Certification Report # 082222-214667
Test Date: August 22, 2022

The Compounder Pharmacy
340 Marshall Avenue, Unit 100
Aurora, IL 60506
Contact: Mike Skerjan

LAMINAR AIRFLOW WORKSTATION
NuAire NU-140-430 (vertical flow)
Serial # 214667070822
Cycle: Semiannual, retest date: February 2023
Location: ISO Class 7 Sterile Compounding Buffer Room

AIRFLOW VELOCITY PROFILE

Instrument
Thermal Anemometer Mfg: TSI, Model# 8384A, Serial # 56050270, Calibrated: August 2, 2022

INDIVIDUAL VELOCITY READINGS (FPM)

Rear	95	96	97	95	96	95	96
Middle	94	93	94	95	96	96	97
Front	96	95	96	95	96	95	96

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

Average Velocity: 95 fpm
Maximum Reading: 97 fpm
Minimum Reading: 93 fpm
Maximum Reading from Average: 2 fpm
Minimum Reading from Average: -2 fpm
Maximum Deviation of an Individual Reading from the Average: 3%

Enclosure Area: 7.67 sq ft
Airflow Volume: 732 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. Blower motor speed set at 45% of capacity.

HEPA FILTER LEAK TEST

Instruments
Aerosol Photometer Mfg: ATI, Model # 2i, Serial # 38843, Calibrated: January 24, 2022
Aerosol Generator Mfg: ATI, Model 6D, Serial # 30720; Gauge Serial # 39535, Calibrated: April 22, 2022

Supply Filter: Qty: 1 Size: 24" x 48" x 3"
Pre-filter: Qty: 2 Size: 12" x 20" x 1"

Procedure: 28 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 15, 2022

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 air sampling was performed with the cleanroom suite in the dynamic operating state.

Procedure: Four air samples were taken in the work zone 6" upstream from the direct compounding area. The air samples were taken 6" from the interior walls and equally spaced left to right. The particle counter flow rate is fixed at 2 cfm (56.6 liters/minute). The considered particle size: 0.5 microns and larger per cubic meter of air. The volume of air sampled: 56.6 liters. The particle concentrations are calculated from the raw data based on the chosen "cubic meter" setting.

Acceptance Criteria: ISO Class 5 Zone, less than 3520 particles .5 microns and larger per cubic meter.

Test Results: Pass. ISO Class 5 zone. Samples resulted in 0, 0, 0 and 0 particles .5 microns and larger per cubic meter.

VIABLE AIRBORNE AND SURFACE SAMPLING

Instrument: Air Sampler Mfg: SAS, Model Super 180, Serial # 17-D-11913, Calibrated: September 20, 2021

Procedure: Two air samples and two surface sample were taken in the LAFW. The samples used a collecting plate that contains 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 above the work surface in the direct compounding area (DCA). One cubic meter of air was sampled. The surface samples were taken on the work surface in the DCA.

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.

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.

Technician: *Jared Mikulecky, NSF/ANSI accreditation #4F970-04, CETA accreditation #1333.*

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