

ROTO MIX

HIGH SHEAR MIXER GRANULATOR



ROTO MIX

The ROTO MIX is a high shear mixer granulator designed for the dry mixing of powders and wet granulation. Mixing and agglomeration of powder particles is achieved by the combined action of the impeller and chopper and liquid binder distribution system. It is supplied in a "through the wall" version, and by locating all the auxiliary equipment in a technical area optimizes the room layout according to GMPs and safety regulations.



IMPELLER

The ROTO MIX 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 and agglomeration 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 horizontal, located on the side wall of the bowl with a horizontal shaft and 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.



PRODUCT BOWL AND DISCHARGE VALVE

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

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.

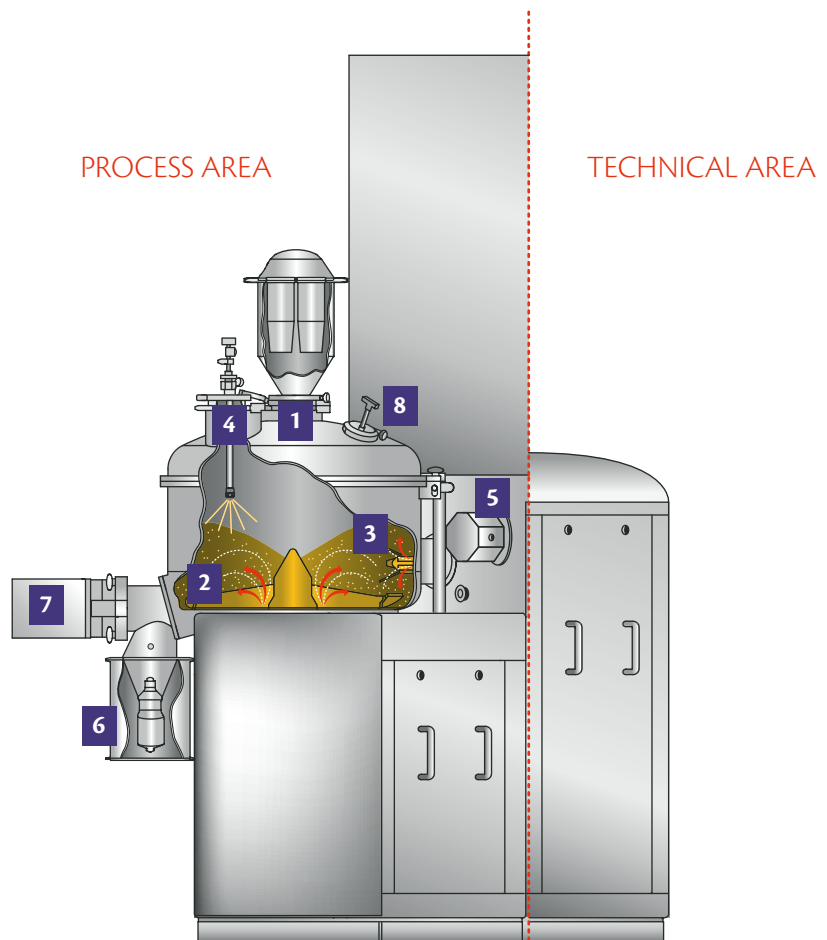
ROTO MIX



IN-LINE MILLING AND GRANULE TRANSFER TO A FLUID BED DRYER

The ROTO MIX can be integrated with the IMILL, for wet granule sizing and direct transfer, in a closed system, to a fluid bed dryer.

1. LOADING OF RAW MATERIAL BY VACUUM OR GRAVITY
2. IMPELLER
3. CHOPPER
4. BINDER SPRAY SYSTEM
5. PERISTALTIC PUMP
6. IMILL –I: IN-LINE MILLING
7. DISCHARGE VALVE
8. SIGHT GLASS AND LIGHT





PROCESSING IN EXPLOSIVE ATMOSPHERE

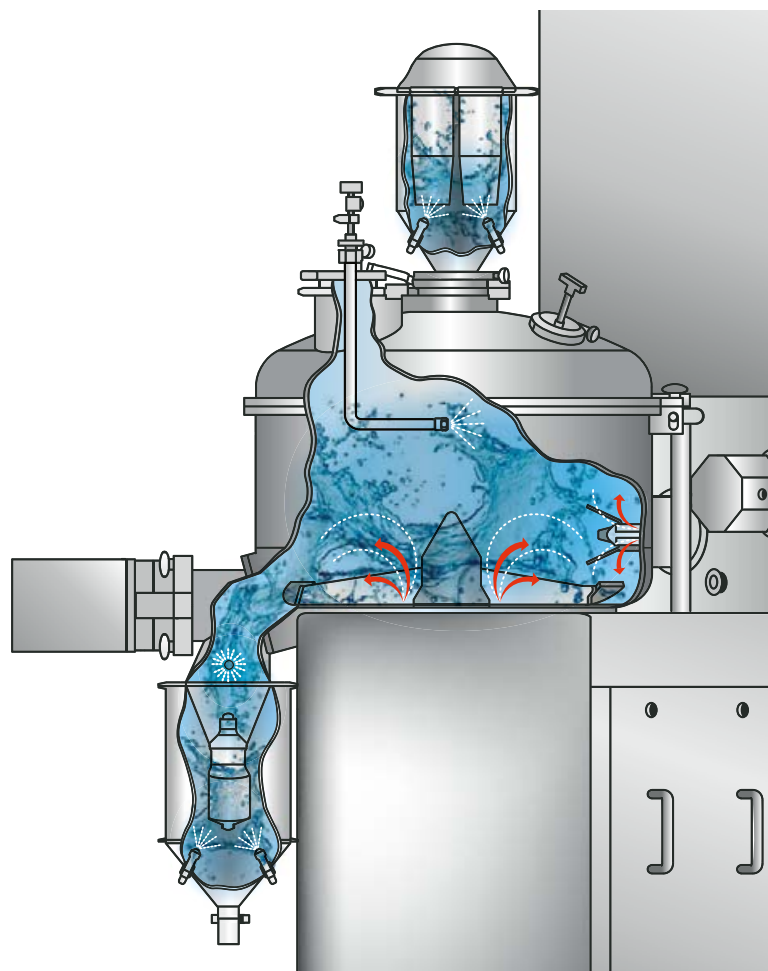
The ROTO MIX can be manufactured in conformity with EC Council Directive 94/9/CE - ATEX (100a) to operate in the presence of flammable organic solvents or dusty environments.

The pneumatic circuit is suitable for use with nitrogen to inertize the system, thus preventing dangerous conditions and adding a further level of safety to the operator.

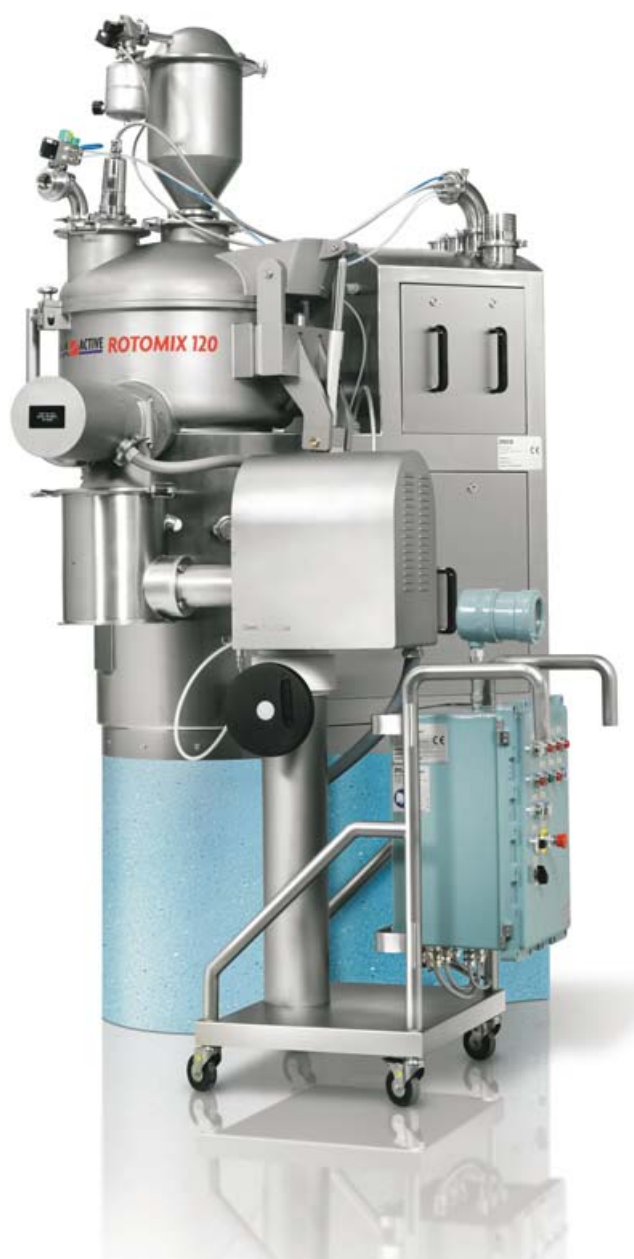
THE WASHING FLUID IS INTRODUCED FROM THE IMPELLER AND CHOPPER SEALS INTO THE ROTO MIX BOWL

WIP - WASH IN PLACE

The washing cycle is basically carried out by introducing the washing fluid from the impeller and chopper seals into the Roto Mix bowl, then running both impeller and chopper at high speed for a certain time. This operation can be repeated with different washing fluid until the final rinsing. Washing heads are strategically located to wash difficult to clean zones when the advanced washing kit is provided.



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CONTROL SYSTEM

The HMI (Human Machine Interface) panel allows the carrying out of the process in either manual or fully automatic mode. Automatic recipes for processing or cleaning can be edited and easily recalled every time to assure batch or washing cycle reproducibility.

The software is prepared to manage different access levels of password and electronic batch records and printouts are also available in compliance with FDA CFR21 part 11.

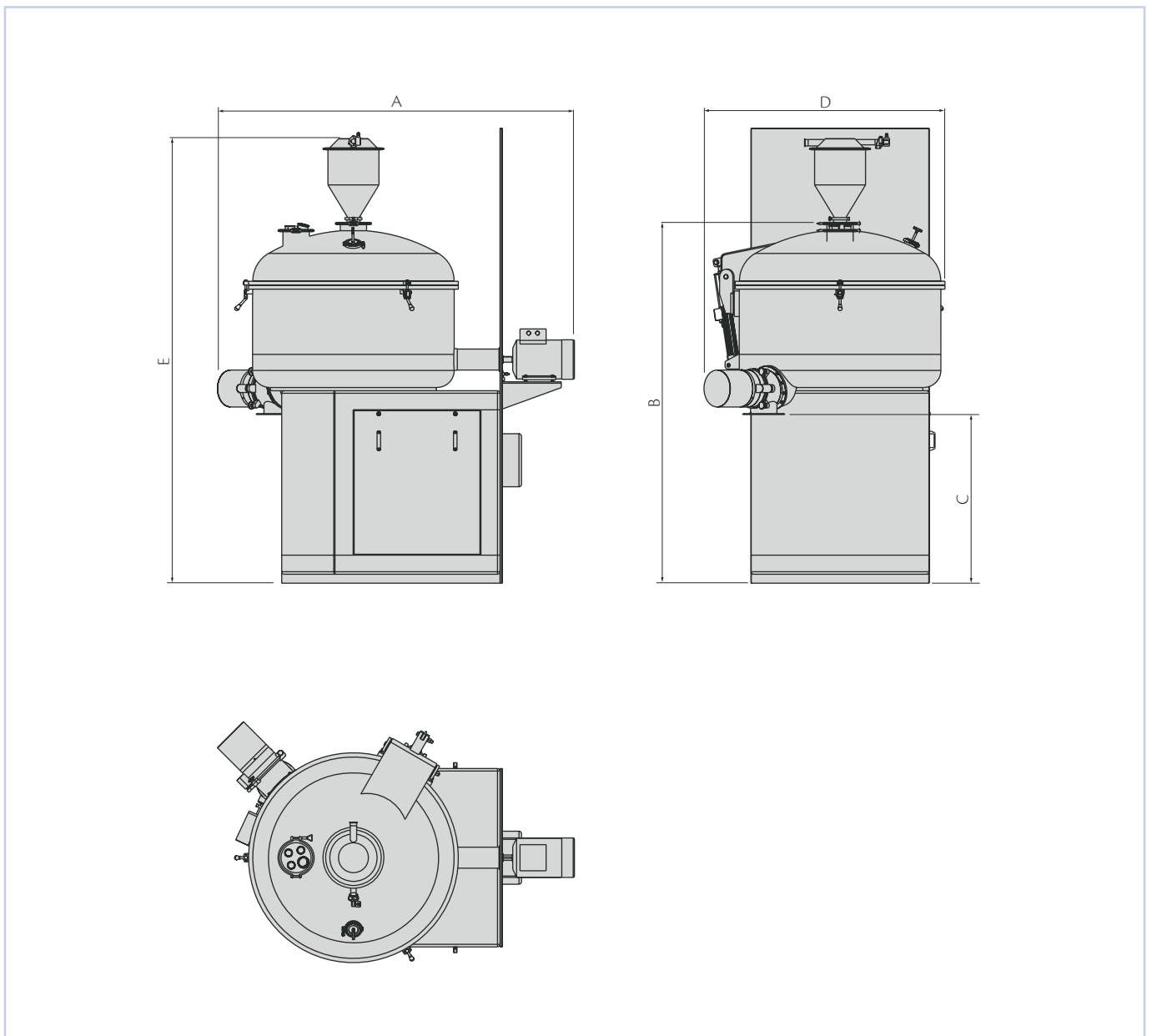
The HMI is suitable for communication in a local network when a granulation suite is set-up with a Ghibli Fluid Bed Dryer and other ancillary equipment.

It is also possible to arrange communication with a plant wide supervision system or for maintenance via modem.

On request the ROTO MIX can be provided with specific ports to integrate control instruments requested by PAT approach, such as torque meter, FBRM, NIR, acoustic detectors, to determine moisture content, content uniformity and monitor granule growth.

ROTO MIX TECHNICAL DATA

ROTO MIX



| MODEL | 60 | 120 | 300 | 600 | 900 | 1200 | 1500 |
|---------------------------|--|--------|--------|--------|--------|--------|-------|
| A (mm) | 1,380 | 1,720 | 2,180 | 2,430 | 2,620 | 2,750 | 2,850 |
| B (mm) | 1,520 | 1,620 | 2,000 | 2,400 | 2,650 | 2,700 | 2,830 |
| C (mm) | 870 | | 1,060 | 1,240 | | 1,300 | |
| D (mm) | 850 | 1,050 | 1,315 | 1,500 | 1,700 | 1,800 | 1,900 |
| E (mm) | 2,120 | 2,220 | 2,600 | 3,070 | 3,320 | 3,370 | 3,490 |
| Bowl capacity (litres) | 60 | 120 | 300 | 600 | 900 | 1,200 | 1,500 |
| Working capacity (litres) | minimum 25% - maximum 70% | | | | | | |
| Impeller power (kW) | 4 | 11 | 18.5 | 30 | 45 | 55 | 75 |
| Impeller speed (rpm) | 15-275 | 15-220 | 10-165 | 10-130 | 10-115 | 10-100 | 10-97 |
| Chopper speed (rpm) | 700-1,450 (up to 2,000 with frequency converter) | | | | | | |
| Weight (Kg) | 500 | 1,200 | 2,000 | 2,750 | 3,200 | 3,500 | 4,000 |

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Certificate
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