

LAMINAR FLOW CLEAN BENCH

Test Report No.: 100085792
Date: November 29, 2017
Client: THE COMPOUNDER
Address: 340 MARSHALL AVE UNIT 100
AURORA, IL 60506
Attn: LYDIA LESNIAK

Mfg./Model: Envirco #10166 ESM-4
Identifying No.: 66043233
Location: 1st Floor
Room: IV Prep
Other: NA

MCI#: AI5159

SUMMARY OF TEST RESULTS

AIRFLOW VELOCITY RESULTS

Test Results on Page 2

FINAL - VELOCITY TEST PASS FAIL AVG PASS AVG/FAIL UNIFORMITY

AEROSOL CHALLENGE INSTALLATION LEAK TEST

Test Results on Page 3

AS FOUND - SUPPLY FILTER PASS FAIL NO TEST NA

FINAL - SUPPLY FILTER PASS FAIL NO TEST NA

INDUCTION LEAK/BACKSTREAMING TEST

Test Results on Page 3

PASS FAIL NOT APPLICABLE

AIRBORNE PARTICLE COUNT TEST PASS FAIL NO TEST

Test Results on Page 3

Note: Noise Level Test and Lighting Intensity Test results are for information only.

Testing Performed In Accordance with Micro-Clean

SOP # LFCB-0616 MCI

Retest Date: MAY, 2018

and CETA CAG-003-2006-13

Remarks: NA

Above Testing Work Performed By


Taylor Schiering

Date 29-Nov-2017

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FINAL AIRFLOW VELOCITY

Anemometer: Mfg. TSI Model 962 S/N P09260017 Cal Due December 26, 2017
 Velgrid: Mfg. NA Model NA S/N NA Cal Due NA

Pass Average Velocity/Airflow Uniformity

All readings within ±20% of Avg.

Fails Average Velocity

Pass Average Velocity/Fail Airflow Uniformity

Number of Readings Taken 8
 Maximum Velocity Allowable/Actual 110 / 105 fpm
 Minimum Velocity Allowable/Actual 73 / 84 fpm
 Average Velocity 92 fpm
 Acceptance Criteria 80 - 100 fpm

Diagram of Velocity Profile Taken at 6 inch(es) from diffuser screen

Supply Filter NA

84 93 87 92
 95 90 86 105

Differential Pressure: GREEN

Blower Speed Required: Increasing Motor Parameters: NA
 Velocity Conforms to: Manufacturer's Specs. & Owner's Requirements

All Readings - For Information Only

NOISE LEVEL

Sound Meter: Mfg. NA Model NA S/N NA Cal Due NA
 "A" Weighted Scale Total NA dBA Background NA dBA Corrected NA dBA

- Readings taken 12 in. in front and 15 in. above the centerline plane of work surface.
- Readings taken on centerline of HEPA(S) 30 in. from filter face for units without a work surface.

All Readings - For Information Only

LIGHTING INTENSITY

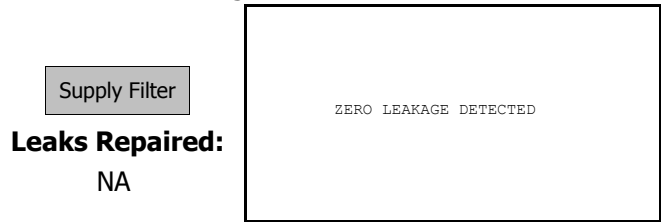
Light Meter: Mfg. NA Model NA S/N NA Cal Due NA
 No. Readings NA Average NA F.C. at work surface
 Readings taken along center line of work surface

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AEROSOL CHALLENGE INSTALLATION LEAK TEST

Photometer: Mfg. Air Technique **Model** TDA-2GN **S/N** 10937 **Cal Due** January 26, 2018

Diagram of repairable filter leaks with challenge concentration of
 A minimum of 10 ug/Liter PAO CAS# 68649-12-7 **and leak concentration as shown:**



Filters marked "100% Scan" were scan tested over the filter media and separate passes made on the surrounding frame/seal. Filter acceptance is 0.01% of the upstream concentration.

[Comments Below:](#)

/ - media leakage NA
 x - frame leakage
 BR - before repair
 AR - after repair
 ZAR - zero after repair

Leaks Repaired:
NA

As Found: Pass Fail No Test NA

Final: Pass Fail No Test NA

Equipment: (See "Particle Count Data")

INDUCTION LEAK/BACKSTREAMING TEST

Device should not exhibit unsealed construction joints or any intrusion of particles from openings.

Pass - Induction Leak/Backstreaming Test Fail - Induction Leak/Backstreaming Test Not Applicable

Comments: NA

PARTICLE COUNT DATA

Particle Counter: Mfg. TSI **Model** 9310-02 **S/N** 93101126005 **Cal Due** February 01, 2018

Note: All particles 0.5 **micrometer and larger were counted.**

Readings shown are in particles per cubic meter of air.

Ambient room particle count = 1555 ppcm (Room Ambient)

Sample Locations are 12 inches from diffuser screen

(1)	0	(3)	0	(2)
		0		
(4)	0		0	(5)

Particle Count locations are identified with sequential numbers, i.e. (1), (2), etc.
 Room ambient count is identified as (Room Ambient).

Particle Count Class Limit for

ISO Class 5 0.5 um & larger (At-Rest) ISO 14644-1:2015

Pass Fail No Test

REMARKS

Supply HEPA Filter(s) Size: 1-24 x 44-1/8 x 6 Alum Frame

Pre Filter(s) Size: 2-22 x 23-3/8 x 1 30%

HEPA Filter(s) Replaced: No **Prefilter(s) replaced:** No

OPERATIONAL NON-VIABLE PARTICLE COUNT USP<797>

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NON-VIABLE PARTICLE COUNT CONDITIONS OF TEST

Type of Clean Zone: Unidirectional	Occupancy State of Test: Operational
Cleanroom or zone Cleanliness Classification: ISO Class 5	Type of Test: Verification
Particle Class Limit In Particles Per Cubic Meter: 3520	Sample Time: 1 in Minutes
Measures Paricle Size in Microns (and larger): 0.5	Sample Volume: 28.3 Liters Per Minute
Number of Paricle Count Sample locations: (L): 1	Total Sample Volume: 84.9 Liters

PARTICLE COUNT VALUES - REPORTED IN PARTICLES PER CUBIC METER

Particle Counter: Mfg. TSI **Model** 9310-02 **S/N** 93101126005 **Cal Due** February 1, 2018

OPERATIONAL PARTICLE COUNTS: The particle counter isokinetic probe is positioned within six inches upstream of the product manipulation point.

For unidirectional flow applications the particle counter isokinetic probe shall be pointed into the airstream.

For nonunidirectional flow applications the particle counter isokinetic probe shall be pointed vertically towards the ceiling.

This sampling point is positioned near the arm convergence point, but not interfering with operator hand and arm movement. The isolator operator shall simulate compounding operations during the three (3) 1-minute sampling periods. Testing performed in Accordance with ISO Std 14644-1: 2015.

EACH READING must not exceed the particle count class limit.

0	0	0
sample 1 (ppcm)	sample 2 (ppcm)	sample 3 (ppcm)

Particle Count Specification: ISO Class 5 (3520ppcm @ 0.5um & larger) Operational per **Pass** **Fail** **No Test**
ISO Std 14644-1: 2015

Remarks: NA

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AIRFLOW VISUALIZATION TEST - USP <797>

This test is performed to verify that airflow smoke patterns demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic (operational) conditions within the unidirectional flow device. The smoke illustrates the importance of proper use of "First Air" in the Direct Compounding Area (DCA).

HORIZONTAL FLOW DEVICES Introduce smoke six inches upstream (15.2 cm) of the DCA and along the:
 a) Vertical axis of the DCA central point, begin at least 12" (30.5 cm) above and below the central point of the DCA.

b) Horizontal axis of the DCA central point extending at least 12" (30.5 cm) to the left and right of the DCA.
 c) Perimeter of the vertical and horizontal axis points.

VERTICAL FLOW DEVICES

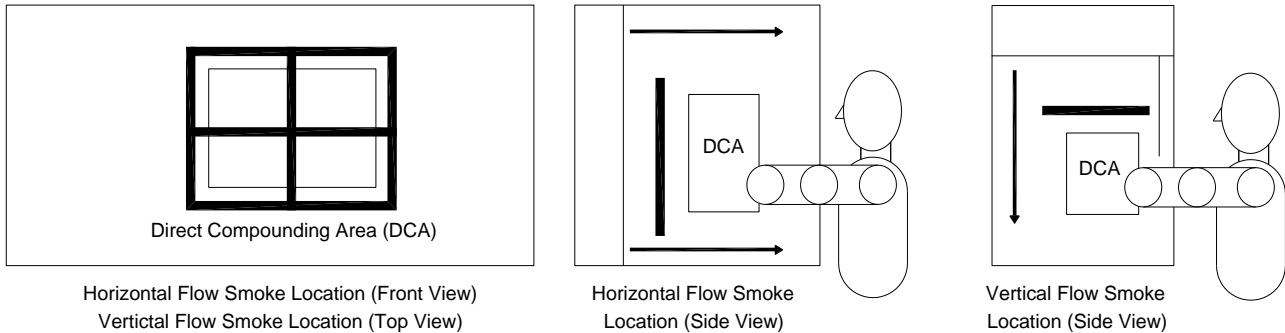
Introduce smoke six inches upstream (15.2 cm) of the DCA along the horizontal axis of the DCA central point, beginning at the IV bar and at least 12" (30.5 cm) to the front, rear, left and right of the DCA central point. Produce smoke along the perimeter of the DCA smoke pattern axes.

ACCEPTANCE:

Device demonstrates acceptable unidirectional airflow patterns for the proper use of "First Air".

HEPA Filter >> DCA >> IV material >> Hands >> Operator

Note: SOLID BAR indicates smoke generation location.



Pass - Airflow Visualization **Fail - Airflow Visualization Test** **No Test**

Under operational conditions, airflow smoke patterns should demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic (operational) conditions within the unidirectional flow device. The smoke illustrates the importance of proper use of "First Air" in the Direct Compounding Area (DCA).

Remarks: NA

Testing Performed In Accordance with Micro-Clean

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Above Testing Work Performed By Taylor Schiering

Date: 29-Nov-2017

Retest Date: MAY, 2018