



Work Order #: 33746	WO Spec Rev. #: D	Customer PO	Customer PO Date
Proposal #: 00366	Specification Rev. #: 1	Date: 09/05/2006	Proposed By: Riepe
Equipment Name:	Square Tray Dryer-Filter Isolator		
Customer: CPS		Contact:	
Address:			
Phone #:	Fax #:	Email:	

Equipment/Process Description:

The purpose of this isolator is to contain potent and toxic active pharmaceutical compounds during product filtration, hand sieve charging, drying in vacuum heat oven, hand sieving and discharging and final dispensing. It will be necessary to use the most efficient equipment to accomplish this purpose.

This isolator is to be multi-purpose, therefore, not only is the aspect of containment considered in the design, but also cleanability to prevent cross-contamination. In addition, it will be necessary to operate in an inert atmosphere using nitrogen. Furthermore, electrical and control systems within the isolator will be explosion proof-including sensors, blowers, etc. Items outside of the isolator will be explosion proof as well. This will be a 5-glove system with a Tray Dryer mounted with a 25" depth w/ a bump out to 28" for filter vessel clearance.

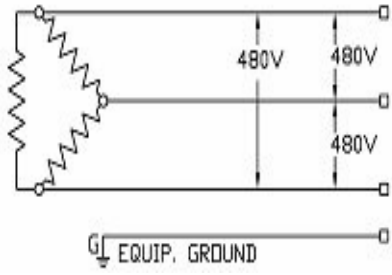
The toxic nature of the product requires the isolator to operate under negative pressure, which will be furnished with make-up using nitrogen supplied by the customer as needed. The negative pressure will be provided in the isolator enclosure by the self-contained built-in HEPA filtered ventilation system provided with the isolator. The isolator will be designed with a safety feature where the pressure sensor sends a signal to the blower to ramp-up during a breach (torn glove-sleeve, open tri-clamp connection, etc.). The system is designed to provide 100 ft/min velocity (negative air flow from outside-to-inside the isolator enclosure) across a gloveport breach opening.

The isolator will have a 270-mm rapid transfer port (RTP) alpha flange mounted on the side of the isolator enclosure. The port will be used for exit of the final product, samples and waste material into a 270-mm beta container connected to the 270-mm RTP alpha flange. To provide additional containment of exiting final product, samples and waste material, the customer should place two plastic bags within the beta container prior to connection. This will allow that the discharged product and materials can be sealed within tied-off bags within the container.

The HC-22 filter will be welded into the floor and the 316L SS "Square" tray dryer bolted to the back wall of the isolator. Square to optimize tray drying volume, and on the back wall to give ease of operation and manipulation during actual process.

The isolator will be equipped with a self-contained PLC controlled HEPA filtered explosion proof ventilation system supplying negative pressure nitrogen (nitrogen source supplied by customer) to the isolator enclosure. The isolator will also be equipped with an oxygen sensing system, which will maintain an atmosphere within the enclosure of $\leq 2\%$ oxygen using customer supplied nitrogen. The enclosure will be equipped with inlet and outlet "push-push" HEPA filters which feature "safe change" using the bag-out method.



<p>6. Continued:</p>	<p>Power:</p> <p><input checked="" type="checkbox"/> 480V 3 Phase 4 Wire</p> <p><input checked="" type="checkbox"/> 60 Hz</p> <p><input type="checkbox"/> 50 Hz</p>	<p>3Ø 480V 3P,4W GROUNDING</p> 										
<p>7. Product Information:</p>	<p><input type="checkbox"/> Liquid <input checked="" type="checkbox"/> Potent Powder <input type="checkbox"/> Suspension</p> <p><input type="checkbox"/> Antibiotic <input type="checkbox"/> Cytotoxic <input type="checkbox"/> Lyophilized <input type="checkbox"/> Multi-product</p> <p><input type="checkbox"/> Chemical: <input type="checkbox"/> Radiological Isotope:</p> <p><input type="checkbox"/> Other: Product Bulk Density:</p>											
<p>8. Product Container Information:</p>	<p>Material: <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Fiber <input type="checkbox"/> Stainless Steel</p> <p>Type: <input type="checkbox"/> Vial <input type="checkbox"/> Ampoule <input type="checkbox"/> Syringe <input checked="" type="checkbox"/> 270 mm Beta Container</p> <table border="1" data-bbox="553 1016 1531 1115"> <tr> <td>Size:</td> <td>Largest:</td> <td>Diameter: 270 mm</td> <td>Height: 400 mm</td> <td>Volume: ≈ 15 liters</td> </tr> <tr> <td></td> <td>Smallest:</td> <td>Diameter: 270 mm</td> <td>Height: 400 mm</td> <td>Volume: ≈ 15 liters</td> </tr> </table>		Size:	Largest:	Diameter: 270 mm	Height: 400 mm	Volume: ≈ 15 liters		Smallest:	Diameter: 270 mm	Height: 400 mm	Volume: ≈ 15 liters
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Section 1B – General Equipment Construction Requirements

1. Chamber Exterior Size: Length x Width x Height: ~ 97" Long x (25" & 28" bump out) Deep x 36" High

2. Overall Equipment Size: Length x Width x Height: ~ 103" Long x 62" Deep x < 98" High

3. Construction Information:

Item	Material	Finish / Color	Size / Gauge	Type / Comments
Shell:	316L SS	Interior: ≤ 22 Ra	7 Gauge	5/8" radius coved corners
		Exterior: ≤ 35 Ra		
Stand:	316L SS	≤ 35 Ra	1 1/2" Sq. tube	
Flashing:	316L SS	≤ 35 Ra	14 Gauge	Qty (2) sections on front upper flashing for maintenance access & HEPA filter change-out
Flashing Cover:	316L SS	≤ 35 Ra	14 Gauge	cGMP / 1° Slope away from HMI
Flashing Gasket:	Neoprene	Black		cGMP
Windows:	Laminated Safety Glass	Transparent	3/8" thickness	Front Hatchback
	Laminated Safety Glass	Transparent	3/8" thickness	On top of isolator chamber for light
Window Gaskets:	Silicone with Gore-Tex	White	3/8" U-channel	
Flat Gaskets:	Silicone with Gore-Tex	White		
HVAC Piping:	316L SS	Exterior: ≤ 35 Ra	3" Diameter	
CIP Piping:	316L SS		1/2" & 1" sanitary tube	
Hardware:	18-8 SS			External
Casters:	N/A			
Leveling Pads:	316L SS	Exterior: ≤ 35 Ra		Six leveling pads with 2" of raise/lower adjustment
Other:				



Section 2 – Equipment HVAC System Requirements

1. HVAC System: <input checked="" type="checkbox"/> On Equipment						
2. Overpressure: <input checked="" type="checkbox"/> Negative						
3. Unidirectional Airflow: <input checked="" type="checkbox"/> No						
4. Velocity Over An Open Glove Port: <input checked="" type="checkbox"/> 100 ft/min						
5. Gas System: Supports Items 7, 8 and 9	<input checked="" type="checkbox"/> Once Through					
	Gas Type: <input checked="" type="checkbox"/> CDA <input checked="" type="checkbox"/> Nitrogen					
	CPS Supplied Components: <input checked="" type="checkbox"/> Regulator <input checked="" type="checkbox"/> Proportional Control Valve Size: 1/2"					
Flow Meter Range (SCFH): 60-600						
7. Oxygen System: See section 7A.13	<input checked="" type="checkbox"/> Monitor <input checked="" type="checkbox"/> Automatic Control Oxygen Range: 0-20.9%					
	<input checked="" type="checkbox"/> Reduction only (no lower limit) Note: Oxygen Analyzer is a Draeger Polytron II					
8. Humidity System:	<input checked="" type="checkbox"/> None (Nitrogen system provides dehumidification – process dependent; no N2 monitoring)					
9. Ammonia Leak Test Pressure Control System: <input checked="" type="checkbox"/> Automatic						
10. Internal Equipment Heat Load: N/A						
11. Temperature System: <input checked="" type="checkbox"/> None						
12. HVAC Filters: See section 7A.14	Type		Inlet		Outlet	
			Qty	Size	Qty	Size
	6" dia. HEPA Push (Radial Flow)		2	6" Diameter	2	6" Diameter
	Pre-Filter		1	6" Diameter	1	6" Diameter
Pressure Sensor Filters		3	0.2 micron			
13. HVAC Blowers:	Type:	Neg. Press.				
	Qty:	1				
	Size:	AF9				
	Motor HP:	2 HP				
14. HVAC Valves:	Type	Qty	Size	Actuation		
	Butterfly	2	3"	Pneumatic		



Section 3 – Equipment Cleaning and Utility Component Requirements

1. Cleaning System: Water Dry Air Solvents: Type: **CIP 100/200**

Item	Qty	Material	Size / Type	Location / Comments
Chamber Drain Valve & Fitting	1		1½” Diaphragm Valve with tri-clamp	Floor of isolator chamber
Cleaning System Valves	2 / 1	316L SS	(2) ½” ball (1) 1” ball	Pneumatically actuated ½” Pneumatically actuated 1”
Spray Wand	1	PTFE	“Dual-Purpose” to deliver liquid & compressed air	In ceiling of isolator chamber (spray wand to deliver cleaning to Isolator, Tray Dryer, & Filter Vessel
Spray Wand Hook	2	316L SS	¼” J-Hook	In ceiling of isolator chamber
Spray Wand Port	1	316L SS	½” tri-clamp	In ceiling of isolator chamber
CIP provisions	6	316L SS / HC-22	½”	(1) SS316L ferrule in Tray Dryer, (1) HC-22 ferrule Mother Liquor Tank , & (4) SS-316L ferrules in Isolator Shell. There is also (6) 316L ferrules capped off on the CIP header.
Spray Balls	4	316L SS	Low Volume Spray	Mounted to the internal Isolator ferrules only (no piping shown)
Vacuum Wand Hook	N/A			
Vacuum Wand Port	N/A			
Item	Qty	Material	Size / Type	Location / Comments
Utility Panel Tri-Clamps	2	316L SS	1½’ tri-clamp	On left side wall of isolator
Utility Panel Compression Fittings	2	Teflon	3/8”	For scale integration
Product Entry Fitting (SLURRY)	1	HC-22	1” spooled tri-clamp	In ceiling of isolator chamber & extended out the back flashing of Isolator.
Product entry Hose (SLURRY)	1	Flexible Teflon	1” tri-clamp fittings at both ends	Connects between 1” tri-clamp in ceiling of isolator chamber to 1” tri-clamp fitting in 316L SS vacuum filter
Nitrogen & CIP Fittings:	2	316L SS	½” tri-clamps	In ceiling of isolator chamber with connections from vacuum filter to ceiling.
Spare:	N/A			



Section 4 – Equipment Material Handling Component Requirements				
Item	Qty	Material	Size / Type	Location / Comments
1. Gloves	3 pair	Hypalon	10" / 9Ambi	In front window panel of isolator chamber mounted on glove ports
2. Glove Sleeves	3 pair	Hypalon	10" / 9Ambi	
3. Glove Ports	5	ErgoClean (Ultem)	10" oval containment style w/ Retainers	Mounted through front window panel of isolator chamber
4. RTP Alpha Flange	1	316 SS / Polypropylene	190 mm mechanical lock-out REV. D	Located in the right side wall
5. RTP Beta Container	1	Polypropylene	190 mm diameter x 200 mm long REV. D	RTP beta container for exit of product
6. Trays	16 REV. B	316L SS – 14ga	8" x 12" x 1"	Trays with handles (Stacked two deep & side-to-side over three rows)
7. Shelving	N/A			
8. Scale <input checked="" type="checkbox"/> CLS Providing		Max. Capacity:	32 kg.	Display: <input type="checkbox"/> Inside <input checked="" type="checkbox"/> Outside
		Accuracy (±):	0.1 gr.	Foot Pedal: <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
		Brand:	Mettler-Toledo KA32SX, ID2sx display	Printer: <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
Note: Scale located on the floor below the Tray Dryer / Display in the Isolator flashing				

Section 5A – Equipment Control System Requirements

1. Control System Type:	<input checked="" type="checkbox"/> AMP2000 (Allen Bradley PLC & HMI) Special Notes: Micrologix 1500 w/ PLC E-Prompt
2. Supply Voltage:	Volts: 480 Phase: 3 Freq. (Hz): 60 Amps: 20
3. Control Panel:	Listing Required: <input checked="" type="checkbox"/> UL Mounting Location: <input checked="" type="checkbox"/> Attached to Equipment NEMA Rating: <input checked="" type="checkbox"/> 4X Purge Classification: <input checked="" type="checkbox"/> X
4. Display Panel Location:	<input checked="" type="checkbox"/> Flashing <input type="checkbox"/> Swing Arm <input type="checkbox"/> Other:
5. Battery Backup:	<input checked="" type="checkbox"/> None <input type="checkbox"/> Controls Only <input type="checkbox"/> Complete System Duration: <input type="checkbox"/> 5 Minutes <input type="checkbox"/> 10 Minutes <input type="checkbox"/> 15 Minutes <input type="checkbox"/> Other:
6. Grounding Provision for Internal Equipment:	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
7. GFCI Power Receptacle:	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
8. Equipment Lighting:	<input checked="" type="checkbox"/> Fluorescent Qty: 1 (XP) Location: Ceiling of isolator enclosure

Section 5B – Equipment Control System Phases of Operation

Phase	Description
Off Phase	Isolator shut down, no pressure control, light operational
Run Phase, Nitrogen	Isolator in normal operation, negative pressure, oxygen sensing and control system operational, alarms operational and lights operational Note: In Nitrogen Mode; O2 level must reach XX% within YY time or an audible alarm will sound with a visual alarm display on the HMI is time is exceeded. (Parameter to be adjustable in parameter settings by administrator)
Chamber Breach Phase	Isolator will sense a loss of negative pressure beyond its capability to compensate in the run phase. The system will automatically increase the speed of the exhaust blower to 100%, shut-off inlet supply valve, and activate a visual and audible alarm until breach is corrected or alarm is silenced.
Cleaning Phase	Isolator will be in normal operation, negative pressure and using room air. The spray wand or balls will be supplied with either water or CDA with the operator choosing the cleaning agent and device. The lights are accessible and D/P alarms operational.



Section 6 – Factory & Site Acceptance Test (FAT & SAT) Requirements			
Notes: Test #'s 1-7 are included at no cost as applicable to the equipment design. Test #'s 8-14 are included at no cost as applicable to the equipment options selected. Test #'s 15-20 are Optional and involve additional charges. SAT tests are only applicable if installation is performed by CPS Barrier.			
FAT	SAT	Inspection / Test	Inspection / Test Description
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Supplied Equipment Review (WC-ATP-01)	Verify that all items specified on the customer's PO, approved assembly drawing and the Equipment Specification are present
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Workmanship, Appearance and Identification Inspection (WC-ATP-02)	Verify workmanship and appearance of the complete Equipment, including welding, polishing and labeling
<input checked="" type="checkbox"/>	N/A	3. Dimensional Inspection (WC-ATP-03)	Verify the general dimensions of the Equipment and the locations of critical components with the approved Equipment assembly drawing
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Product Manipulation Systems Functional Inspection (WC-ATP-04)	Verify that the Equipment product manipulation systems (such as doors, RTP's, gloves & containers) operate properly
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Calibrated Instrument Checklist (WC-ATP-05)	Verify that the Calibrated Instruments are listed correctly on the Inspection Form
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Electrical Control System Test (WC-ATP-15)	Verify that all electrical controls (controllers, monitors, alarms, lights, switches and indicators) operate as specified
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Ammonia Leak Test (WC-ATP-06)	Verify that no leaks are detectable around seal joints with Ammonia inside the Equipment chamber
<input type="checkbox"/>	<input type="checkbox"/>	8. Unidirectional Airflow Test (WC-ATP-08)	Determine the air velocity and uniformity at specified locations in the Unidirectional Airflow Equipment
<input type="checkbox"/>	<input type="checkbox"/>	9. CIP Sequence of Operations (WC-ATP-14A)	Verify the performance of the CIP equipment in regard to the sequence of operations
<input type="checkbox"/>	<input type="checkbox"/>	10. Oxygen Concentration Control System Test (WC-ATP-19)	Verify that the Equipment controls the oxygen level as specified
<input type="checkbox"/>	<input type="checkbox"/>	11. Humidity Control System Test (WC-ATP-18)	Verify that the Equipment controls the humidity level as specified
<input type="checkbox"/>	<input type="checkbox"/>	12. Temp Control System Test (WC-ATP-11A)	Verify that the Equipment controls the chamber temperature as specified
<input type="checkbox"/>	N/A	13. Atmospheric Oven Temp Control System Test (WC-ATP-11B)	Verify the temperature performance of the dryer oven
<input checked="" type="checkbox"/> REV.C	N/A	14. Vacuum Oven Temp Control System Test (WC-ATP-11C)	Verify the temperature performance of the dryer oven
<input type="checkbox"/>	N/A	15. Helium Leak Test (WC-ATP-07)	Verify that no leaks exceed the specified leak rate at known standard conditions around seal joints with Helium inside Equipment chamber
			Leak Rate: 1 x 10 ⁻⁴ cc/sec Test Pressure: 2" Water Column
<input type="checkbox"/>	N/A	16. VHP (H2O2) Chemical Indicator Test (WC-ATP-12)	Verify that all surface areas inside the Equipment chamber are reached through the H2O2 decontamination process
<input type="checkbox"/>	<input type="checkbox"/>	17. Measure Air Changes Per Hour Test (WC-ATP-09)	Determine the rate of air changes per hour within the Equipment
<input type="checkbox"/>	N/A	18. Air Flow Smoke Test (WC-ATP-22)	Determine airflow patterns in the Equipment and ensure that air flows without dead zones and eddies
<input type="checkbox"/>	N/A	19. CIP Coverage Test (Riboflavin) (WC-ATP-27)	Verify the coverage of liquid delivered by CIP spray balls and/or spray wand inside the Equipment chamber using Riboflavin
<input type="checkbox"/>	<input type="checkbox"/>	20. HEPA/ULPA Filter Integrity Test (CLS-1017-M1)	Verify the Equipment's HEPA / ULPA filters for integrity using an aerosol



Section 7A – Additional Items

Note: Items identified as optional are priced separately and not included in the system price, please contact your Technical Sales Representative for further information and recommendations.

Item	Item Description
1	<u>REQUIRED:</u> CPS to provide DOP ports on HEPA filter housings for HEPA filter challenge testing
2	<u>REQUIRED:</u> CPS to provide HC-22 product pressure filter of 18” outside diameter / 16” inside diameter <u>welded</u> in floor of isolator chamber. CPS to provide 16” diameter, 10” diameter and 6” diameter baskets for various volumes of product. Product filter will have removable hinged cover to allow access to filter basket for product handling. Filter to accommodate for a temperature range between 15-25° C. <u>Temperature measurement on bottom of Filter required.</u> Filter shall accommodate for a pressure range of vacuum – 2 bar overpressure. Surface finish to be Ra 0.5 internal (portion of filter within the isolator enclosure) and Ra 35 finish on exterior of filter which is outside and beneath the isolator enclosure. Bottom of filter housing shall be sloped to drain. HC-22 tri-clamp connections to be provided on the product filter lid and bottom. <u>CPS to provide sight glass with fiber optic light</u> on top of filter. Filter cover to 1½”, 1” and ½” tri-clamps made of HC-22.
3	<u>REQUIRED:</u> CPS to provide a 316L SS vacuum drying oven inside dimensions ~21”W x 17”H x 29”D & outside dimensions ~25”W x 21”H x 31”D <u>bolted onto back wall</u> of isolator chamber; centered between the left two glove ports. Tray dryer vacuum oven to have hinged 316L SS door. There will be four ^{REV. B} shelves within the dryer that also act as the heating coils. Oven to operate with full vacuum design with operation at 50 millibars. Design temperature of oven to be 15-120° C. Oven to have spray ball. Oven to have a tri-clamp drain port in bottom of unit. CPS to provide ports for nitrogen inlet, temperature sensor, water loop, manometer and secondary air/nitrogen port. <u>Dryer to have site glass with fiber optic light.</u>
4	<u>REQUIRED:</u> CPS to provide a fitting on the inlet “push-push” HEPA filter housing for connection of customer supply nitrogen source. Nitrogen supply will be 90 psig.
5	<u>REQUIRED:</u> CPS to provide a total of one (1) set of double in-line 0.22 µ filters mounted on floor of isolator with 1” spooled tri-clamp fittings through floor of isolator. These filters are for the CPS provided vacuum pump & line.
6	<u>REQUIRED:</u> Integrated Explosion Proof Mokon Heater and stainless steel water piping.
7	<u>REQUIRED:</u> Vacuum Pump system, piping and controls for tray dryer and pressure filter. Hard pipe the vacuum pump vent to the exhaust connection with stainless steel piping. Piping to be supported on the back of the shell & stand.
8	<u>REQUIRED:</u> The 1” 316L SS manual ball valve on the bottom of the Tray Dryer
9	<u>REQUIRED:</u> Add a nitrogen regulator for tie in to the Tray Dryer hard piping so that nitrogen is sent to either the Isolator or the Tray Dryer separately.
10	<u>REQUIRED:</u> Wireway required
11	<u>OPTION:</u> 50 Liter 316L SS mother liquor tank. The drain connection on the bottom of the tank is machined out of a block to meet ASME standards. Cutting off the TC end and extending the piping, is not a viable option, therefore CPS to add required pipe with support off from the caster bolting flange so that the system does not need to be recertified. The connection of the TC is a high pressure clamp connection, and the manual ball valve to be welded into the extension piece on one side with a TC connection on the other. Note: all casters on tank to be non-rotating for maneuverability.
12	<u>OPTION:</u> Mettler-Toledo KA32 SX scale platform washable and explosion proof: ID1Plus Terminal for scale, Rs232 for ID1 (Stainless Steel)



13	<p>OPTION: OEL Testing; with the use of an electronic Dustrac Instantaneous read out meter and cartridge testing method. Testing will use Lactose as the test media. Cartridges would be sent out to a mutually agreed upon lab and Owner would be responsible for the lab fees only. Carlisle would include the site labor to do the testing on our end, with help supplied by the Owner operators. Testing will be to prove the CPS guarantee of less than 1.0 microgram/m3 based on 8 hour time weighted average.</p>
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Section 7B – Equipment Design Exceptions

Note: The following items have been identified as special exceptions that are not included in the equipment design and price, please contact your Technical Sales Representative for further information and recommendations.

1	
2	

Section 8 – Equipment Specification Revision History

Rev. #	Revised By	Rev. Date	Revision Description	Released
A	SJW	9/28/06	Initial release from Proposal Spec	9/28/06 SJW
B	PJE	12/19/06	Updated per defined quantities	
C	PJE	3/14/07	Added FAT Test for tray dryer and updated business name change.	3/14/07 CSS
D	PJE	4/2/07	Alpha, Beta change from 270 to 190.	4/11/07CSS