

## Containment **POTENT**





# FPS *iftech sy why* our

our values?



## Experience

Over the years we grew as one of the largest manufacturers in micronization and containment equipment. This growth is the results of our ability to listen and understand in depth your process and your needs.

## Reliability

You can trust the advice and assistance our experts: serving you is our mantra.





## Performance

Our performance is the satisfactions our customers have when running our systems at the highest level, day in, day out. We live for that.

## **Technology**

The solutions we supply are driven by our relentless efforts to deeply understand the needs of our customers and their pharmaceutical environment.

Our numbers: +1000 Installations +40 Countries

our approach

# stems

# challenges are 💋 our solutions

Mour process

## **High Containment**



Rigid isolator systems for sterile or HPAPI processing are fully integrated with the process to be protected. Well proven solutions are combined with innovative ones, maintaining safety as our first priority.

## Micronization

Fluid energy mills are more and more adopted for size reduction of new or established molecules. Derived from optimized experience and specific energy calculation, our jet mills are cutting edge solutions for pharmaceutical needs.

Our processes can be combined Hybrid tech together or with other machiner giving end users the integration together or with other machineries, required for each specific application.

## Mour challenge

**Flexibility** 

In a high quality and fast changing industry, we remain flexible during project execution, to respond to new requests from our customers.

## Efficiency

Cost and time management are the paramount for projects management, allowing for fast project execution.





## Isolators for HPAPI Production



Production and handling of HPAPI or toxic products (in gas, liquid or powder form) need the total product separation from the environment to protect the operators. A negative pressure regime is maintained within the internal volume of the isolator. Turbulent airflow is generally adopted. The operator accesses to the inside of the isolator via glove ports or half-suit.

Containment level from 10 ug/m<sup>3</sup> down to the low nanogram level are guaranteed with adequate designs and configurations.

FPS is the trusted containment partner of many leading OEMs. This requires a long collaboration and gives FPS a complete understanding of the process. The result for the customer is a bundle solution where both the process equipment and the isolator work seamlessly as one unit.

**Isolators for HPAPI Production** are available for many applications: Laboratory, Synthesis, Filtration & Drying, Production Reactor Charging, Process vessel discharging, Pilot Milling & Micronization, Production Milling & Micronization, Dispensing,...

Dustiness Potential Quantity handled	Low	Medium	High	
Micro (<10g)	EP0 EP0	EP1 EP0	EP2 EP0	
Small (<10.000g)	EP1 EP1	EP1 EP2	EP2 EP3	
Medium (<100 kg)	EP1 EP2	EP2 EP3	EP3 EP4	
Large (>100 kg)	EP2 EP3	EP3 EP4	EP3 EP4	
Task duration	Short Long			



## **Synthesis**





## Milling & Micronization Pilot Size









## Containment system for HPAPI Pilot Plant

It includes Filtration, Reaction, Drying, Milling, Micronization, Dispensing and Packaging systems

Hazard group	Exposure limit	OEB (solids)	EP0	EP1	EP2	EP3	EP4
А	1,000 - 10,000 µg/m³ dust	OEB1	1	1	1	1	2
В	100 - 1,000 µg/m³ dust	OEB2	1	1	2	2	3
С	10 - 100 µg/m³ dust	OEB3	2	2	3	3	4
D	1 - 10 µg/m³ dust	OEB4	2	3	3	4	4
Е	0.01 - 1 μg/m³ dust	OEB5	3	4	4	4	4
F	<0.01 µg/m³ dust	N/A	4	5	5	5	5



**Process vessel charging** 

## Process vessel discharging











## Isolators for HPAPI Formulation and Packaging



The containment of the formulation activities of HPAPI Oral Solid Dosage Form requires high integration with the process machines without affecting their functionalities and performances. The goal is to guarantee to the operator the best use of the process equipment while assuring high containment. FPS had been collaborating with leading OEMs for many years and has provided the newest technologies for their processes.

The process is kept separated from the environment by means of closed rigid walls around the formulation machines. Suitable air barriers are provided when continuous operations are requested. Dedusting machines and powder suction units can be integrated inside the isolators to provide a higher containment.

Negative pressure regimes with turbulent airflows are typically used. Isolators are generally supplied with glove ports. We can guarantee a Containment Performance Target down to the low nanogram level.

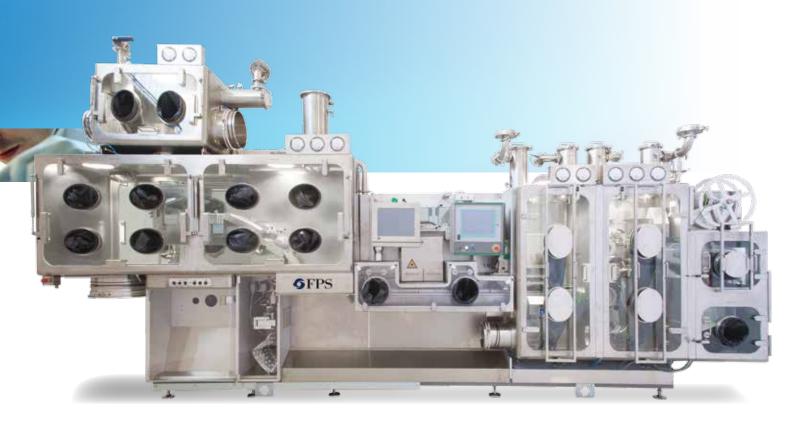
Typical applications are spray dryers, granulators, extruders, mixers, powder screens, tablet presses, capsules filling, pan coating machines and blistering machines.

**OSD Isolators** are also used to contain the following processing: dispensing, In Process Quality Control (IPQC) and HPLC analysis.

### **Formulation**







### **Containment system for blister machine**

Multi-chamber isolator with fully integrated blistering machine to process batches of capsules/tablets.





Containment | Milling | Micronization

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