











Containment Performance: OEB at 150 ŋgr/m³ OEB5 in Active Configuration

DOUBLE CHAMBER DISPENSING ISOLATOR





DOUBLE CHAMBER DISPENSING ISOLATOR

- DISPENSING INTO BOTTLE OR BAG & LARGE CONTINUOUS LINER
- PRE CHAMBER BOTTOM CONTINUOUS LINER BAG OUT
- CHAMBER SIDE CONTINUOUS LINER WASTE BAG OUT
- PNEUMATIC CONTAINERS LIFTING PLATFORMS







INTERNAL FEATURES AND FINISHES

- INDUSTRIAL SCALE ATEX RATED & IP64
- BAG OUT CHUTE CONDUCTIVE CAP SECURED BY INFLATABLE SEAL
- ROUNDED CORNERS
- INTERNAL MIRROR FINISHING RA<0,4 MICRON
- SCOTCH BRITE EXTERNAL FINISHING

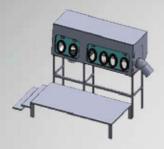




CONTROL SYSTEM

- CFR 21 PART 11 COMPLIANT CONTROL SYSTEM
- DIFFERENTIAL NEGATIVE PRESSURE CASCADE CONTROL
- PUSH PUSH SAFE CHANGE HEPA FILTERS
- IP64 WEIGHING SCALE









OEB4 in Passive Configuration OEB5 in Active Configuration

DOUBLE CHAMBER DISPENSING ISOLATOR









DOUBLE CHAMBER DISPENSING ISOLATOR

- DISPENSING INTO IBC VIA SPLIT VALVE
- PRE CHAMBER BOTTOM CONTINUOUS LINER BAG OUT
- CHAMBER SIDE CONTINUOUS LINER WASTE BAG OUT
- EMBEDDED TECHNICAL AREA





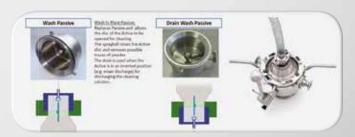


DOUBLE CHAMBER DISPENSING ISOLATOR

- CFR 21 PART 11 COMPLIANT CONTROL SYSTEM
- DIFFERENTIAL NEGATIVE PRESSURE CASCADE CONTROL
- PUSH PUSH SAFE CHANGE HEPA FILTERS
- IP64 WEIGHING SCALE





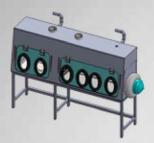


DOUBLE CHAMBER DISPENSING ISOLATOR

- CONTAINED TRANSFER BY SPLIT VALVE
- WIP/CIP PERFORMED BY SUPPLY PW AND WFI THROUGH ROTATING SPRAY BALLS
- WASHING MEDIUM DRAINED BY PASSIVE WIP/CIP FLANGE











Containment Performance: OEB at 150 ŋgr/m³ OEB5 in Active Configuration













DOUBLE CHAMBER DISPENSING ISOLATOR

INDUSTRIAL & ANALYTIC WEIGHING SCALE





DOUBLE CHAMBER DISPENSING ISOLATOR

- IP55 IN NORMAL OPERATION
- IP64 DURING CIP









Funnels utilised to improve dispensing accuracy and containment performance



 Manual/automatic raise and lower devices to handle docking with container below isolator.





TRANSFER VIA SPLIT VALVE & CHARGEBOTTLE

EXHAUST FAN DEDICATED TO EACH CHAMBER





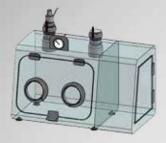




REACTOR CHARGING GLOVE BOX

- ALLOY BODY AND FULLY ANTACID MATERIAL
- ATEX RATED
- NITROGEN PURGING











POLYCARBONATE GLOVE BOX

- UNIVERSAL PC GLOVE BOX
- PRE CHAMBER EQUIPPED WITH 1 GLOVE
- MAIN CHAMBER EQUIPPED WITH 2 GLOVES AND A BAG OUT CONTINUOUS LINER
- ON THE BENCH CLOSED BOTTOM
- OVER A MOBILE SUPPORT SKID CONFIGURATION
- NEGATIVE PRESSURE CASCADE





CSV Containment presents a new technology to contain charging operations. In order to manipulate the powders under controlled conditions, the company introduce to the market a **Drum Unloading Machine** containment system **(DUM)** with the aim of proposing a turnkey solution based on proprietary and innovative CSV technology, which allows confining operations for any type of loading. This technology immediately proved to be an innovative solution for contained drum handling in general.

The system has the function of a pass box, but at the same time does not allow the body of the drum to enter the loading chamber, thus making it unnecessary to clean the drum, as it is not expose to the contaminant. For this purpose, CSV Containment has designed and implemented a **Double Iris Interface system (DIT)**, positioned as in a pass box, instead of the classic folding doors. The result is a cylindrical pass box (rather than square or rectangular, usually done), without folding doors, but with opening and closing ends at full diameter by means of an elastic diaphragm made of elastomer. This solution becomes particular when the pass box must guarantee the seal and must be operable from the outside of the insulator to which it interfaces.

The double elastic barrier allows to minimize the contact surface of the drum with the inner contaminated chamber atmosphere and eventually to automate, without introducing consumables, the drum insertion and extraction operations itself. Furthermore, a negative or positive pressure difference (pressure cascade) between the double iris pass box and the adjacent rooms (external or internal chamber) is achievable.



DOUBLE IRIS INTERFACE





DRUM ON THE OUTER IRIS CLOSED





DRUM THROUGH THE OUTER IRIS OPEN UP TO THE INNER IRIS CLOSED





DRUM SQUEEZED BY THE OUTER AND INNER IRIS





OUR WORKSHOP

Rigid isolators and DIT Stations are produced and tested at our mechanical workshop, very well known for production of tanks, reactors, heat exchangers, distillation columns, agitators, filters and anything else relating to fine chemical and pharmaceutical manufacturing.

Excellent machining of: HASTELLOY C22/276 - HASTELLOY B3 - DUPLEX - AISI 316L - AISI 304 - Aluminum/ALLOYS - Carbon Steel

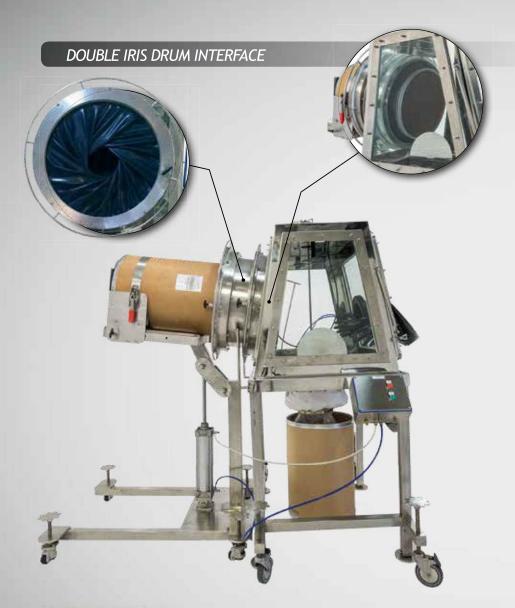














OEB4 in Passive Configuration OEB5 in Active Configuration













OPTIONAL CONFIGURATIONS

- FULLY AUTOMATED
- PURGED WITH NITROGEN
- NEGATIVE/POSITIVE PRESSURE CONTROL
- HUMIDITY OR O2 CONTROL













SINGLE IRIS DRUM UNLOADING MACHINE

- GMP / REACH DUST FREE APPLICATION
- MANUAL OR FULLY AUTOMATED DRUM HANDLING
- NEGATIVE PRESSURE OR ATMOSPHERE CHAMBER
- LIGHT AND MOVABLE











DRUM IRIS DISPENSING CALIBRATOR TO IBC

- SINGLE CHAMBER
- DRUM IRIS INTERFACE PASS BOX







DRUM IRIS DISPENSING CALIBRATOR TO IBC

- DISCHARGING THROUGH THE MILL INTO IBC
- SPLIT VALVE CONTAINED CONNECTION
- ATEX RATED
- NITROGEN PURGING & NEGATIVE PRESSURE
- OFFLOADING CHUTE CIP VIA ROTATING RETRACTABLE SPRAY BALLS



DRUM IRIS PLANT VACUUM TRANSFER

- FULLY AUTOMATED & CONTAINED DRUM HANDLING
- AUTOMATED DRUM LINER BAG IN & OUT
- CONNECTED TO THE PLANT/EQUIPMENT VACUUM
- ATEX RATED







DRUM IRIS PLANT VACUUM TRANSFER

- BOTTOM HOPPER ROTARY VALVE
- VENTURI DEVICE NEGATIVE PRESSURE
- NITROGEN INJECTION





• PRE CHAMBER: OPENABLE FRONT PANEL

PRE CHAMBER: DOUBLE IRIS BACK INTERFACE



DOUBLE CHAMBER DRUM IRIS REACTOR CHARGING

- PNEUMATIC DRUM HANDLING
- MANUAL IRIS INTERFACE
- PUSH PUSH SAFE CHANGE HEPA FILTERS









DRUM IRIS PNEUMATIC TRANSFER

- FULLY AUTOMATED & CONTAINED DRUM HANDLING
- AUTOMATED DRUM LINER BAG IN & OUT
- ATEX RATED











DRUM IRIS PNEUMATIC TRANSFER

- BOTTOM HOPPER ROTARY VALVE
- PNEUMATIC TRANSFER VIA VENTURE DEVICE
- COMPRESSED AIR MOTOR FLUID
- NITROGEN INJECTION





- LIGHT MOBILE SKID
- INTEGRATED DRUM HANDLING DEVICE
- MANUALLY OPERATED DOUBLE IRIS DRUM INTERFACE













DRUM REACTOR CHARGING

- TELESCOPIC MOBILE SKID
- MANUALLY OPERATED DOUBLE IRIS DRUM INTERFACE
- CONTAINED MAN-WAY REACTOR CHARGING

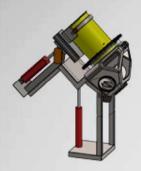




DRUM REACTOR CHARGING

- ALLOY BODY & FULLY ANTACID MATERIALS
- NEGATIVE PRESSURE VENTURI DEVICE











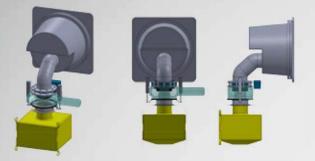




DRUM IRIS TWO MOVEMENTS

- 90° SKID ROTATING
- 180° DRUM ROTATION
- MANUALLY OPERATED DOUBLE IRIS DRUM INTERFACE







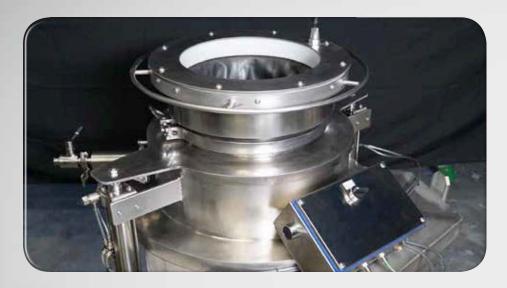




BIG BAG IRIS DOCKING CHARGING

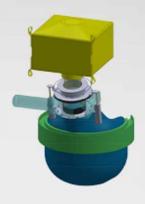
Contained Big Bag Coupling and separation

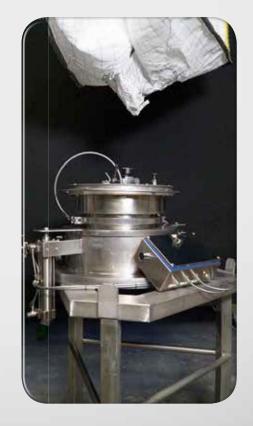




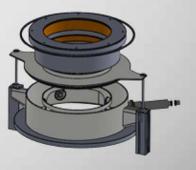






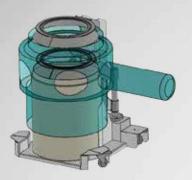






BIG BAG IRIS DOCKING DISCHARGING























ROTATING DRYER CONTAINED CHARGING/DISCHARGING

- ALLOY BODY & FULLY ANTACID MATERIALS
- NEGATIVE PRESSURE VENTURI DEVICE











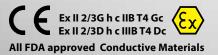




DRUM IRIS SAMPLING

- SOLVENT AND DUST FREE APPLICATION
- MANUAL OR FULLY AUTOMATED DRUM HANDLING
- NEGATIVE PRESSURE/INERT ATMOSPHERE
- LIGHT AND MOVABLE











DOUBLE IRIS _HIGH POTENT CONTAINMENT









IRIS AUTOMATION AVAILABLE







DRUM IRIS HIGH CONTAINED DISPENSING

- HIGH CONTAINED APPLICATIONS
- INERT N₂ NEGATIVE PRESSURE CHAMBER
- %O₂ CONTROL FIX AND MOVABLE
- PUSH PUSH SAFE FILTER CHANGE
- PRODUCT TRANSFER OUT VIA RAPID TRANSFER PORT
- SAMPLES AND WASTE BAG OUT VIA CONTINUOUS LINER



DRUM IRIS MATERIAL HANDLING

- MANUAL OR FULLY AUTOMATED DRUM HANDLING
- RAW MATERIAL TRANSFER VIA DOUBLE IRIS INTERFACE
- FIX OR LIGHT MOVABLE STATION









DRUM IRIS HANDLING/DISPENSING

- MANUAL OR FULLY AUTOMATED DRUM HANDLING
- RAW MATERIAL TRANSFER VIA DOUBLE IRIS INTERFACE
- PRODUCT TRANSFERRED OUT VIA SPLIT VALVE
- SAMPLES AND WASTE BAG OUT VIA CONTINUOUS LINER











CONTAINED TRANSFER _INTO SPLIT CHARGEBOTTLE/BAG





DRUM IRIS REACTOR CHARGING

- FULLY AUTOMATED
- PURGED WITH NITROGEN
- NEGATIVE/POSITIVE PRESSURE CONTROL

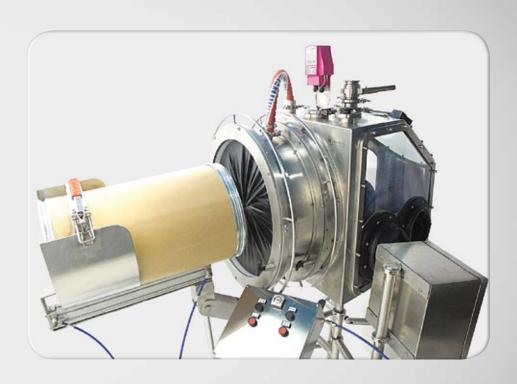
• HUMIDITY OR O₂CONTROL











DRUM IRIS HIGH CONTAINMENT REACTOR CHARGING

- RAW MATERIAL TRANSFER IN VIA DOUBLE IRIS INTERFACE
- INERT N₂ NEGATIVE PRESSURE CHAMBER
- %O₂ CONTROL

DRUM DOUBLE IRIS PASS BOX

- DRUM TRANSFER VIA DOUBLE IRIS INTERFACE
- THE DOUBLE IRIS INTERFACE CAN BE PRESSURIZED OR FOGGED CREATING A DIFFERENTIAL PRESSURE CASCADE BETWEEN THE CHAMBER AND THE BACKGROUND









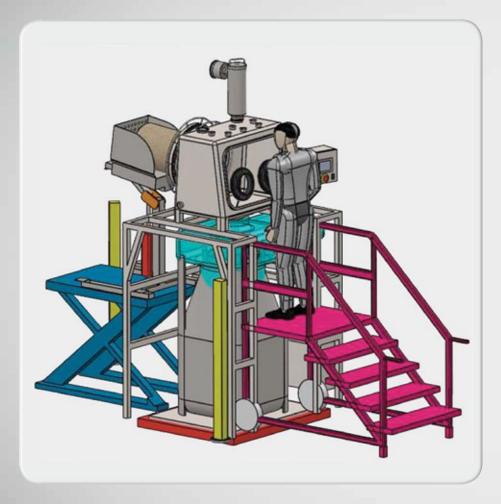


EXTRA LARGE DRUM IRIS REACTOR CHARGING STATION

- BIGGER CHAMBER FOR BIGGER BATCH SIZE
- BIGGER CHAMBER TO MINIMIZE THE TOTAL TRANSFERS

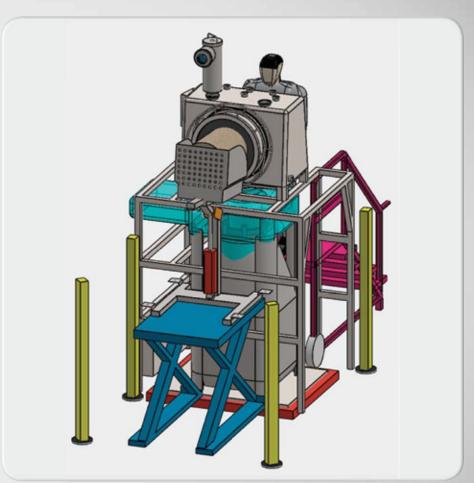








DRUM IRIS TO IBC ALLOWS OPERATOR TO TRANSFER DRUMS INTO AN IBC JUST WAITING FOR THE DRUM STANDING IN THE FRONT OF THE STATION; A FULLY AUTOMATIC DRUM HANDLING SYSTEM INTEGRATED INTO THE IRIS PNEUMATIC OPENING/CLOSING SEQUENCE MAKES THE STATION SUITABLE TO WORK ON HIGHER NOT ACCESSIBLE LEVEL OVER THE IBC.



DRUM PLATFORM

OPERATOR HAS JUST TO POSITION THE DRUM ON THE LIFTING PLATFORM AND MOVE TO THE STATION FRONT «CALLING» FOR THE DRUM. SAFETY BARRIER MAKES ANY DRUM HANDLING OPERATIONS SAFE.









ERGONOMIC HUMAN MACHINE INTERFACE

- OPERATOR CAN CONTROL THE STATION FROM THE HMI POSITIONED IN FRONT OF THE STATION AT THE WORKING LEVEL
- INERT N₂ NEGATIVE PRESSURE CHAMBER
- %O₂ CONTROL

FLEXIBLE IBC CONNECTION

A FLEXIBLE ISOLATOR ENCLOSES THE ATMOSPHERE BETWEEN THE STATION BOTTOM AND THE IBC ALLOWING OPERATOR TO OPEN/CLOSE THE IBC CHARGING PORT AT CONTAINMENT















FULLY AUTOMATED DRUM HANDLING

DRUM TRANSFER VIA DOUBLE IRIS INTERFACE
AUTOMATED CYCLE TO INTEGRATE THE DRUM LIFTING, ROTATION AND SLIDING
WITH THE OUTER AND INNER IRIS OPENING AND CLOSE SEQUENCE.













DRUM IRIS LUMP BREAKER

- BOTTOM HOPPER EQUIPPED WITH A STRONG LUMP BREAKER
- LUMP BREAKER CAN BE CONNECTED TO A CHARGING CHUTE OR TO A PNEUMATIC TRANSFER SYSTEM

DRUM IRIS LUMP BREAKER

- RAW MATERIAL TRANSFER IN VIA DOUBLE IRIS INTERFACE
- MANUAL OF FULLY AUTOMATED DRUM HANDLING
- INERT N₂ NEGATIVE PRESSURE CHAMBER
- %O₂ CONTROL









CAPACITY

- 800 KG/HOUR
- 50 KG/DRUM 16 DRUMS
- 25 KG/DRUM 32 DRUMS
- HIGHLY CONTAINED PERFORMANCES





















THE CHOPPER BREAKS THE LUMPS WHILE THE BOTTOM CALIBRATION GRID ASSURES THE POWDER SIZE TO BE TRANSFERRED





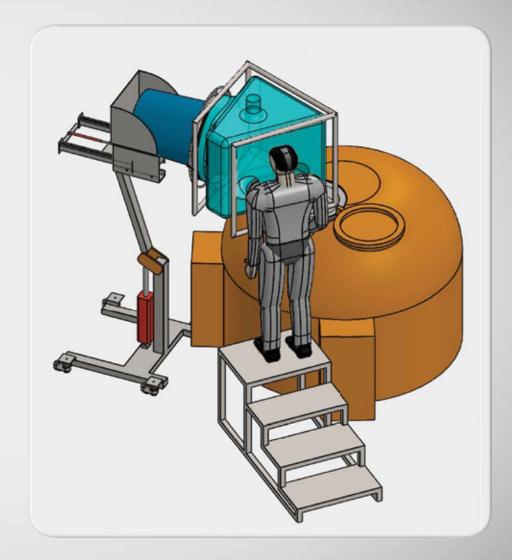






DOUBLE IRIS PASS BOX FEATURES/APPLICATIONS

- ROUND SHAPE PASS BOX
- PASSING THROUGH THE WALLS INTERFACE
- DRUM INTERFACE
- CAN BE COMPLETELY TRANPARENT
- CAN BE PRESSURIZED
- CAN WORK IN NEGATIVE PRESSURE
- CAN BE FOGGED
- DOUBLE IRIS CAN BE OPERATED BY:
 ONE SIDE (OUTISDE AN ISOLATOR OR OUTER A CLASSIFIED ROOM)
 TWO SIDE IN BETWEEN A WALL



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- MINIMIZE CLEANING & CLEANING VALIDATION NEEDS
- RAW MATERIAL TRANSFER VIA DOUBLE IRIS INTERFACE
- LIGHT AND MOVABLE STATION
- DEVELOPED FOR MANWAY CHARGING APPLICATIONS
- TO BE GMP/REACH COMPLIANT





DRUM IRIS FLEXIBLE REACTOR CHARGING INSTALLED ONTO AN OPEN MANWAY SUPPORTED BY THE DRUM IRIS LIFTER.













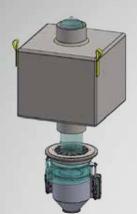
- OPEN THE MANWAY
- FIX AND SECURE THE STEEL LIGHT FRAME EQUIPPED WITH THE FLEXIBLE ENCLOSURE
- TRANSFER THE DRUM THROUGH THE IRIS
- ACCESS THE INNER DRUM LINER TO OFFLOAD THE POWDER





- ACCESS THE INNER DRUM LINER TO OFFLOAD THE POWDER
- TRANSFER OUT THE EMPTY DRUM
- AFTER HAVING COMPLETED THE LOADING OPERATIONS PUT A SPECIAL DOUBLE CAP ON THE LOADING POINT
- SEPARATE THE CAPPED CHAMBER AND THE MANWAY HOPPER
- VENTING THE REACTOR
- REMOVE THE HOPPER
- CLOSE THE MANWAY









- TUBE IN TUBE DOCKING TO CLOSE THE POWDER OFFLOADING FLOW
- FLEXIBLE ISOLATOR TO CONTAIN THE BIG BAG COUPLING AND DETACHING OPERATIONS
- IRIS FOR SQUEEZING THE BIG BAG OFFLOADING NECK & DOSING THE POWDER FLOW
- EASILY UPGRADABLE TO HIGH CONTAINMENT CONFIGURATION & PERFORMANCES
- PLUG AND PLAY INSTALLATION VIA CLAMP CONNECTION
- PNEUMATIC OR MANUAL ACTUATION
- VENTING AND CUSTOM MADE SIZING AVAILABLE

















IRIS DEBLISTERING ISOLATOR

- TABLETS TO BE DEBLISTERED TRANSFER IN BY DOUBLE IRIS PASS BOX
- PRODUCT BAG OUT VIA CONTINUOUS LINER
- NEGATIVE PRESSURE CONTROL; -50PA WITHIN 14 SEC
- SMEPAC CONTAINMENT PERFORMANCE: 44 NANOGRAMS/M3
- PLUG AND PLAY CONFIGURATION







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IRIS TANK TRANSFER

- IRIS TANK TRANSFER ABLE TO EMBRACE CONTAINERS UP TO 1 METER DIAMETER.
- ITT LIFT UP & DOWN OVER THE TANK BODY
- PRODUCT TRANSFER BY ANY KIND OF VACUUM LANCE
- OEB4 PERFORMANCE CONTAINMENT LEVEL











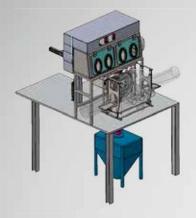


IRIS PNEUMATIC TRANSFER

- MOVABLE LIGHT SKID
- SUITABLE FROM ZERO TO ANY DRUM DIAMETER/SIZE
- MANUAL AND PNEUMATIC (IRIS AND DRUM LIFTER ACTUATORS) VERSION AVAILABLE
- SUITABLE TO ANY PNEUMATIC/VACUUM TRANSFER DEVICE SYSTEM
- ANTISTATIC FLEXIBLE CHAMBER
- UPGRADABLE FROM DUST FREE PURPOSE TO HIGH POTENT CONTAINMENT PERFORMANCES

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DRUM IRIS DISPENSING

- UNIVERSAL DOUBLE IRIS INTERFACE TO FIT ANY DRUM Ø
- DISPENSED POWDER OFFLOADING
- WASTE BAG OUT VIA LINER
- ATEX RATING ZONE 1,21
- NEGATIVE PRESSURE CONTROL
- NITROGEN PURGING AND O₂% CONTROL
- CONTAINMENT PERFORMANCE = 190 NANOGRAMS/M³















IRIS Cleaning CAP



Cleaning phase with Inner IRIS Open



End of Cleaning



Conductive Rotating Spray Ball



Cleaning phase with Inner IRIS Closed



End of Cleaning

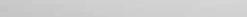




















DRUM IRIS TECHNOLOGY SUPPORTS

- DRUM SLEEVE COUPLING
- NO DIAPHRAGM PRODUCT CONTACT
- HIGHER CONTAINMENT PERFORMANCES









AVAILABLE SIZE:

- DN100 /4"
- DN200/8"
- DN350/12"
- DN560/22"
- DN700/27"

AVAILABLE MATERIAL BODY:

- STAINLESS STEEL (AISI316L OR AISI304)
- ALLOY
- POM
- HDPE

AVAILABLE DIAPHRAGM MATERIAL:

- EPDM CONDUCTIVE BLACK
- EPDM WHITE
- FKM
- SILICON
- NATURAL RUBBER

AVAILABLE ACTUATORS:

- MANUAL
- PNEUMATIC SEMIAUTOMATIC
- PNEUMATIC FULLY AUTOMATIC
- CUSTOMIZATION ON REQUEST









- PNEUMATIC
- MOBILE
- ATEX RATED
- TELESCOPIC FROM 800 TO 1800 mm
- PROVIDE WITH AN HORIZONTAL SHUTTLE
- 60KG STANDARD LOAD CAPACITY

















Standardized Measurement of Equipment Particulate Airborne Concentration

Containment Target Definition

Air Sampling Surface (Swab) Sampling Real-time Aerosol Monitoring

Test Facility & Environmental conditions

Test Personnel

Surrogate

Sampling strategy

Sample Methods

Data Analysis

Documentation





METHODS AND SURROGATES

Our method uses a grouping of different samples placed within the air space surrounding the containment enclosure, plus samples located at potential breach points, the worker, the test enclosures, and the air inside and outside the test environment. We developed highly sensitive and specific analytic methods to monitor the following surrogates: Lactose, Naproxen and

All our methods are validated according to ICH Q2 (R1)

LACTOSE NAPROXEN

- . HPLC-UV CPT/OEL* > 10 ng/m3
- LC-ESI-MS HPLC-FLUORESCENCE
- CPT/OEL* > 1 ng/m3 CPT/OEL* > 10 ng/m3

• HPLC-ED • CPT/OEL* > 100 ng/m3

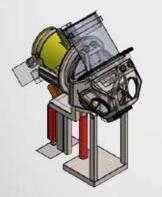
- MANNITOL
- LC-ESI-MSCPT/OEL* > 10 ng/m3



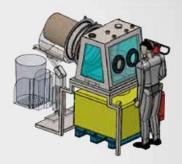
Certificate delivered by the European Commission, as the institution managing Horizon 2020, the EU Framework Programme for Research and Innovation 2014-2020



DOUBLE IRIS DISPENSING



DRUM EMPTYING SKID



DRUM TO FIBC



FIBC IRIS INTERFACE





















CSV Life Science Tasty solutions

CSV LIFE SCIENCE

VIA SELVANESCO 75 - 20142 MILANO - ITALIA www.csv-ls.com info@csv-ls.com PHONE: +39 02 274393.1 FAX: +39 02 27439320



LUCA VIETRI ANDREA PEDERZINI a.pederzini@csv-ls.com **ROBERTO FURLAN**

I.vietri@csv-ls.com r.furlan@csv-ls.com MOBILE:+393357594461 MOBILE:+393355911943 MOBILE:+39 340 9777 631

