

ROTO CUBE

SINGLE-POT PROCESSOR



ROTO CUBE

ROTO CUBE technology is the benchmark for single pot process in granulation. It combines high shear mixing and granulation processes with drying and milling in the same equipment to obtain dry granules ready for use thus enhancing sustainability in manufacturing.

ROTO CUBE runs the whole granulation process in a single contained bowl thus eliminating contact between product, operator and the environment for any type of product. It manages the wet granulation and drying process, from the loading of raw powders to the discharge of dry granules, already sized for the next manufacturing step for making tablets, capsules or sachets.

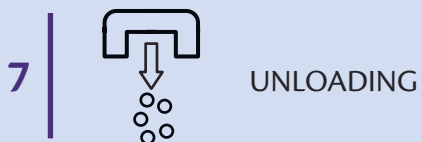
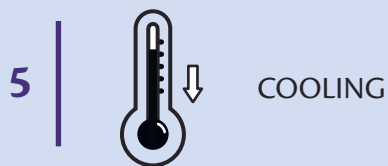
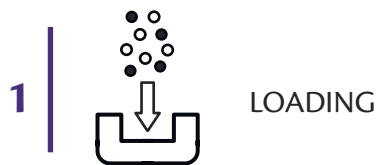
- PROCESS IN HIGH CONTAINMENT
- REDUCED RISK OF CONTAMINATION
- MAXIMUM PRODUCT YIELD

- MINIMUM MANPOWER, SPACE AND ENERGY
- SAFE USE OF SOLVENTS
- ACCURATE DETECTION OF PROCESS END-POINT
- CONTROL SYSTEM (PAT, DATA INTEGRITY, VIRTUAL MACHINE)
- QUICK WASHING-IN-PLACE
- FAST PRODUCT CHANGE OVER



ROTO CUBE PROCESS FLOW DIAGRAM

ALL IN ONE BOWL



WET
GRANULATION

WATER BASED
ALCOHOL BASED
EFFERVESCENT
TEMPERATURE SENSITIVE
OXYGEN SENSITIVE



MELT
GRANULATION

WAX GRANULES
MODIFIED RELEASE GRANULES



CHEMICAL
REACTION

API ENCLOSURE IN POLYMERS
SALIFICATION OF API
API COMPLEXATION WITH EXCIPIENTS
API CRYSTALLIZATION

PROCESS GOALS

- REDUCED PRODUCT TRANSFERS
- ENHANCED SUSTAINABILITY
- MAXIMUM REPRODUCIBILITY
- MINIMUM OPERATOR INTERVENTION
- EXCELLENT PRODUCT FLOWABILITY
- OPTIMAL GRANULES SIZE DISTRIBUTION

ROTO CUBE GRANULATION



PROCESS BOWL AND IMPELLER

The process bowl is designed with no dead zones for mixing and cleaning. It has a wide curvature radius on the bottom that prevents sticking of product.

The ROTO CUBE has a unique impeller design created for the manufacture of pharmaceutical granules.

The impeller has three blades with a little wing on each tip and is driven to obtain the optimum shear for granulation at every speed. It provides the appropriate movement to achieve the highest mixing, agglomeration and drying efficiency.

The impeller has scrapers on the bottom of every blade to assure the minimum tolerance from the bottom of the bowl to prevent product sticking and maximize product yield.



CHOPPER

The chopper is located on the side wall of the bowl and has a horizontal shaft. It runs at variable speed, counter directional to the impeller to prevent lumps forming.

The chopper can also control granule growth to achieve regular particle size distribution.



BINDER ADDITION

The liquid binder is usually transferred by means of peristaltic pump through an airless nozzle while running both impeller and chopper at the proper speed. Alternative transfer systems can be configured based on liquid amount and viscosity, considering other types of pumps, nozzles with integrated control including binder tanks, mass flowmeter or scale.



DISCHARGE VALVE

The discharge valve is located on the side wall of the bottom of the bowl and has a GMP design to facilitate discharge operation. It is also easy to wash in place and has full access for inspection due to the valve housing that can be completely opened.

ROTO CUBE DRYING



The basic drying system of ROTO CUBE single pot technology consists in applying vacuum in the process bowl so to dramatically decrease the vapor tension of the binding liquid and consequently its boiling temperature. In the meanwhile the product is heated by conduction through the hot water circulating in the jacket of the process bowl.

Evaporation rate can be also enhanced by GAST gas stripping option: a very

gentle air or nitrogen stream that once injected into the process bowl helps removing the vapors.

Furthermore, to promote heat transfer and minimize product sticking the product mass is gently kept by running the impeller at low speed intermittently and/or using the option of tilting the bowl so to promote contact between the bowl surface and the product mass.



TILTING BOWL

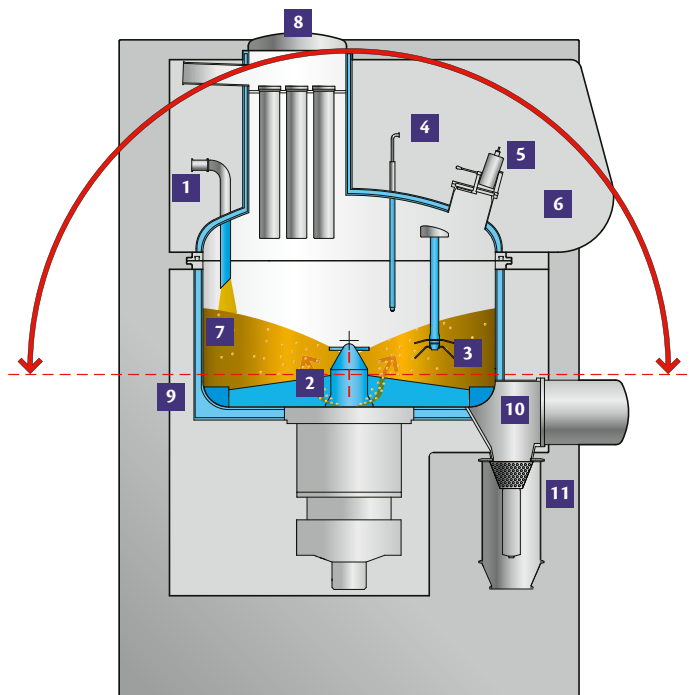
- PROMOTES HEAT TRANSFER
- TREATS PRODUCT GENTLY AND PRESERVES THE GRANULES SIZE
- MINIMIZE STICKING OF PRODUCT ON THE WALLS OF THE BOWL
- MAKES REPLACEMENT OF THE FILTERS EASY THANKS TO THE BOWL INCLINATION
- HELPS DURING INSPECTION AND MECHANICAL MAINTENANCE

ROTO CUBE



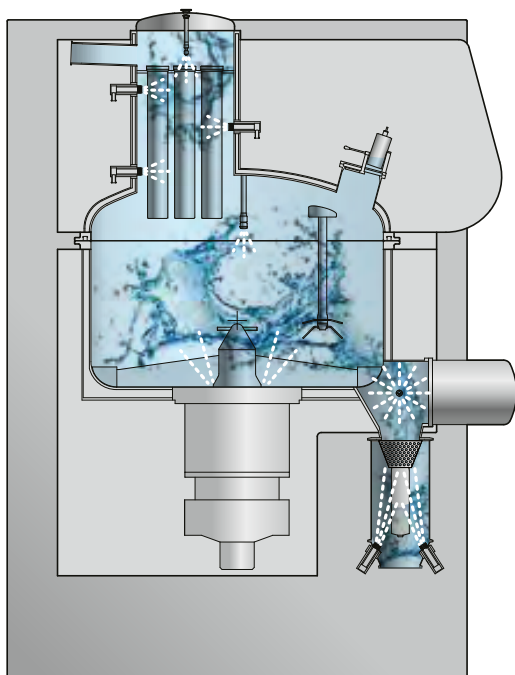
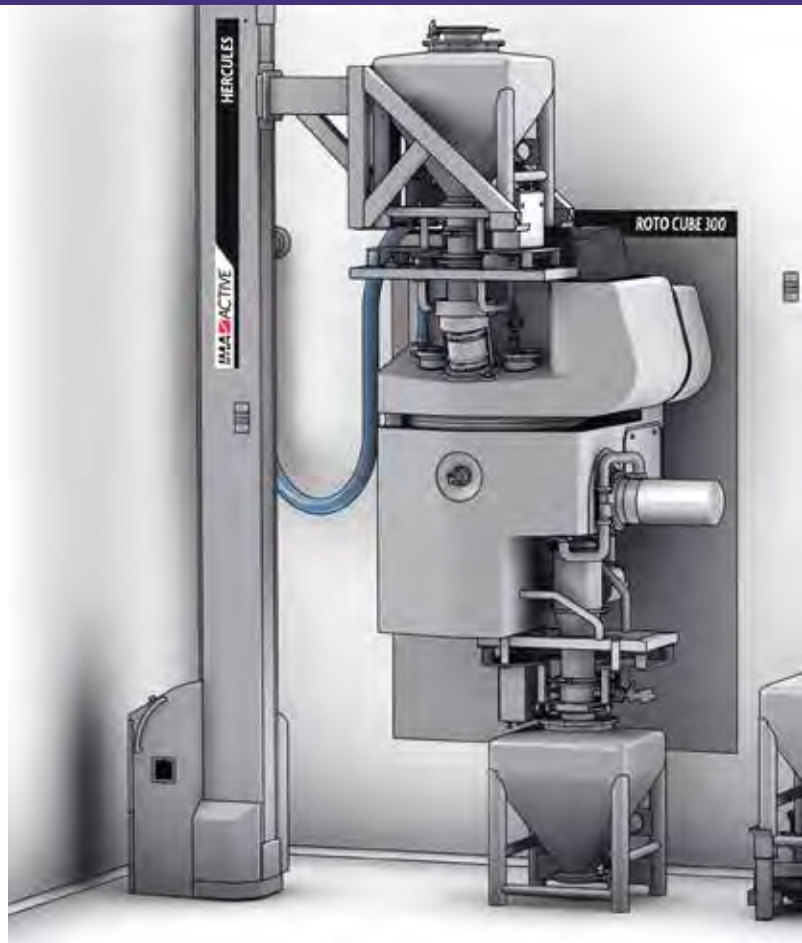
ALL IN ONE CUBE

1. PORT FOR PRODUCT LOADING (BY VACUUM OR GRAVITY)
2. IMPELLER
3. CHOPPER
4. PORT FOR ADDITION OF THE BINDER
5. LIGHT/SIGHT GLASS OR VIDEO CAMERA (OPTIONAL)
6. JACKETED LID FOR FULL ACCESS TO THE PROCESS BOWL
7. FULLY JACKETED PROCESS BOWL
8. VENT FILTERS ON VACUUM LINE
9. PROCESS BOWL WITH TILTING OPTION
10. VALVE FOR PRODUCT DISCHARGE
11. IN-LINE DRY MILL



COMPACT DESIGN FOR PROCESS CONTAINMENT

ROTO CUBE is all in one granulation solution ideal for processing HAPI in high containment since all the process phases are carried out in the same bowl. Product transfers and surface in contact with the product are significantly reduced, especially when product loading and discharge can be managed by means of high containment valves.



WASH IN PLACE

ROTO CUBE includes a kit for full automatic washing in place for easy cleaning validation and total reproducibility of the washing cycle.

In combination with Hydrowash washing skid the washing recipes manage dispensing of detergents and different kinds of water. GMP design makes easy visual inspection and full access for swab tests after cleaning.

Retractable washing sprayballs allows to wash it immediately after end of production with no operator intervention preserving high containment.

ROTO CUBE



CONTROL SYSTEM

MAX, the latest generation of IMA HMI, is created paying maximum attention to User Experience and based on Visual Design to enhance User Interaction. MAX ensures prompt responsiveness, enhanced predictability and easy learning.

MAX HMI is based on iFix SCADA, IoT ready, to make easier connection with fluid bed or other ancillary equipment in a granulation suite. Communication can be extended to a plant-wide supervision system and also to IMA remote service assistance.

Automatic recipes, reports and audit trails reports for processing or cleaning can be edited and managed to ensure maximum efficiency and consistent results in compliance with current directives and guidelines (ANSI/ISA-88, FDA CFR21 part 11, GAMP®, MHRA GMP Data Integrity).

PROCESS CONTROL

MAX allows to easily achieve granulation end-point by means of impeller's power consumption. In addition it can work with control instruments required for PAT approach, such as torquemeter, NIR, acoustic detectors, to detect moisture content, content uniformity or monitor granule growth.

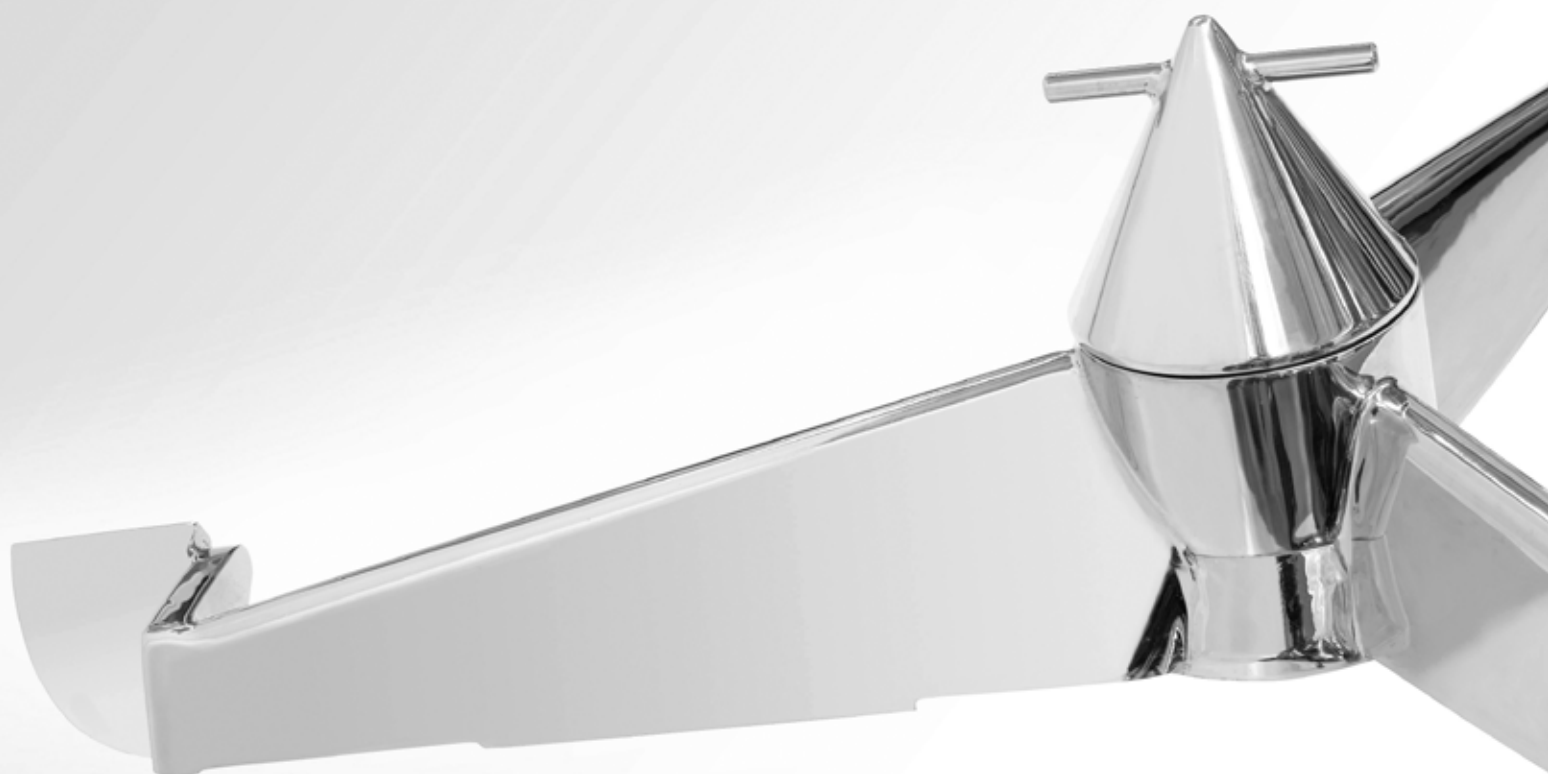




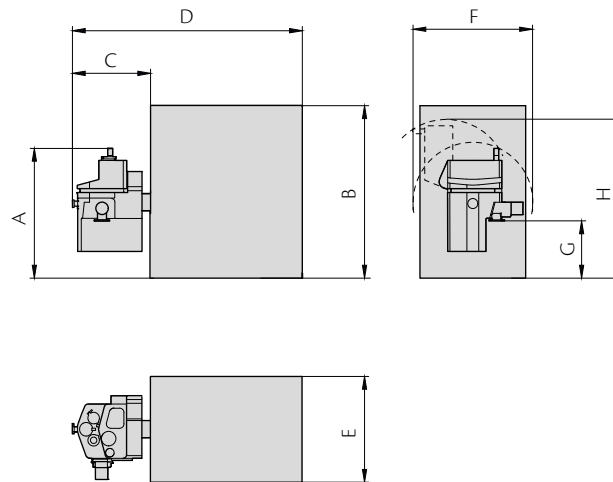
TECHNICAL DATA

Model	12	30	60	120	300	600	900	1200	1500
Bowl capacity (l)	12	30	60	120	300	600	900	1,200	1,500
Product quantity (l)	4-8	10-20	20-40	40-80	100-200	200-400	300-600	400-800	500-1,000
A (mm)	1,400	1,450	2,200	2,360	2,900	3,100	3,500	3,500	4,300
B (mm)	2,020		2,400		2,680	2,880	3,380	3,380	4,200
C (mm)	770	920	1,300	1,375	1,750	2,000	2,130	2,250	2,360
D (mm)	2,610	2,760	3,570	3,650	4,330	4,600	4,700	4,860	4,860
E (mm)	1,075		1,660		2,000		2,200		2,200
F (mm)	1,400	1,400	2,450	2,550	3,000	3,700	3,950	4,100	4,200
G (mm)	720	675	900		1,075	1,060	1,320	1,270	1,350
H (mm)	1,730	1,870	2,700	2,950	3,510	3,860	4,450	4,670	4,790
Impeller speed (rpm)	20-597	20-434	20-347	10-277	10-205	10-163	10-142	10-130	10-122
Chopper speed (rpm)	700-1,500								

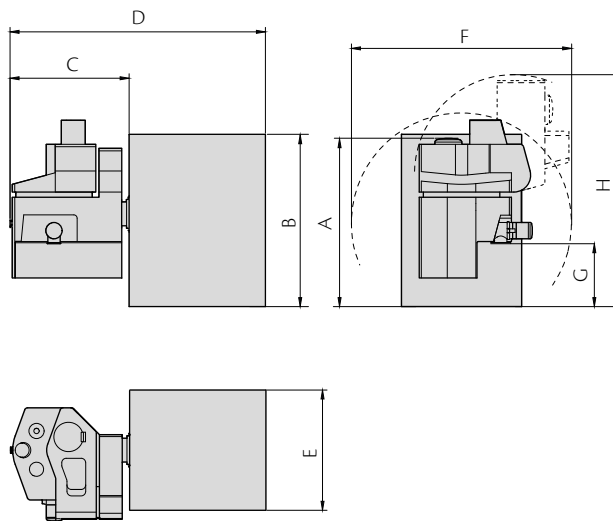
Sizes over 1500 litres are available on request.



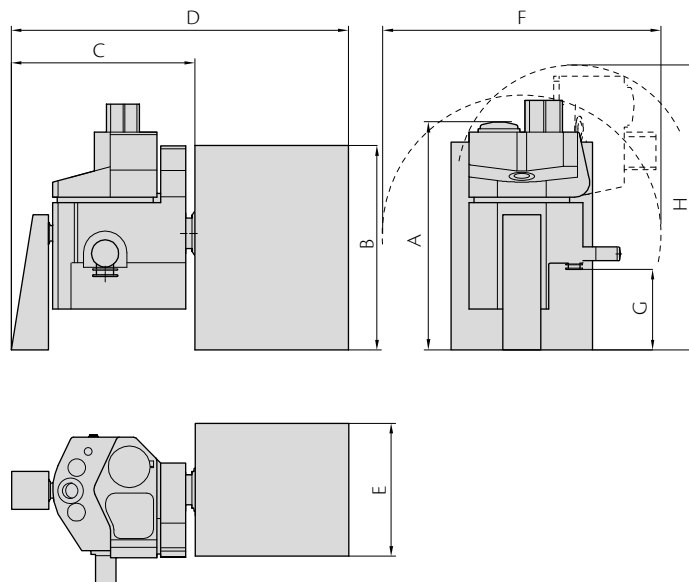
ROTO CUBE 12-30



ROTO CUBE 60 - 1200



ROTO CUBE 1500



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