

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 3, 2020

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 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.

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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