

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: March 29, 2021

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. All samples resulted in 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 3, 2020

Procedure: Two air samples and two surface sample were taken in the LAFW. The 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 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.