

PROFESSIONALS IN CONTAINMENT

SOLID DOSE CONTAINED PRODUCTION



KNOWLEDGE OF PROCESSING





THE INCREASE IN THE DEVELOPMENT OF HIGHLY HAZARDOUS ACTIVE PHARMACEUTICAL INGREDIENTS AND CONSEQUENTLY MORE RESTRICTIVE REGULATIONS IN TERMS OF OPERATORS AND ENVIRONMENTAL SAFETY HAVE BROUGHT A SIGNIFICANT GROWTH IN THE DEMAND OF PROCESS CONTAINMENT INSTALLATIONS WORLD-WIDE.

5

OEB 5
<1 µg/m³

4

OEB 4
1-10 µg/m³

3

OEB 3
10-100 µg/m³

2

OEB 2
100-1,000 µg/m³

1

OEB 1
1,000-5,000 µg/m³

A RISK BASED APPROACH



WITH MANY DIFFERENT INSTALLATIONS FOR DISPENSING, HANDLING, GRANULATION, TABLETING, CAPSULE FILLING AND COATING FOR 3 TO 5 OEB PRODUCTS, BOTH FOR PRODUCTION AND R&D APPLICATIONS, IMA HAS A WIDE AND CONSTANT KNOWLEDGE OF PROCESSING HIGHLY POTENT PRODUCTS.

CONTAINMENT INSTALLATIONS MUST BE DESIGNED ON A RISK BASED APPROACH.

A PRELIMINARY ANALYSIS HAS TO BE CARRIED OUT TO IDENTIFY CRITICALITIES AND POTENTIAL RISKS, CONSIDERING BOTH THE PHARMACEUTICAL REQUIREMENTS OF THE PROCESS TO BE PERFORMED AND THE PLANT CONDITIONS IN TERMS OF REGULATIONS, LAYOUT AND INDUSTRIAL TARGET.





3



4



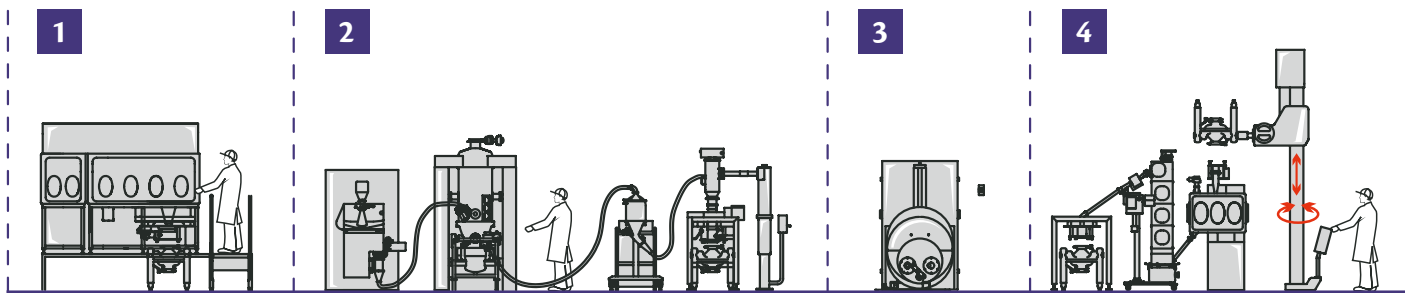
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DISPENSING

GRANULATION

BLENDED

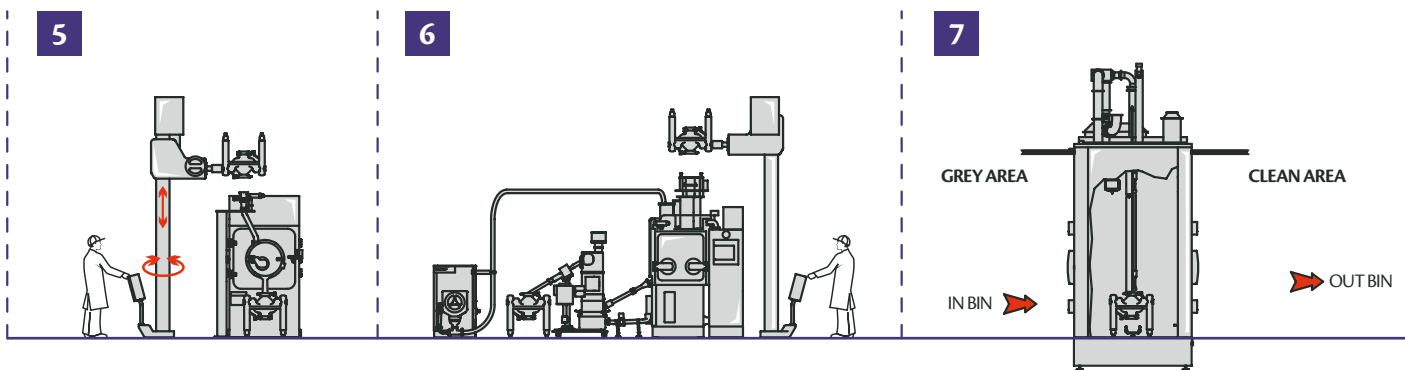
TABLETING



COATING

CAPSULE FILLING

WASHING AREA



6



7

ROTO CUBE HIGH
SHEAR GRANULATOR
AND SINGLE-POT
PROCESSOR CONNECTED
TO HERCULES LIFTING
COLUMN AND
TWINVALVE FOR
CONTAINED PRODUCT
FEEDING
AND DISCHARGE



HIGH CONTAINMENT STRATEGIES

- ISOLATION OF PROCESS AREAS, MINIMIZATION OF CONTAMINATED PARTS
- GLOVE PORTS AND RTP FOR SAFE ACCESS TO PROCESSING AREAS
- DUST TIGHT DOCKING SYSTEMS FOR FEEDING/ DISCHARGING
- CONTAINMENT MEASURES ON ANCILLARY EQUIPMENT (I.E. EXIT CHUTES, DEDUSTERS, METAL DETECTORS, SAMPLE COLLECTORS, IPC TESTERS, CONTAINERS)
- WIP/CIP



ZANASI THC, TOTAL HIGH CONTAINMENT CAPSULE FILLING MACHINE, CONNECTED TO WASHABLE DEDUSTER

CONTAINED PROCESSING



Product transfer to the PH-Bin by using TwinValve



Cyclops bin tumbler

ALL MACHINES ARE DESIGNED FOR CONTAINED PROCESS, THEREFORE CONTAINMENT MEASURES ARE NECESSARY ONLY TO EQUIPMENT INFEEED AND OUTLET.

AIR TREATMENT

Technical containment solutions are applied to air exhausted from the processing area for drying and/or dust extraction such as bag-in bag-out systems.

NEGATIVE PRESSURE

A negative pressure inside the processing areas ensures both environment and operator safety.



Glove ports on Adapta capsule filler

GLOVE PORTS AND RTP (RAPID TRANSFER PORTS)

Safe access to production areas is guaranteed by glove ports on machine doors and RTP: they allow the operator to work in the protected area without breaking the containment.

PRODUCT DISPENSING AND BLENDING INTO SEALED IBCs

IBCs are used for product dispensing of the raw materials prior to blending. Blending is then carried out on bin tumblers so that no product feeding and discharge are required inside the blending area.

Dispensing isolators are supplied by IMA Life.



Inflatable seals on Pressima THC tablet press

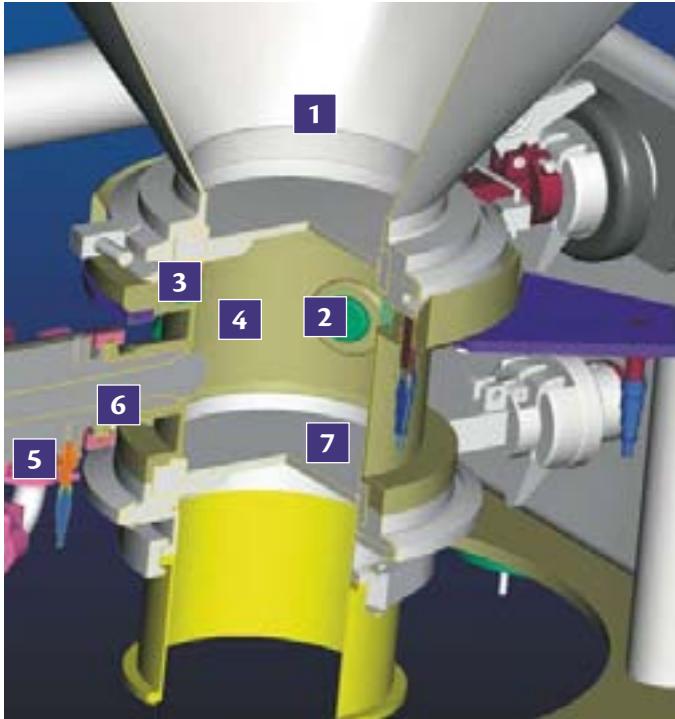
SEPARATION OF THE AREAS

On all equipment the production and mechanical areas are completely separate, thus limiting the surface contamination. This separation is achieved by the use of silicone bellows, V-ring and inflatable seals.

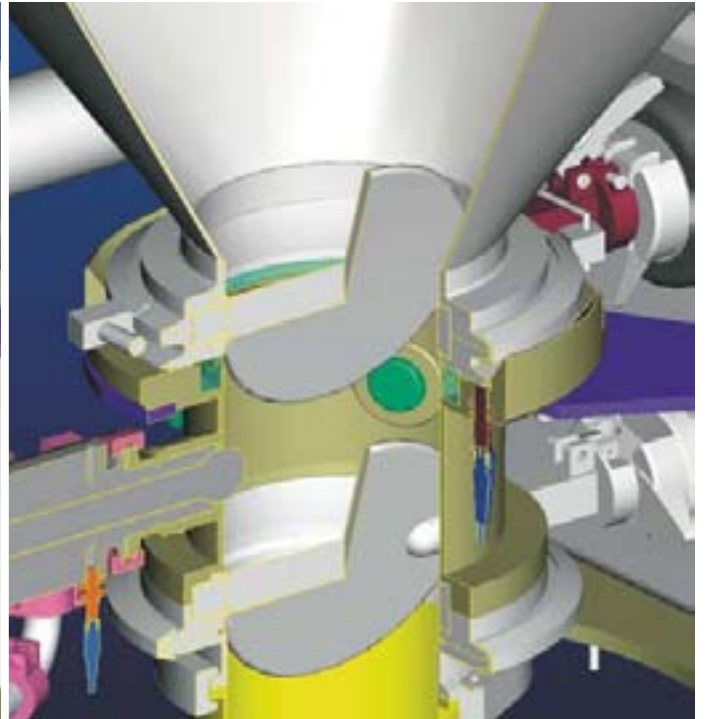


HERCULES LIFTING AND BLENDING COLUMN

PRODUCT TRANSFER AND FEEDING



TwinValve with closed valves



TwinValve with opened valves for product transfer

- 1** PASSIVE VALVE
- 2** VACUUM SENSOR
- 3** V-RING FOR VACUUM BARRIER
- 4** INTERMEDIATE CHAMBER WITH NEGATIVE PRESSURE
- 5** ASPIRATION LINE
- 6** CLEANING SPRAY HEAD (PATENTED)
- 7** ACTIVE VALVE

IBCs ARE MAINLY USED FOR PRODUCT HANDLING. A STANDARD BIN CAN BE EASILY FITTED WITH CONTAINMENT VALVES TO ENSURE SAFE PRODUCT LOADING AND UNLOADING.



COMPRIMA TABLET PRESS CONNECTED TO HERCULES LIFTING COLUMN AND TWINVALVE FOR CONTAINED POWDER TRANSFER



PRODUCT TRANSFER AND FEEDING



PERFIMA, PERFORATED COATING PAN, CONNECTED TO HERCULES LIFTING COLUMN AND TWINVALVE FOR CONTAINED TABLET TRANSFER INTO THE PAN



TwinValve cleaning spray head in extracted position, vacuum open



TwinValve cleaning spray head during cleaning with water/solvent



TwinValve with cleaning spray head in retracted position, vacuum closed

Product transfer can be easily carried out by using the high containment TwinValve that achieves containment levels up to OEB 5. This system is composed of two sanitary butterfly valves (active and passive) with a mini-hopper in between. The passive valve is installed on a IBC and the active valve is installed on the machine inlet or outlet. The small chamber that is created between the two valves when they are tight connected can then be cleaned by compressed air, steam, water and/or other fluids before or after product transfer by means of a telescopic orbital spray head.

THE ACTIVE TWINVALVE CAN BE INSTALLED FOR ANY TYPE OF PRODUCT TRANSFER WHEREVER A CONNECTION BETWEEN MACHINES, OR MACHINES AND IBCs, IS REQUIRED:

- AT THE DISCHARGE OF AN ISOLATOR TO DISPENSE SMALL QUANTITIES OF HAPI.
- FOR FEEDING EITHER A GRANULATOR, TABLET PRESS OR CAPSULE FILLER WITH POWDERS OR GRANULES OR A COATING PAN WITH CORES, IN THIS LAST CASE THE IBCs CAN BE ELEVATED BY A COLUMN LIFTER AND DOCKED ON AN ACTIVE TWINVALVE.
- AT THE DISCHARGE OF EITHER A GRANULATOR, TABLET PRESS, CAPSULE FILLER, OR A COATING PAN TO COLLECT THE PRODUCT INTO AN IBC IN A COMPLETELY CLOSED SYSTEM.

CONTAINMENT FOR ANCILLARY EQUIPMENT

ANCILLARY EQUIPMENT FOR PROCESS MACHINES CAN ALSO BE DESIGNED FOR CONTAINMENT, CLOSED BY INFLATABLE SEALS AND WASHED IN PLACE AT THE END OF THE PRODUCTION CYCLE. THEREFORE PRODUCT SAMPLING, IPC UNITS FOR WEIGHT CHECK, DEDUSTING AND METAL CHECK, ETC. ARE ALL DESIGNED AND INSTALLED TO MAINTAIN THE HIGHEST DEGREE OF CONTAINMENT. WHENEVER IS NOT POSSIBLE, DUE TO DESIGN CONSTRAINTS, THE ANCILLARIES THEMSELVES CAN BE ENCLOSED IN SUITABLE ISOLATORS, WHERE OPERATOR ACCESS IS BY GLOVE PORTS AND RTPs. A WASH IN PLACE PROCESS CAN ALSO BE CARRIED OUT.



Isolated statistic weight checking unit for capsule fillers



Isolated statistic weight checking unit for capsule fillers



Contained sampling on Pressima THC tablet press

ISOLATION AT
PRODUCT EXIT
ON ZANASI THC
CAPSULE FILLER



CLEANING AUTOMATION

ALL THE IMA ACTIVE MACHINES HAVE THE POSSIBILITY TO BE AT LEAST PRELIMINARY WET BEFORE THE DISMANTLING OF PARTS THAT HAVE BEEN IN CONTACT WITH THE PRODUCT. HOWEVER MORE SOPHISTICATED LEVELS OF AUTOMATION CAN BE SUPPLIED FOR THE CLEANING PROCESS, UP TO COMPLETELY AUTOMATIC CLEAN IN PLACE SYSTEMS.



Spray gun inside the machines



Spray gun port on machine doors



Clean In Place on Comprima tablet press

Wetting and washing inside the isolators can be carried out through the glove ports using the spray guns fitted inside the structure for this purpose. As an alternative, the isolator can be fitted with fixed spray nozzles for completely automatic washing. A water draining point is available for each unit: machine and ancillaries. All stainless steel tubes, complete with tri-clamp connections, are enclosed in a service tunnel.



WASH IN PLACE ON
ZANASI THC CAPSULE FILLER

CONCLUSIONS

IMA IS AWARE THAT CONTAINMENT HAS TO BE APPROACHED AS A GLOBAL ENGINEERING ISSUE IN A MANUFACTURING PLANT.

IF YOU ARE THINKING OF CONTAINED SOLID DOSE PRODUCTION, **IMA is THE PARTNER** FOR THE DEVELOPMENT OF TECHNICAL INNOVATIONS AND DEDICATED SOLUTIONS TO YOUR SPECIFIC NEEDS.





IMA  **ACT**
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Certificate
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