Northern Air Flow

Certification Report # 111319-66043233
Test Date: November 13, 2019

The Compounder Pharmacy
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LAMINAR AIRFLOW WORKSTATION
Mfg/Model: Envirco Model #10166 (vertical flow)
Serial #66043233
Cycle: Semiannual, retest date: May 2020
Location: ISO Class 7 Sterile Compounding Buffer Room

AIRFLOW VELOCITY PROFILE

Instrument

VelociCalc Air Velocity Meter Mfg: TSI, Model# 9565-P, Serial # 9565P1830028, Calibrated: August 1, 2019

INDIVIDUAL VELOCITY READINGS (FPM)

Rear	98	99	98	99	98	99	98
Middle	98	99	100	99	102	101	100
Front	95	96	92	93	94	96	98

Readings taken 6" from the filter/diffuser, IV bar removed.
Readings taken 6" from sidewalls.

Average Velocity: 98 fpm
Maximum Reading: 102 fpm
Minimum Reading: 92 fpm
Maximum Reading from Average: 4 fpm
Minimum Reading from Average: -6 fpm
Maximum Deviation of an Individual Reading from the Average: 6%

Enclosure Area: 7.9 sq ft
Airflow Volume: 772 cfm

Acceptance Criteria: The average velocity must be between 90 and 110 feet per minute. Individual readings must not vary more than ±25% or 16 feet per minute, whichever is greater, from the average velocity. Testing procedure per IEST-RP-CC002.3 and the manufacturers specifications.

Velocity Profile Test Results: Pass. Fan speed set at 80% of capacity.

HEPA FILTER LEAK TEST

Instruments

Aerosol Photometer Mfg: ATI, Model# TGA-2G, Serial # 12376, Calibrated: December 21, 2018
Aerosol Generator Mfg: ATI, Model 6D, Serial # 30720, Calibrated: February 15, 2019

Supply Filter: Qty: 1 Size: 24" x 48" x 6"
Pre-filter: Qty: 2 Size: 30" x 48" x 1"

Procedure: 26 µg/l of PAO aerosol was introduced to the intake of the laminar airflow workstation. The HEPA filter was scanned 1" from the filter face with overlapping strokes at a rate of 2"/second, using a 1 cfm flow rate photometer. The perimeter was scanned for possible filter/frame separation or filter gasket leaks. The penetration cannot exceed .01% of the upstream concentration. Leak test procedure per IEST-RP-CC034.3 section 6.2.1.

Filter Leak Test results: Pass. The HEPA filter was scanned without any significant aerosol detection, < 0.001%.

AIRFLOW SMOKE PATTERN TEST

Instrument: Fog Generator, Degree Controls C' Breeze, Model# FM51300-A01, Serial # 1547-1084941-001

Procedure: A FDA approved GRAS aerosol was used to visualize airflow with the unit in the "at rest" and in the "operational" mode. A pharmacy technician assisted and typical manipulations were simulated in the center of the work zone. The smoke was introduced downstream of the HEPA filter and visualized as it flowed across the direct compounding area (DCA). The client video taped this test.

Smoke Pattern Test Results: Pass. Smoke test confirms unidirectional airflow within the LAFW. Smoke was visualized moving across the critical zone, leaving the DCA and not re-entering.

CLEANLINESS CLASSIFICATION TEST FOR PHARMACY APPLICATION

Instrument: Particle counter Mfg: Solair, Model 3200+, Serial # 080339003, Calibrated: April 11, 2019

Per USP 797, the primary engineering control unit should be tested to assure compliance to ISO 14644-1:2015, Cleanrooms and Associated Controlled Environments, Part 1: Classification of Air Cleanliness. The cleanliness classification test is performed using a particle counter to measure particle counts within the cabinet workzone. The particle counter was set to measure 0.5 micron and larger particles at the appropriate measuring rate.

Procedure: Four nonviable air samples were taken in the work zone under dynamic operating conditions. Manipulations that would be typical operating procedures were simulated while the air was sampled 6" upstream from the activity. Two cubic feet of air was sampled, particles .5 microns and larger were counted.

Acceptance Criteria: ISO Class 5 zone, < 100 particles .5 microns and larger per cubic foot.

Test Results: Pass. ISO Class 5 zone. All samples resulted in 0 particles .5 microns and larger per cubic foot.

VIABLE AIRBORNE AND SURFACE SAMPLING

Instrument: Air Sampler Mfg: SAS, Model Super 180, Serial # 17-D-11913, calibrated: June 27, 2019

Procedure: Two air samples and two surface sample were taken in the LAFW. The air samples used a collecting plate that contained a medium that supports the growth of bacteria and one that supports the growth of fungi. The viable sampling was performed prior to other testing procedures in the certification process. The air samples were taken upstream from the direct compounding area while manipulations were simulated. One cubic meter of air was sampled. The surface samples were taken on the work surface.

Acceptance Criteria: USP 797 recommended ISO Class 5 Zone. Action levels are exceeded when air sample results are > 1 cfu per cubic meter of air sampled and > 3 cfu per each surface sample plate. The recovery of fungi/mold in any area is considered not in compliance.

Test Results: Pass. < 1 cfu bacteria air plate. < 1 cfu fungal air plate. < 1 cfu bacteria surface sample plate. < 1 cfu fungal surface sample plate.

The samples were incubated and analyzed at U.S. Micro-Solutions. The reporting documents are included with this report. The documents include action levels, incubation time and temperature, media type and interpretations.

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