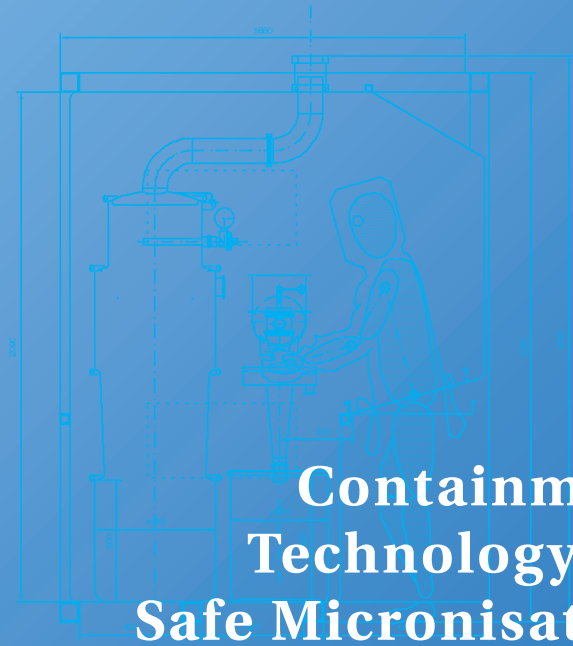
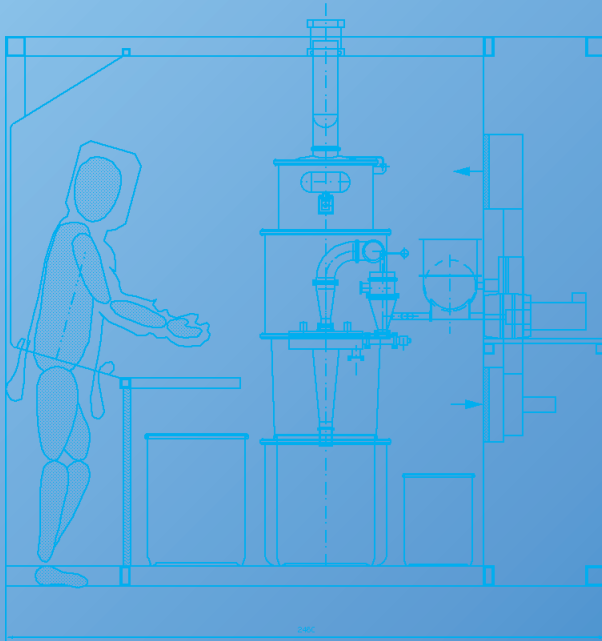


APT™

ADVANCED POWDER TECHNOLOGY
AND MICRONISATION

ISOPAK-2



Containment
Technology for
Safe Micronisation



SUPERJET MICRONISER

SuperJet Isopak-2 ...

Sanitary, USDA-accepted design characterizes Isopak-2 series. They feature sophisticated designs, in line with Good Manufacturing Practice and with the most demanding pharmaceutical specifications worldwide.

Isopak-2 is a typical machine for toxic, sterile and high active pharmaceuticals in batches of 50-70 kgs. Nitrogen-inerted isolators are used with reactive chemicals and metal alloys that present risk of explosion or oxidation.

In production since 1990, this machine was repeatedly improved in terms of versatility, containment technology and compactness.

PROCESS EQUIPMENT

All process equipment are located in the safe, contained environment:

- SuperJet microniser with direct collection of the product from the grinding chamber, without risk of fiber contamination. It has a nozzle ring with optimized grinding angles, a horizontal venturi feeding system that avoids metal contamination and built-in, static classifying system that assures very narrow, particle size distribution
- Twin-shaft feeder, volumetric type, with concave-profile, self-cleaning, screws, able to break the agglomerates and to assure an accurate feeding of poor flowing products, for the whole batch.
- High-efficiency, dust separator combining inertial and static effects, with membrane filter cartridge, reverse-pulse, automatic cleaning and final, safety HEPA that exhausts breathing air quality to the atmosphere.



SUPERJET ISOPAK-2, WITH DISPENSING

APT M

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Process equipment are AISI316 stainless steel and hand polished with extrafine, mirror finish 320-360 grit, Ra 0.25-0.32µm. Super-mirror finish of contact parts, 400-600 grit Ra 0.16-0.25µm is also available.

TOTALLY SAFE ISOLATOR

The new concept of total containment technology is applied to Isopak-2 that features a modular design isolator. It holds all the process equipment and is kept negative or positive pressures, to avoid contamination of the product or of the environment.

Inside the isolator, the working areas are Class 1000 or better, with laminar flows and high-speed, air recirculation through HEPA filters to capture the ultra-fine dust released during the disassembling and cleaning operations.

Purified water showers, washing sinks, vacuum and ultrasonic cleaners and trapped drains allow perfect cleaning of all components, inside the contained environment, without risk of cross-contamination.

The dialogue with the external room is made through airlocks that are kept at differential pressure in respect to the working environment and to the room.

Clean-in-place, on and off-line steam sterilized equipment along with sterile, contained environments are used for highly sensitive products.

CAREFUL ERGONOMICS

The isolator's design is subject of a particular ergonomic study to assure that all the process equipment and air filtration systems can be serviced without breaking the containment.

The working areas are easily accessible through half-suits and feature service and stand-by lights that are built into the ceiling to assure perfect working conditions according to all GMPs.

The double-walled half-suit allows natural breathing and permits heat discharge. Breathing air supply, located inside the isolator, has independent air flow controls, fan and HEPA filters. By virtue of a pressure-equilibrium phenomenon, the half-suit is suspended by a cushion of air around the operator, thereby facilitating movement. Vision is



SUPERJET ISOPAK-2, HALF-SUIT DETAIL

very wide through the transparent helmet, welded on the half-suit.

Many process and auxiliary controls are duplicated inside the isolator, to allow operation from the half-suit.

OPTIONS

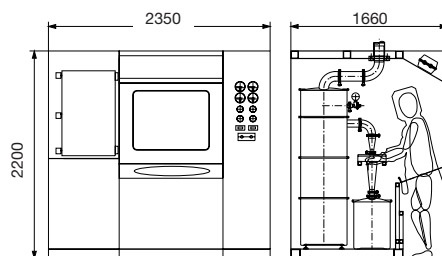
Due to the modular design, the following options can be applied, at any time:

- high-precision, electronic pressure controls that monitor the microniser with proportional pressure regulators, specifically dimensioned for very quick response and steady operation
- synoptic and LCD-alarm display with fault messages in plain english
- electronic motor controller allowing stepless regulation of feed screw speeds across the specified range and features adjustable current limiting circuit factory-set to prevent overloading
- sterilizing air filters for each process line, USDA-approved and certified.
- batch validation equipment including 4-20mA pressure transducers and multi-pen process recorder that document each event and alarm.

SuperJet Isopak-2 can be customized according to the product specification. Complete powder processing and transfer lines are also available.

TECHNICAL CHARACTERISTICS

SuperJet Microniser	JM2
Nominal size	8 inch
	205 mm
Air/Inert gas @ 7bar	3.0 Nm ³ /min
	110 scfm
Supply (rec'd)	10 bar
	145 psi
Installed power	3/4 kW/HP
Expected output	0.4-38 kg/hr



ALL DIMENSIONS IN MILLIMETERS

... what a high-tech microniser should be