



Pharmacy Cleanroom Testing and Sampling Report

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Data Report #091218

Prepared for:

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Attention:

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SUMMARY

CETA Certification Guide for Sterile Compounding Facilities CAG-003-2006-11 was used as a guide for the evaluation and certification process.

The Primary Engineering Controls

The primary engineering control units (PECs) were tested and certified. This includes two laminar airflow workstations. The PECs met relevant standards and specifications. The standards are listed on the individual reports. The PECs maintain the sterility and cleanliness of critical zones and are the primary safeguard for CSPs. The direct compounding area met the USP<797> recommended air quality as determined by nonviable particle count and viable air and surface samples (ISO Class 5 air and not more than 1 colony forming unit (cfu) for air samples and not more than 3 cfus for surface samples).

Viable Environmental Sampling

The USP <797> recommended viable environmental air and surface sampling was performed inside the PECs, in the buffer area and ante-area. The sampling was performed in accordance with CETA application guide CAG-009-00 "Viable Environmental Sampling & Gowning Evaluation." The USP<797> recommended sampling method of volumetric impaction at locations prone to contamination was followed. Two air samples were taken in the PECs, the buffer area and ante-area, one with a growth medium that supports the growth of bacteria and one that supports the growth of fungi. All viable samples resulted in colony forming unit counts below USP<797> action levels. All samples were incubated and analyzed at US Micro Solutions. The environmental results are trended over time, the trending chart is on page 9.

Nonviable Environmental Particle Test

A discrete particle counter was used for this test that specifies the measurement of airborne particles .5 microns and larger. The particle count results along with the recommended ISO class for each location can be found on page 8. The maps on pages 6 and 7 show the locations of the air samples. This test is intended to directly measure the performance of the engineering controls used to create the various levels of air cleanliness. The USP<797> recommended air cleanliness levels for the direct compounding zone, the buffer areas and the ante-area were met.

Air Change Per Hour & Pressure Differential

Pressure differential and HEPA filtered supply air was measured for the buffer area and ante-area. The air changes per hour were calculated. The acceptance criteria, recommended levels and results for each room can be found on pages 3 and 4.

HEPA Filter Leak Testing

The ceiling HEPA filters were leak tested. All the filters in the buffer areas and ante-area passed this test. Testing procedure and results can be found on page 5.

Posting date, September 29, 2017. A revised USP 797 and USP 800 are anticipated to become official on December 1, 2019.

Testing equipment, calibration reports will be provided on request:

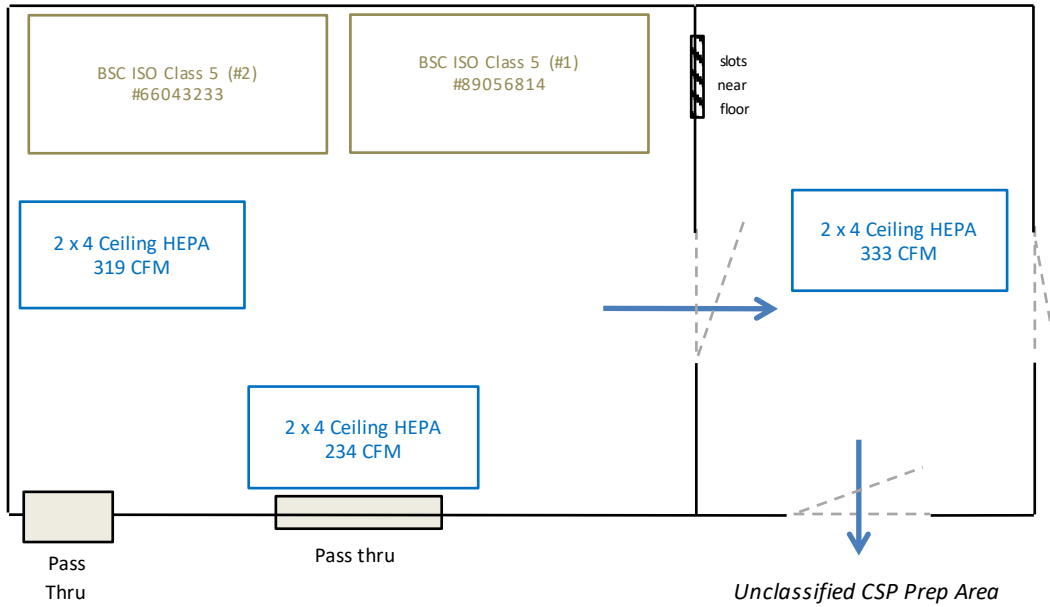
Air Sampler Mfg: SAS, Model Super 180, Serial # 17-D-11913, calibrated: June 26, 2018
Thermal Anemometer Mfg: TSI, Model# 8384A, Serial # 56050270, Calibrated: August 30, 2017
Micromanometer/Balometer Mfg: TSI, Model #EBT721, Serial #90936001, Calibrated: October 9, 2017
Aerosol Photometer Mfg: ATI, Model# TGA-2G, Serial # 12376, Calibrated: December 27, 2017
Aerosol Generator Mfg: ATI, Model 6D, Serial # 30720, Calibrated: February 14, 2018
Fog Generator Mfg: Degree Controls, Model C' Breeze # FM51300-A01, Serial # 1547-1084941-001
Particle counter Mfg: Solair, Model 3200+, Serial # 080339003, Calibrated: April 6, 2018

Technician: Jared Mikulecky - NSF accredited #4F970-04, CETA accredited #1333

AIR CHANGES PER HOUR

Sterile Compounding Buffer Room
 Iso Class 7
 652 cubic feet (97" x 121" x 96")

Ante-Area
 ISO Class 8
 323 cubic feet (60" x 97" x 96)



HEPA filtered supply air was measured with an airflow capture hood, measuring directly in airflow volume (cfm). Measured HEPA filtered supply air volume listed above.

USP<797> acceptance criteria for an ISO Class 7 sterile compounding buffer room:

> 30 ACPH with at least 15 coming from the air supply through the ceiling HEPA filters.

Ceiling HEPA supply air: $(319 + 234) \times 60 / 652 = 51$ ACPH.

LAFW recirculated HEPA filtered air: $1633 \times 60 / 652 = 150$ ACPH

Results

Pass 51 ACPH from ceiling HEPA filter.

150 ACPH from the PECS

USP<797> acceptance criteria for an ISO Class 8 ante-area:

Minimum ACPH for an ISO Class 8 ante-area is not specified in the current version of USP 797. The revised USP 797 that is anticipated to take effect December 2019 will require > 20 ACPH.

Ceiling HEPA supply air: $333 \times 60 / 323 = 62$ ACPH

Pass 62 ACPH

PRESSURE DIFFERENTIAL

Sterile Compounding Buffer Room

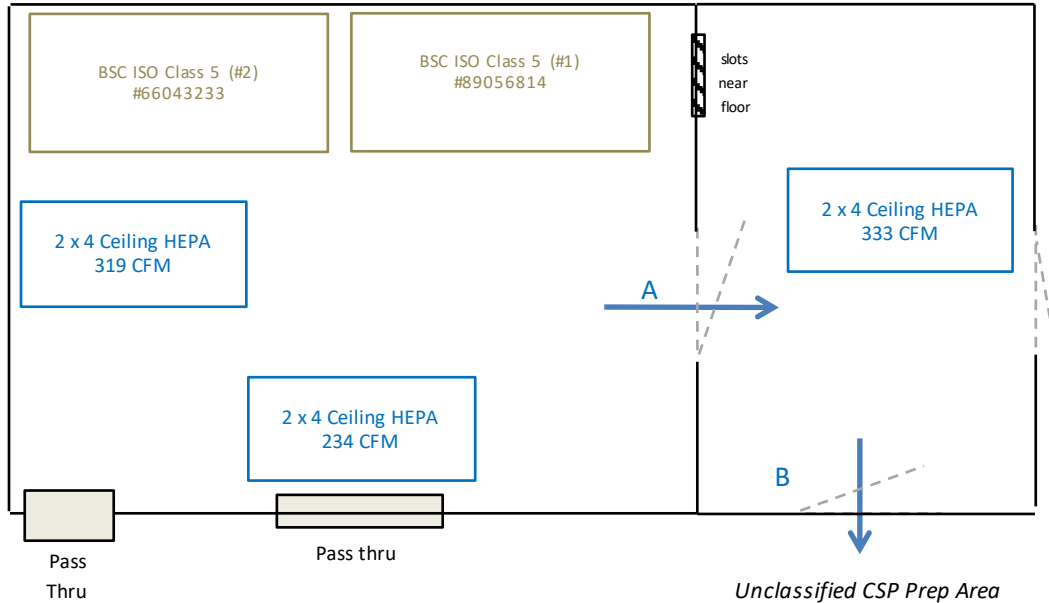
Iso Class 7

652 cubic feet (97" x 121" x 96")

Ante-Area

ISO Class 7

323 cubic feet (60" x 97" x 96)



USP<797> acceptance criteria for an ISO Class 7 sterile compounding buffer room:

A, Pressure differential must not be less than 0.02" W.C. positive pressure relative to the adjacent ante-area.

Pass +.049" W.C measured

USP<797> acceptance criteria for an ISO Class 8 ante area.

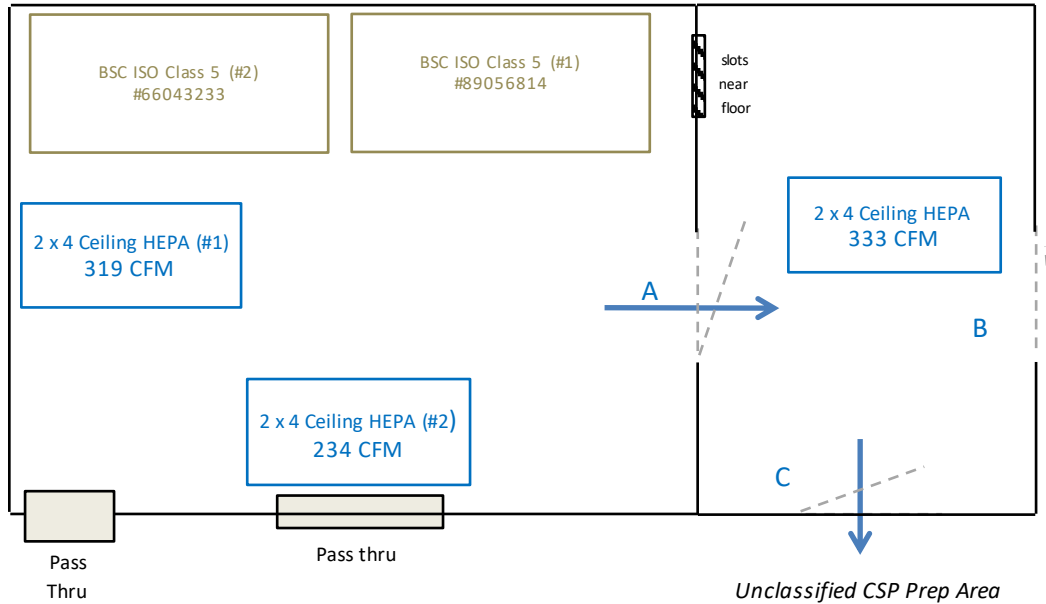
C, Positive pressure differential > 0.02" W.C. relative to adjacent unclassified area .

Pass +.048" W.C measured

CEILING HEPA FILTER LEAK TEST

Sterile Compounding Buffer Room
Iso Class 7
652 cubic feet (97" x 121" x 96")

Ante-Area
ISO Class 7
323 cubic feet (60" x 97" x 96)



Procedure, Introduce a polydisperse aerosol (PAO) upstream of the filters at a distance that ensures a concentration that is uniform over the entire upstream face of the filter. Scan the downstream filter face with an aerosol photometer. The sampling probe is moved in a series of parallel, slightly overlapping strokes across the test area one inch from the filter face at a scan rate of 2 inches per second. Testing is in accordance with IEST-RP-CC034.3 section 6.2.1

Acceptance criteria: The leak penetration cannot exceed 0.01 % of the upstream concentration.

Compounding Buffer Room

Filter 1: 319 cfm. 21 $\mu\text{g}/\text{L}$ of aerosol was introduced upstream of the filter. The HEPA filter was scanned without any significant aerosol detection (<.001%).

Results: Pass

Filter 2: 234 cfm. 29 $\mu\text{g}/\text{L}$ of aerosol was introduced upstream of the filter. The HEPA filter was scanned without any significant aerosol detection (<.003%).

Results: Pass

Ante-Area

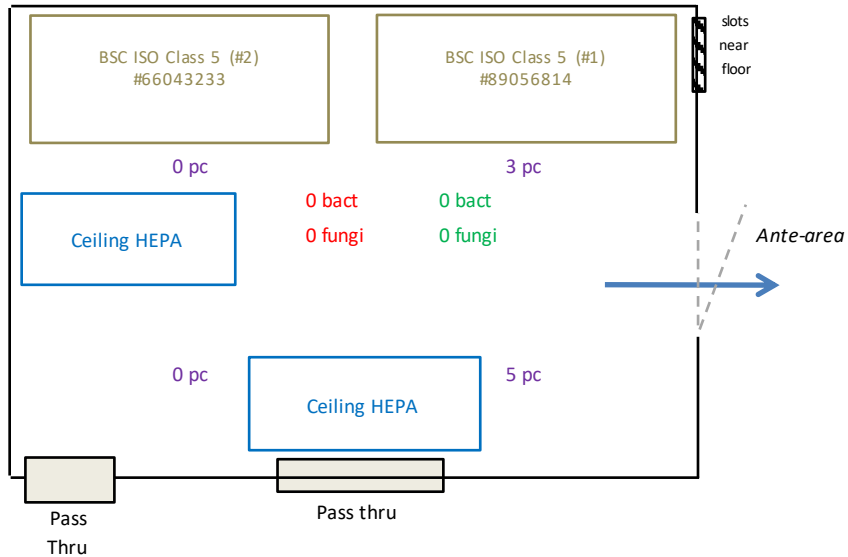
Filter: 333 cfm. 20 $\mu\text{g}/\text{L}$ of aerosol was introduced upstream of the filter. The HEPA filter was scanned without any significant aerosol detection (<.002%).

Results: Pass

STERILE COMPOUNDING BUFFER ROOM

ISO Class 7 Area, 652 cubic feet

Environmental Viable & Nonviable Sampling



USP<797> acceptance criteria for an ISO Class 7 buffer area:

Results

Nonviable particle counts, (pc) < 10,000 particles .5 microns and larger per cubic foot. Results and locations shown on the map.

Pass

Viable air samples, ≤ 10 cfu:

One cubic meter of air sampled in the center of the room.

Pass, < 1 cfu bacteria, < 1 cfu fungi

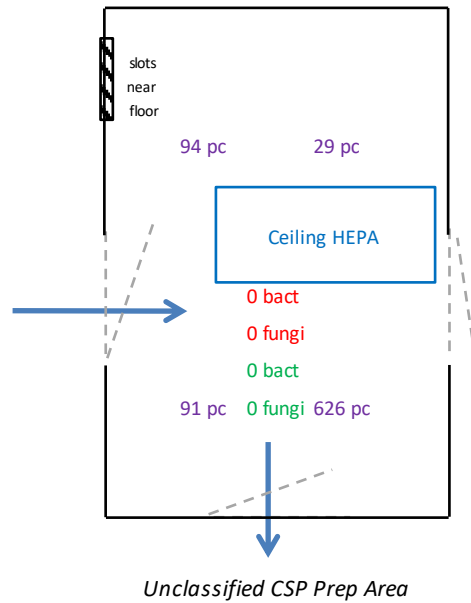
Viable surface samples, ≤ 5 cfu:

Two surface samples on top of cart.

Pass, < 1 cfu bacteria, < 1 cfu fungi

ANTE-AREA
ISO Class 7 Area, 323 cubic feet

Environmental Viable & Nonviable Sampling



USP<797> acceptance criteria for an ISO Class 8 ante- area:

Results

Nonviable particle counts, (pc) < 100,000 particles .5 microns and larger per cubic foot. Results and location shown on the map.

Pass

Viable air samples, ≤ 10 cfu:
One cubic meter of air sampled in the center of the room.

Pass, < 1 cfu bacteria, < 1 cfu fungi

Viable surface samples, ≤ 5 cfu:
Two surface samples on top of the counter.

Pass, < 1 cfu bacteria, < 1 cfu fungi

ENVIRONMENTAL NONVIABLE PARTICLE TEST

Test includes a one minute sample at each location at a flow rate of 2 cubic feet per minute. Particle counts include particles .5 microns and larger per ISO Standard 14644-1. The particle counts were taken with the rooms in the operating/dynamic state.

Location	Particle Count	Particle Count (per cu ft.)	USP <797> Recommended ISO class	Pass/Fail
Inside the Laminar Airflow Workstation Serial #89056814	0	0	5	Pass
	0	0		
	0	0		
	0	0		
Inside the Laminar Airflow Workstation Serial #66043233	0	0	5	Pass
	0	0		
	2	1		
	0	0		
Sterile Compounding Buffer Room	6	3	7	Pass
	0	0		
	0	0		
	9	5		
Ante-Area	188	94	7	Pass
	58	29		
	1251	626		
	182	91		

Locations as marked on maps.

ISO Class 5: < 100 particles .5 microns and larger per cubic ft.

ISO Class 7: < 10,000 particles .5 microns and larger per cubic ft.

ISO Class 8: < 100,000 particles .5 microns and larger per cubic ft.

VIABLE and NONVIABLE ENVIRONMENTAL SAMPLE TRENDS

Location	Primary Engineering Control Units															
	Laminar Airflow Workstation Serial #89056814								Laminar Airflow Workstation Serial #66043233							
ISO Class	5								5							
9/12/18	Ob	Of	Ob	Of	0	0	0	0	Ob	Of	Ob	Of	0	0	1	0

Location	Sterile Compounding Buffer Area								Ante-Area							
	ISO Class	7								7						
9/12/18	Ob	Of	Ob	Of	3	0	0	5	Ob	Of	Ob	Of	94	29	626	91

Sample Results

Viable Air Sample, total colony forming units. (b-bacteria, f-fungi)

Surface Sample, total colony forming units. (bacteria)

Particle Counts

Per USP<797>

ISO Class	Viable Air Samples	Surface samples	Nonviable Particle counts
5	≤ 1 cfu	≤ 3 cfu	≤ 100 particles .5μ and larger per cubic foot
7	≤ 10 cfu	≤ 5 cfu	≤ 10,000 particles .5μ and larger per cubic foot
8	≤ 100 cfu	≤ 100 cfu	≤ 100,000 particles .5μ and larger per cubic foot