allows sterilization without the use of a pure steam generator.

- ❑ Internal polish level of $Ra < 0.1 \mu m$ for the fluid jet mill
- ❑ Easy to clean and to revalidate
- ❑ Easy to assemble and to disassemble
- ❑ Special bag filters which allows easy cleaning operation
- ❑ Sterilizable spray nozzles
- ❑ Fluid jet mill with open manifold totally sterilizable



Technical details are described in the machine Data Sheet.

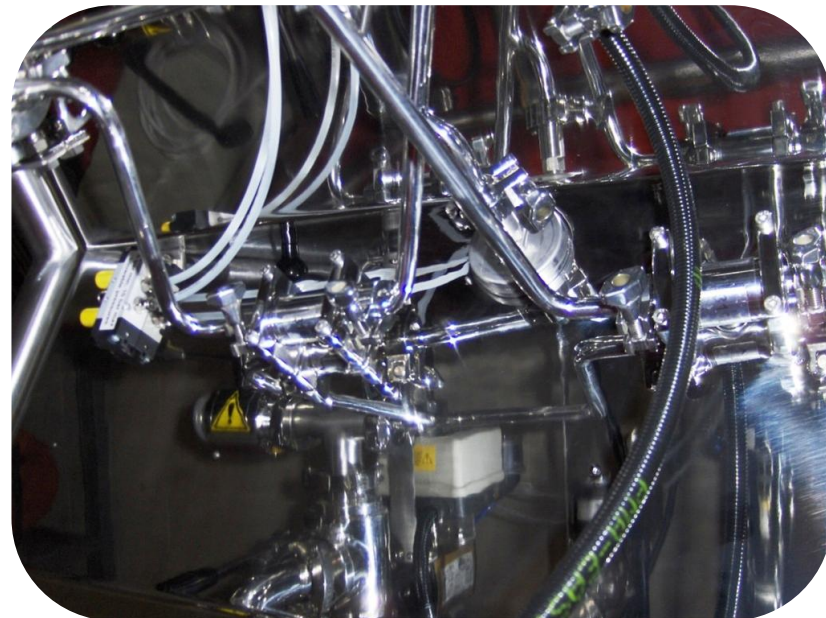


Explosion Proof

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.



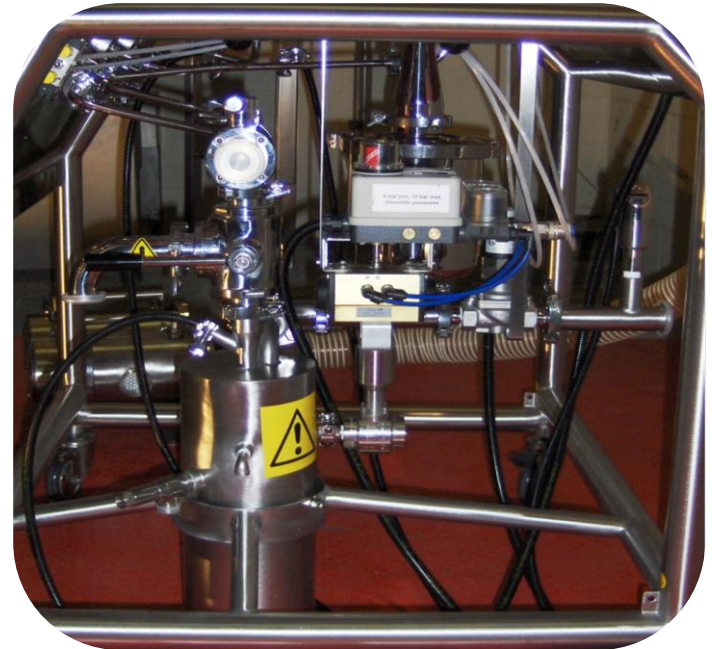
Technical details are described in the machine Data Sheet.



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

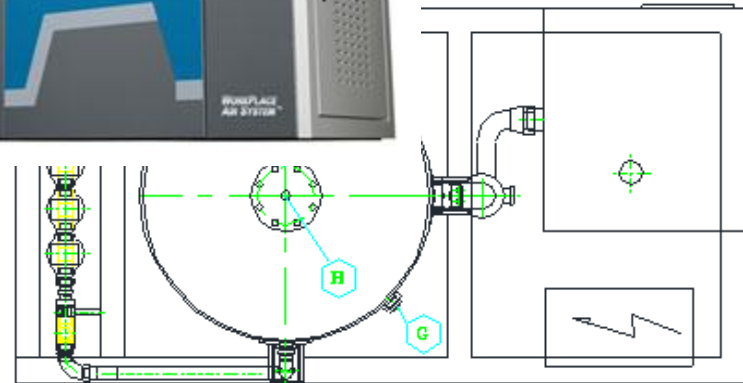
Skid mounted system for feeding treated process gas to the jet mill, this system could be supplied in many different versions. Custom designed according to the client's requests, for many different fluid media such as air, nitrogen, with cryogenic system etc...

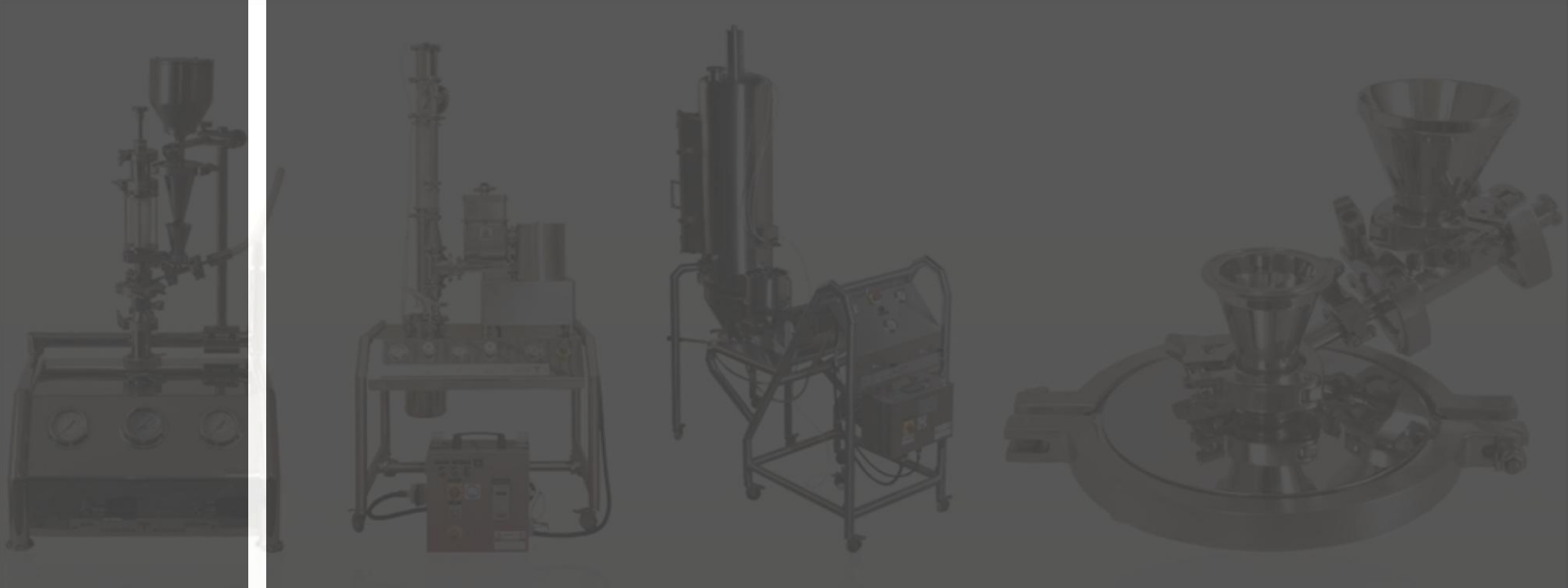
The system is made up by the following components:

- ❑ 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