CRIOX System

Patented
Vacuum Dryer
Powderer
For Multiple
Products

italvacuum

CRIOX System

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Powdering while drying

The CRIOX System, a very successful international patent, is a rotary bi-conical vacuum dryer, able to carry out the complete extraction of solvents and water from humid masses after centrifugation or filtration steps.
During the drying process, the CRIOX System crushes the possible blocks inside the mass and breaks the lumps that could be formed, permitting to obtain at the end of the process dry powders ready to be riddled and packed.

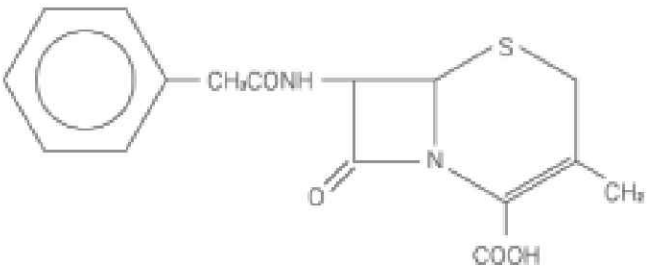
CRIOX is **multi-product**. It is studied in the least detail for allowing its use with the widest range of possible products with crystalline or amorphous structure, whether they are intermediates or fine chemicals, end products, thermo sensitive products, delicate, more or less thin, degradable, photosensitive, sterile or injectable, active pharmaceuticals ingredients or chemically reactive.

CRIOX is **multi-purpose**. It can also be used as an effective fast blender or homogenizer.

CRIOX is **versatile** and **profitable** for it minimizes times required to re-establish the line, wash, clean and inspect the plant and it permits to shift rapidly from a product campaign to another.

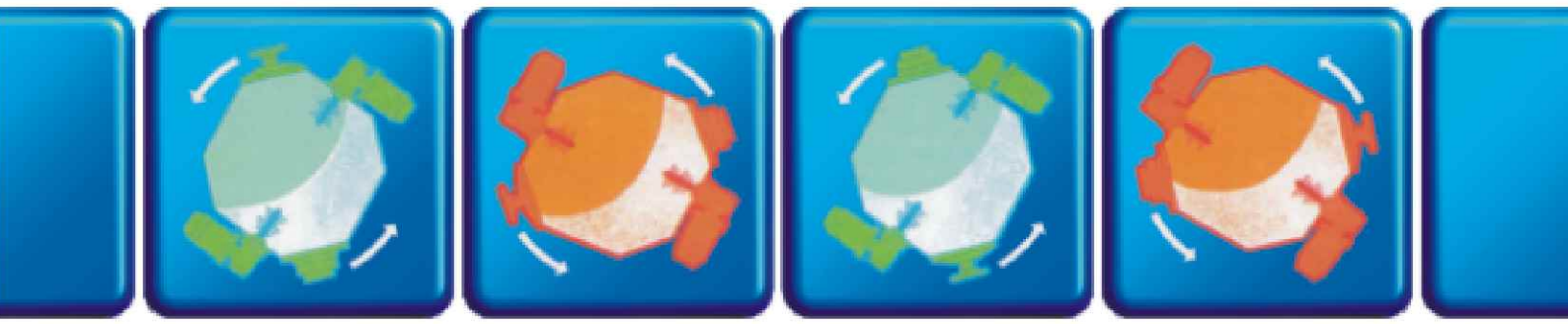
CRIOX is **safe** for both operators and product, for it has been designed and built in compliance with the ever more severe safety regulations and with **cGMP** and **ATEX** Standards.

The CRIOX System is particularly suitable for the treatment of **Active Pharmaceutical Ingredients (API)**, **Fine Chemicals** and **Intermediates**



The reasons of a success

1. Absolute safety for the personnel, the environment and the product according to cGMP rules
2. Perfect homogeneity and uniformity of the dried batch with no deposits of product
3. Scalable powdering of the product during the drying cycle
4. Reduced drying times thanks to the action of lump-breaking units that increase the surface of the product exposed to evaporation
5. Very low final moisture values, in accordance with the p.p.m. limits required by pharmacopoeia
6. Low working temperatures, for the benefit of the most delicate products
7. Extremely high final vacuum values (lower than 0.01 mbar)
8. Fast and total unloading of the product thanks to the conical shape and the use of vibrators
9. Ease of internal and external cleaning, and of inspection, facilitating the SWAB test execution
10. Wide availability of weldable materials and inner coatings
11. FDA validation and approval
12. ATEX certification.



The continuous revolution of the drying chamber and the combined action of the lump-breaking units.

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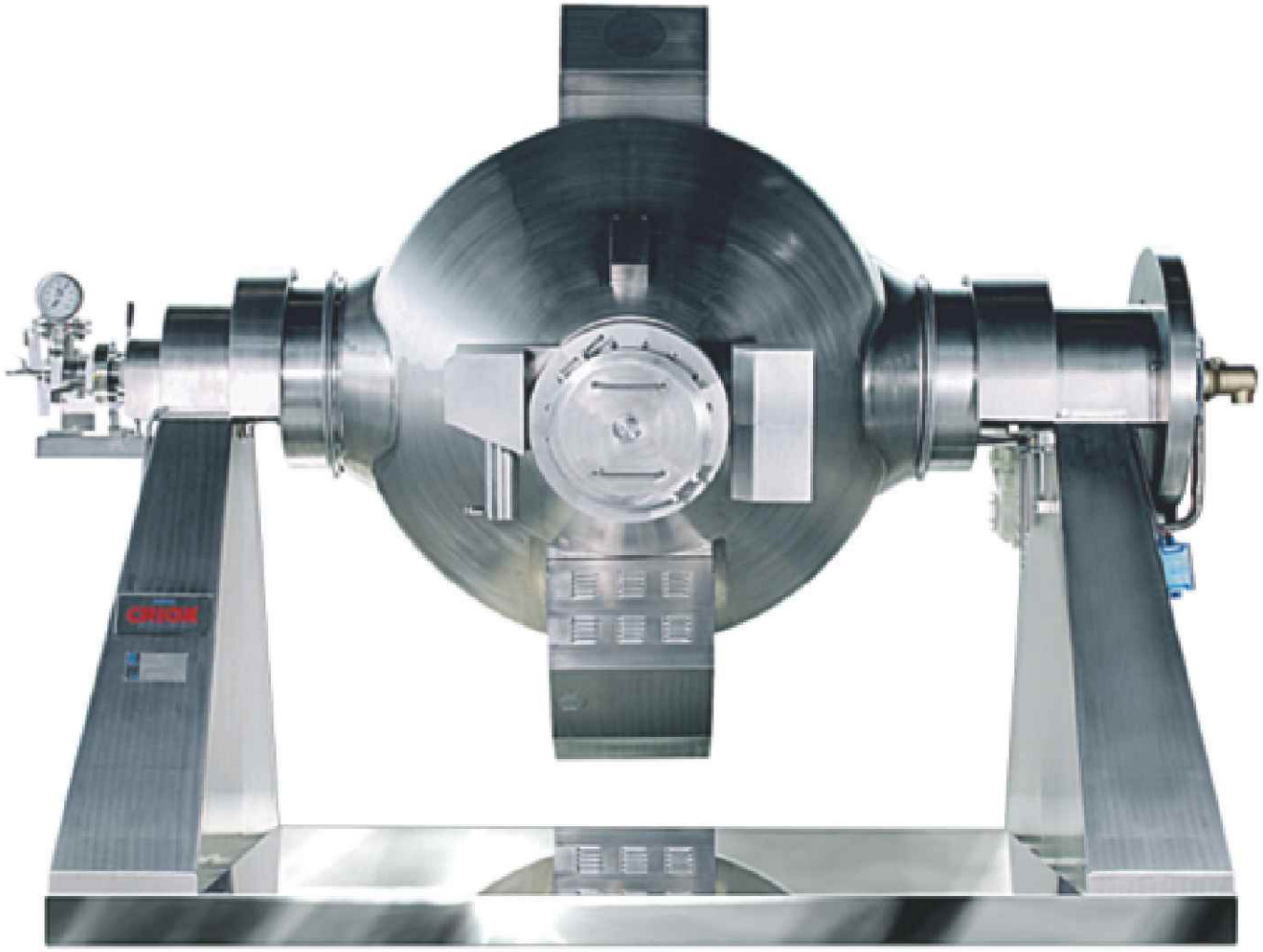
A shape studied for the best possible result

The central body of the CRIOX System consists of a bi-conical rotating drying chamber, characterized by soft lines without edges and sharp corners. During the system rotation, this structure allows the total and continuous revolution of the mass to be dried and an extremely **homogeneous mixing**. The speed of rotation of the chamber is adjustable, permitting an agitation ranging from delicate to moderate. This permits to treat even products with weak bonds, without modifying their molecular structure. For the parts in contact with the product, the standard version of CRIOX is made of stainless steel AISI 316L (1.4404), but on request it can be made of other weldable materials, such as ALLOY C-22 (2.4602) and AISI 904L (1.4539).

The particular shape of the CRIOX System allowed also to realize successful versions with internal coating made of particular fluorine-polymer materials, characterized by a high resistance against products containing extremely corrosive substances (acids and bases).

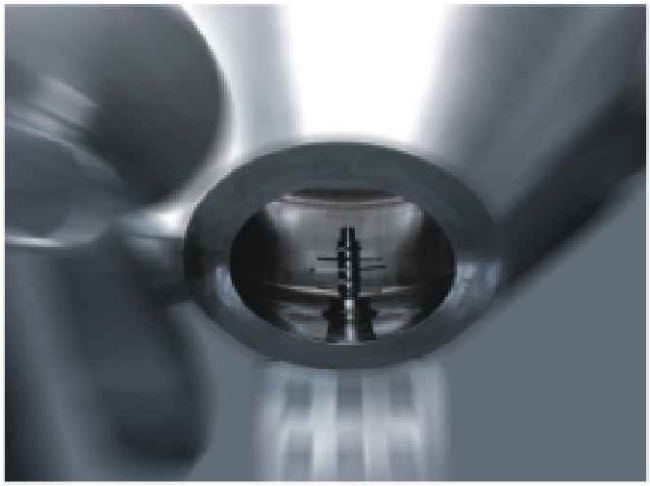
The success obtained by these executions led Italvacuum to realize other versions with enamelled drying chamber, in which the application of a special enamel, consisting of alkaline boron silicates, on the steel support, makes the CRIOX chemically inert inside.

For these specific versions, the blades of the lump-breaking units are made of ALLOY C-22 (2.4602) or other materials compatible with the process.



No lumps

The bi-conical shape of the rotating chamber by itself could not lead to the desired results if it wasn't for two powerful lump-breaking blade sets that are the peculiar characteristic of the CRIOX System and that permit to increase the surface of the product exposed to evaporation and the effectiveness of mixing. The speed of rotation of the lump-breaking unit is adjustable from slow to fast, in function of the type of process. Anyway, the action of the lump-breaking unit causes no mechanical stress in the treated product. During chamber rotation, the lump-breaker group goes alternatively in and out of the product, cleaning itself when not in contact.
The lump-breaking blades not only avoid agglomerate formation but also permit to mill and **powder** the mass dried during the last step of the process, limiting the subsequent use of the mill as much as possible. This leads to loose products ready to be stored or to powders with a controlled final particle size distribution, which could then be riddled.
By acting on the core of the mass of the product to be dried, the lump-breaking units reduce consistently the drying time ensuring extremely low moisture levels, that often cannot be achieved by other systems. Furthermore they permit to operate at low working temperatures, for the benefit of the purity of the most delicate thermo sensitive products, as it avoids their degradation. The shafts of the lump-breaking units are provided with a double mechanical seal fluxed with a fluid compatible with the process. This system is designed to ensure the perfect vacuum-tightness and the absolute purity of the dried and pulverized batch.



Lump-breaking units

Effective filtering systems

In vacuum drying processes, the filtering unit must be able to keep all the powder in the drying chamber, letting only the solvent vapours pass through. At the same time, it must ensure the lowest possible pressure drop, in order to achieve very low final pressure values.
Special filtering systems can meet all the process requirements: i.e. metal sintered cartridge filters or PTFE filters, suitable for very thin powders and whose effectiveness during the process is ensured by an automatic C.I.P. system for nitrogen back-flow washing.

Internal filter with back-flow C.I.P. system and inner vacuum detection

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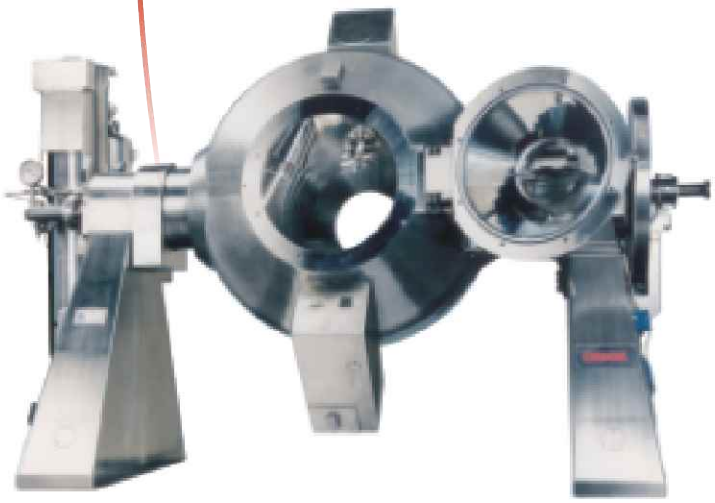
Handy, safe and intelligent

A machine suitable for multiple products must be above all easy to clean in order to:

- meet the validation procedures set by FDA Standards
- avoid products contamination
- help and speed up changes in products campaign.

The ease of cleaning for chemical and pharmaceutical industrial plants is usually referred to the following general criteria: internal washing, inspection and dismantling of internal parts.



CRIOX System with open hatch

Internal washing

Thanks to the rotation of the drying chamber and the combined action of the lump-breaking units, only very few rinses, with small quantities of fluid, are necessary to achieve the required p.p.m. values, hence reducing the quantity of wastewater to be disposed of. Furthermore, inside the chamber, a **C.I.P. (Clean In Place) device** can be applied, able to spray the washing fluid in all the directions. Thanks to this fast and complete internal cleaning, CRIOX System permits to shift rapidly from one product campaign to another.

Inspection and dismantling of internal parts

Inspection and dismantling of internal parts are possible by opening the manhole port lid and the loading hopper. Moreover, in order to perform the **SWAB test** required by the FDA standards for the validation of the washing procedures, Italvacuum designed and patented a large hatch that permits to open completely the machine and to carry out all the required operations with extreme easiness and safety.

Inside the drying chamber, the CRIOX System presents only the lump-breaking units, with blades that can be removed easily thanks to their small size, and the powder filter that can be easily pulled out by means of a special tool.

Installation with partitioning

Clean room installation

CRIOX can be easily cleaned both inside and outside. Thanks to the waterproof casing of the entire machine (cGMP "particle free" configuration), covering insulation, electrical and hydraulic circuits, the external cleaning is extremely easy and effective as it permits to remove the product deposits from slots and joints. This characteristic, combined to the **"partitioning" solution**, permits the installation in clean room, allowing the pressurization and separation of the sterile room from the technical one.

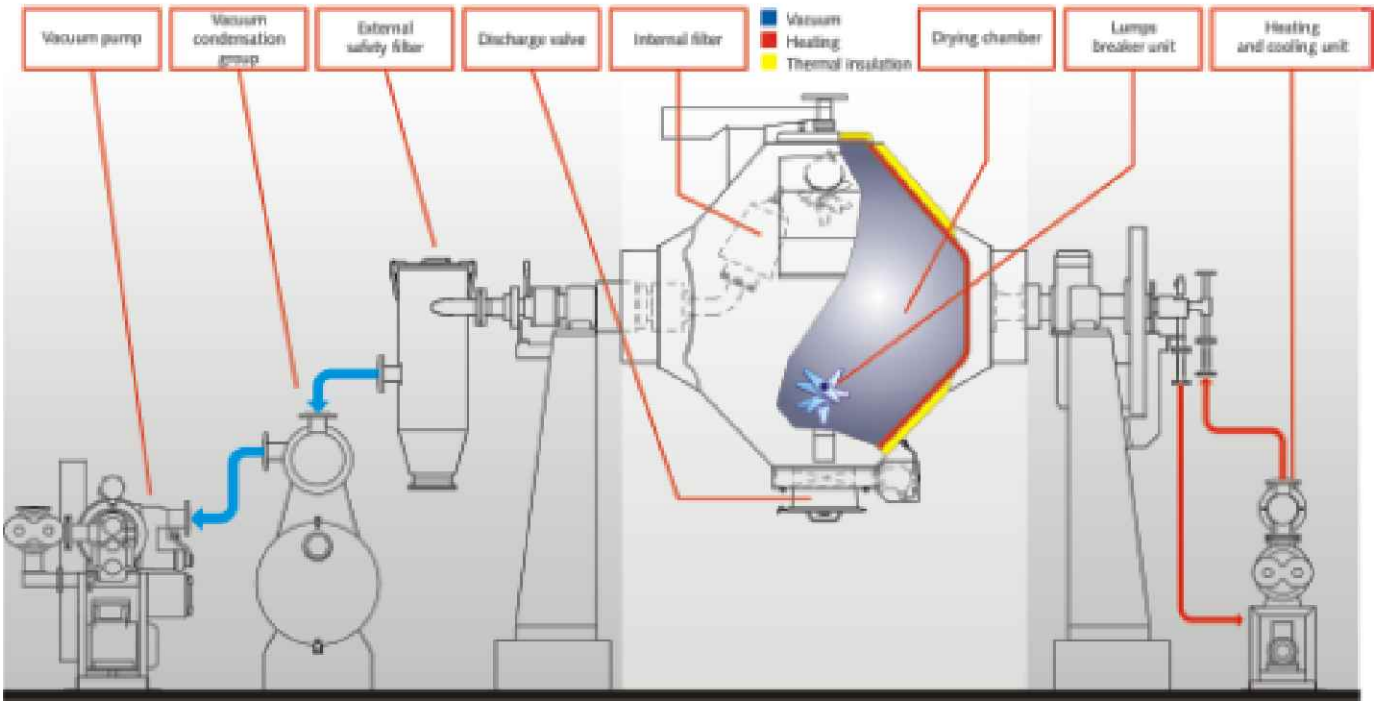
Turn-key plants for every process requirement

In addition to the dryer Italvacuum also supplies all the units necessary for the plant, adequately dimensioned in order to meet every process requirement:

- **Heating and cooling unit** for the thermal regulation of the system
- **Vacuum condensing unit** with tank for the recovery of the extracted solvents
- **External safety filter**
- **High vacuum unit** consisting in the new Italvacuum SAURUS939 piston pump
- **Control panels with PLC** for the complete management of the plant, provided with software which could be certified according to CFR 21 Standard, Part 11, and able to ensure the reproducibility between the dried batch and connectable to centralized supervision systems.

Special suspended execution for the CRIOX System

Operator's interface



Standard installation diagram of the CRIOX System representing the different units realized by Italvacuum

Accessories

Automatic and clean loading/unloading systems

In order to load and unload the product, Italvacuum realized particular pneumatic systems that permit to have a fixed connecting position and a movable approaching element to be connected every time to the loading/unloading hopper of the CRIOX, hence creating a closed connection, perfectly insulated from the surrounding environment.

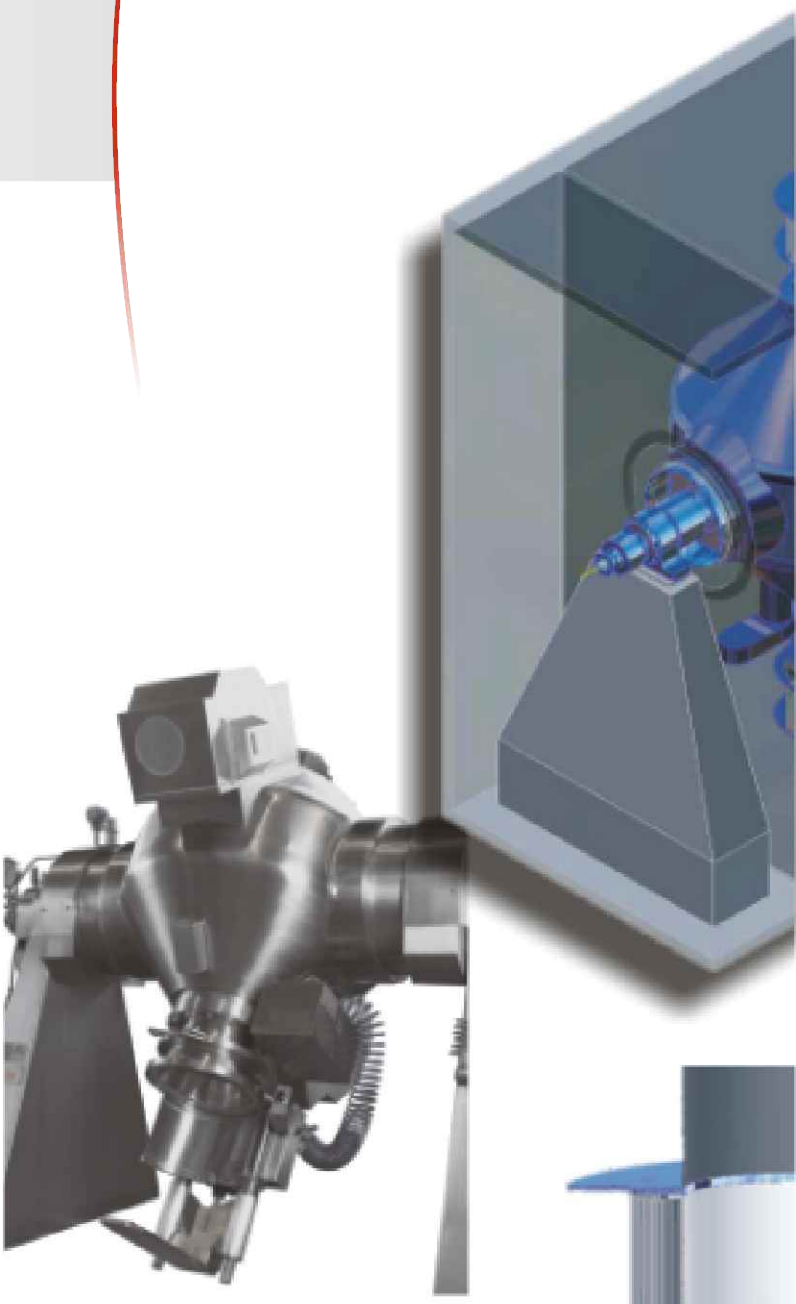
The movable part can be provided with an optimized special cleaning device called **Clean Connex** - consisting of a washing C.I.P. head and a draining and drying element, that after every loading/unloading operation, and before disconnection, cleans and dries the surfaces that came in contact with the product and that will be exposed to the environment.

The Clean Connex device is patented.

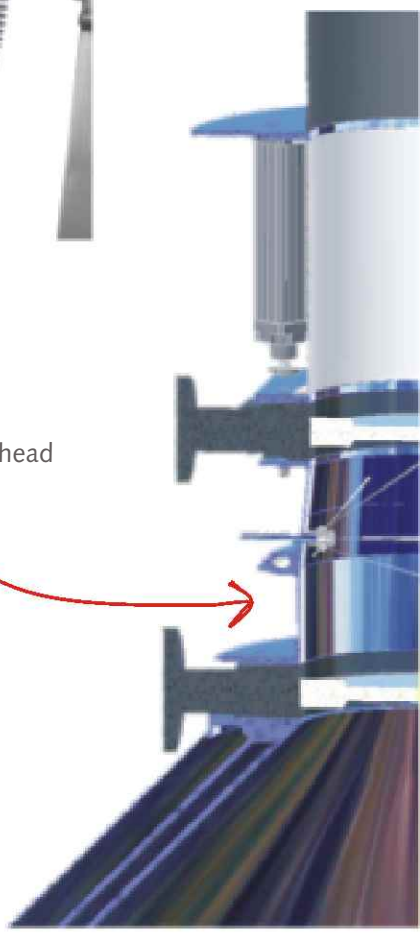
For dryers of small and medium size a pneumatic drum loading device also exists; this device is very easy to be used and particularly appropriate thanks to the rotation of the chamber.

For each loading/unloading solution, the flexibility of design and the peculiar configuration of the CRIOX System permits the use of both butterfly valves (standard equipment) and active or passive split valves, that are mounted directly on the dryer.

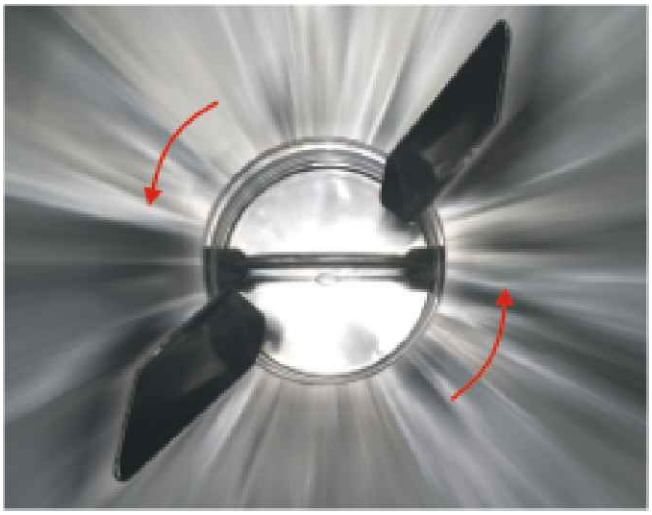
Pneumatic loading system



Drum loading system



Detail of the Clean

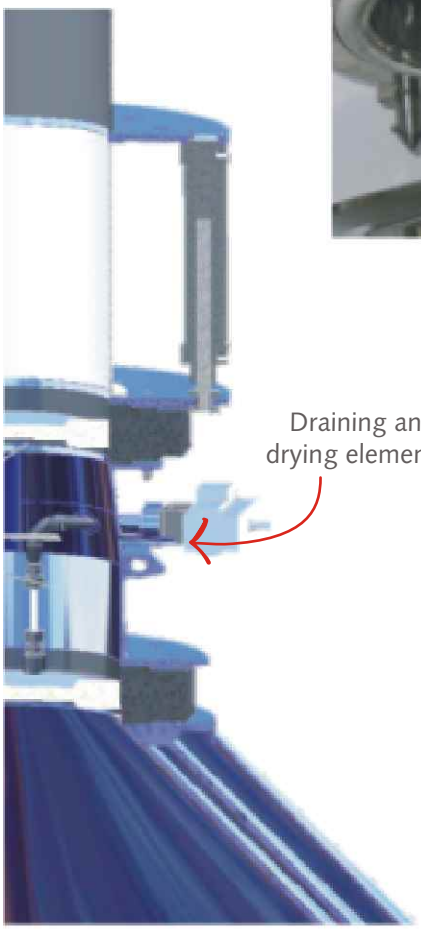


Internal view of the Easy Unloading device

Total unloading system

Thanks to the experience gained over the years in the vacuum process application, Italvacuum realized a special total unloading device that, through its rotation permits the total removal and extraction of the dried products that slide with difficulty from the CRIOX chamber. This device called **Easy Unloading** - ensures the absolute vacuum tightness and causes no problem for the internal cleaning.

Clean Connex device



Connex device

Absolute safety

The CRIOX System could be used in potentially explosive atmospheres due to the presence of gas, vapours, fog or air and powder mixtures.
The design and realization of the CRIOX System is in fact compliant to the requirements of the **ATEX 94/9/CE Directive** (Equipment and protective systems intended for use in potentially explosive atmospheres): the compliance of the whole machine and its various components was assessed according to what foreseen for the **Device group II - Category 2** - non-electric equipment.

Services

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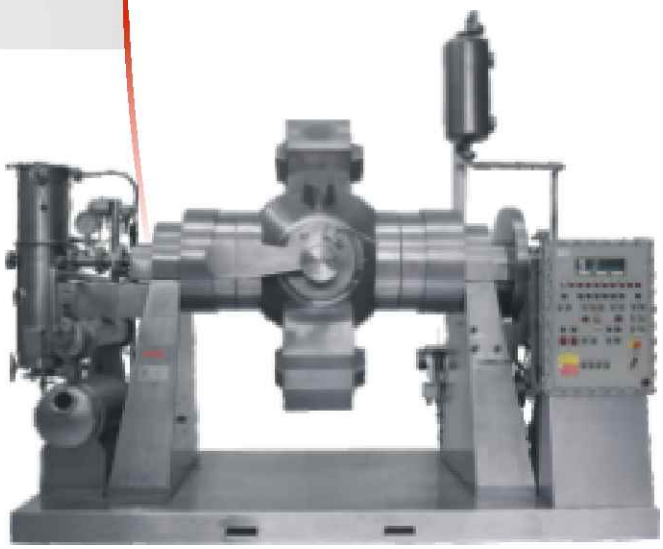

From laboratory scale to industry: the best way for an accurate choice of the industrial plant

For drying trials of the customer's products, Italvacuum has a wide range of pilot installations.
During the trials with the pilot installation it is possible to extract some product samples without breaking the vacuum and to vary at any time the process parameters in order to define the ideal drying path.
In this way the customer can make the best choice for the Italvacuum installation both in terms of dimensions and performance. On the other side the personnel of Italvacuum can obtain important information on the product to be dried, in order to adapt the industrial installation to the customer needs.
The tests are completed and formalized by drawing up a detailed report.

The Italvacuum post-sales service: another warranty for your productions

The start-up of the installation is just the beginning of our relation with the customer. This relation will last for years starting with an efficient policy of preventive maintenance with planned interventions. The maintenance plans are organized individually considering the customer's specific processes. This means a remarkable cost saving and more tranquillity.
At the same time, for the solution of any inconvenient or breakdown, Italvacuum is able to offer prompt and efficient technical assistance services both at the customer's site with the intervention of specialized personnel or from its site through on-line diagnostic, in case the customer's installation has a control system supplied by our company.
For an efficient management of the spare parts, Italvacuum has a computerized warehouse that allows the prompt and immediate delivery of original spare parts anywhere in the world.
Moreover, Italvacuum can fully overhaul its own used plants and regularly supports the customer in upgrading the delivered installations with new technical solutions that have been developed in the meantime - as well as adapting the machines to the new ATEX regulations.

Integrated quality

ITALVACUUM has implemented a Quality Management System with **ISO 9001** certification covering from design to production of every single component, from end product sale to plant installation and technical assistance. In addition, acknowledging the importance of the welding process in the qualitative result and the reliability of the end product, ITALVACUUM has considered to certify its own processes and personnel complying to **ISO 3834-2** norms.

SINCERT
Sistema di gestione per la qualità certificato
IIS
UNI EN ISO 9001

SINCERT
Requisiti di qualità per la saldatura certificati
IIS
UNI EN ISO 3834-2

Dimensions

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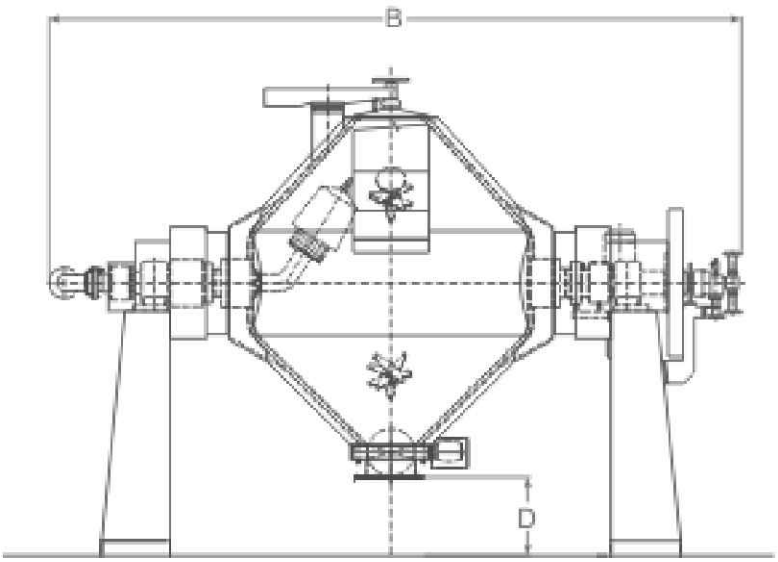
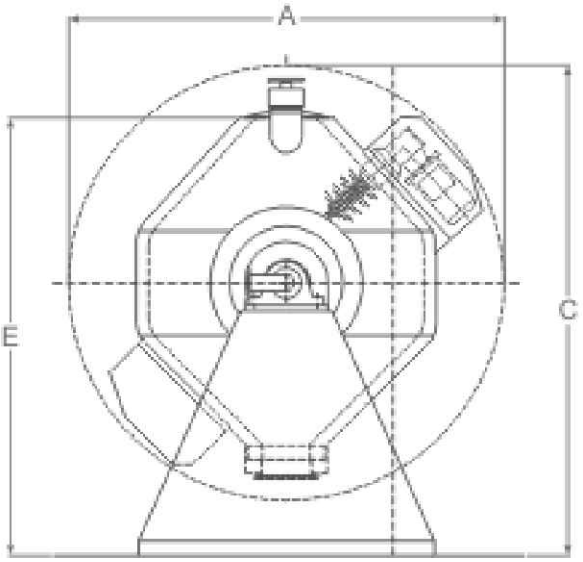
The CRIOX System can be designed for a **wide range of dimensions**, for it can be built with total volumes ranging from 55 to 12,000 litres. The maximum loading level is function of the treated product. On the other side there's no minimum loading limit, as the action of the blades is effective also with few litres of product.





CRIOX Model		RBG 55	RBG 200	RBG 350	RBG 600	RBG 1000	RBG 1500	RBG 2000	RBG 3000	RBG 4000	RBG 6000	RBG 8000	RBG 10000	RBG 12000
Total volume	(l)	55	200	350	600	1000	1500	2000	3000	4000	6000	8000	10000	12000
A	(mm)	1150	1730	1950	2100	2300	2460	2600	2920	3120	3560	3750	4000	4300
B	(mm)	2060	3120	3350	3600	3800	4050	4250	4650	5000	5500	5750	6500	7000
C	(mm)	1825	2200	2400	2630	2850	3100	3160	3360	3500	3850	3950	4200	4400
D	(mm)	780	780	780	830	810	815	730	630	560	530	360	360	360
E	(mm)	1520	1520	1900	2175	2425	2710	2770	2975	3120	3490	3600	3900	4100

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Vacuum Process Innovations since 1939

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