

Howorth Air Technology – Pure Protection

DownFlow Booth and 5D HCS OEL Test Data

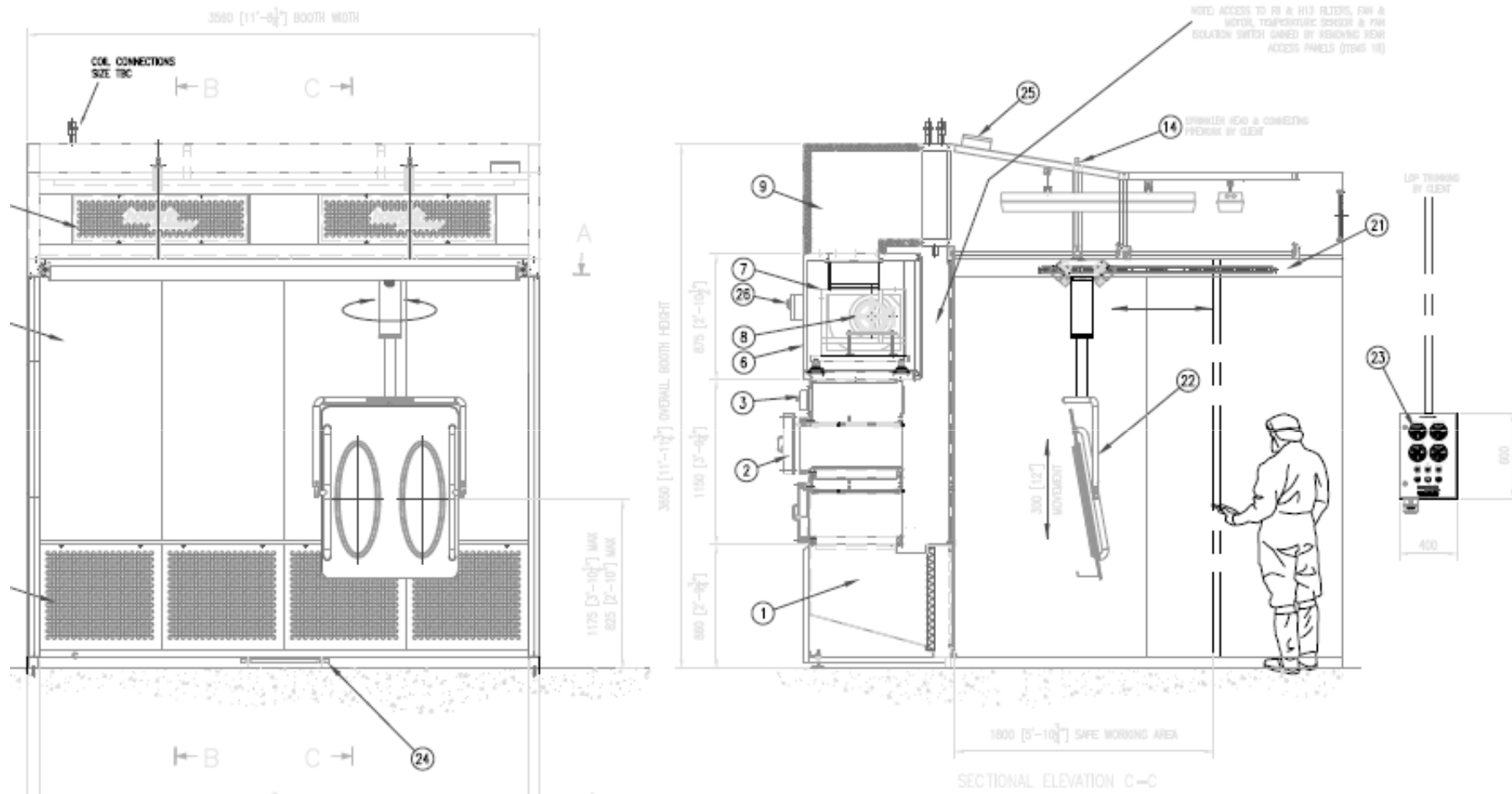


DownFlow Booth – Project Overview

The Howorth DownFlow Booth and 5D High Containment Screen was supplied to a Global Pharmaceutical Manufacturing company to be utilised for Dispensing, Weighing and Milling Activities:

- Design OEL: 1 to 10µg/m³ with High Containment Screen based on 8hr TWA
- 3.4m Internal Width x 2.7m Deep (including 1.8m Containment Zone) x 2.85m Working Height
- Manufactured from 316L and 304 stainless steel
- Dedicated extraction system including Fine Dust and HEPA Filtration housed within safe change housings
- Howorth 5D High Containment Screen
- Integrated cooling system

DownFlow Booth– General Arrangement



DownFlow Booth Assembly including Howorth 5D High Containment Screen

DownFlow Booth– Installed Assembly



5D High Containment Screen– Overview

Operation of High Containment Screen

- 5 Degrees of freedom
 - Side to Side
 - Forwards and Backwards
 - Rotate
 - Raise / lower
 - Tilt adjustment of 25° from 90° standing position
- Full movement within the Containment Zone only
- Height Adjustable over a 300mm vertical range
- Ergonomic benefits for operator



OEL Test Results

Summary

- Independent Containment Verification Testing was carried on the Downflow Booth and High Containment Screen assembly.
- The containment performance target (**CPT**) was **10 microgram per cubic meter ($\mu\text{g}/\text{m}^3$)** based on the lower end of the customer criteria.
- Containment verification was conducted using lactose powder as the surrogate material for active pharmaceutical ingredients (APIs). Air and surface samples were collected to determine whether airborne contaminant concentrations were below the CPT during typical work activities to be conducted within the downflow booth.
- The containment verification testing activities were performed in a manner that was consistent with recognised industry guidelines including the International Society of Pharmaceutical Engineering (ISPE) SMEPAC Committee document entitled, “Assessing the Particulate Containment Performance of Pharmaceutical Equipment (APCPPE) – A Guide,”

OEL Test Results

Sampling and Work Protocol

The sampling and work protocol replicated the work activities and the locations of air and surface samples collected. Work activities were evaluated as follows:

- Dispensing and Weighing of four 100 gram jars
- Compression of approximately 30 grams
- Milling of 100 grams

The work activities are representative of activities that will be conducted within the downflow booth and were selected based on the potential to produce the highest concentrations of airborne contaminants with three iterations of each work activity performed in the downflow booth.

- Personal samples were collected at the breathing zone of the operators to evaluate personal exposures.
- Different operators were used to evaluate differences in operator technique.
- Source samples were collected to identify potential contaminant emission sources at select points at and around the process and equipment.
- Area samples were collected to evaluate ambient airborne contaminant concentrations in the areas at and adjacent to the contaminant-generating process.

This data was used to evaluate the potential for migration of airborne contaminants away from the process or Equipment and/or potential exposures to employees who may be observing the process or equipment.

OEL Test Results – Sample Locations



BASELINE SAMPLE LOCATIONS

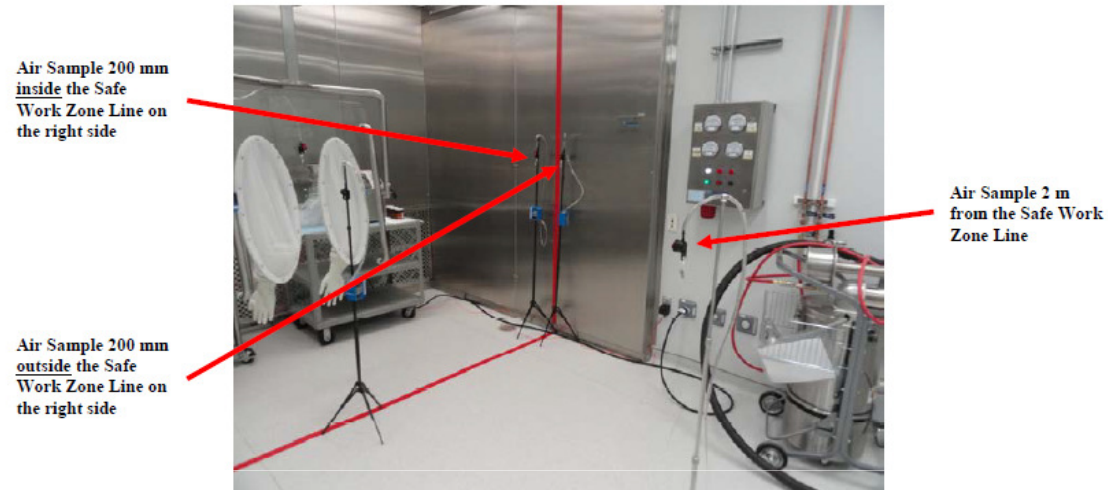
Air Sample 200 mm inside the Safe Work Zone Line on the left side

Air Sample 200 mm outside the Safe Work Zone Line on the left side

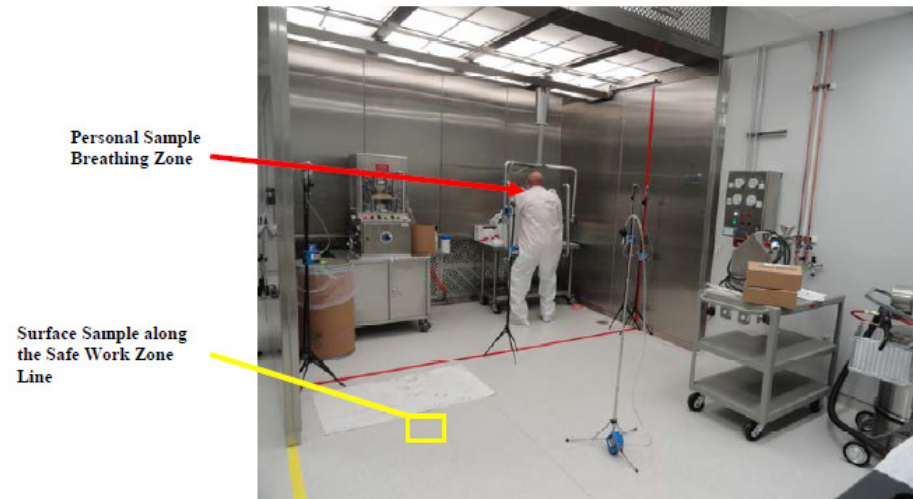


AIR SAMPLE LOCATIONS

OEL Test Results – Sample Locations



AIR SAMPLE LOCATIONS



AIR AND SURFACE SAMPLE LOCATIONS

OEL Test Results – Dispensing & Weighing Activities

	Air Sampling Results ($\mu\text{g}/\text{m}^3$) <i>Sample Time 30 mins</i>		
Sample Location	Iteration 1	Iteration 2	Iteration 3
Personal Sample Breathing Zone	<0.0483	<0.0485	<0.0485
Approx 200mm from the GlovePorts on the High Containment Screen	<0.0405	<0.049	<0.049
Approx 200mm inside the Containment Zone	0.0816	<0.0493	<0.0493
Approx 200mm outside the Containment Zone	<0.0421	<0.0505	<0.0505
Collected at the face of the Containment Zone limit	<0.0408	0.0494	<0.049
Collected 2m from the Containment Zone line	<0.0403	<0.0483	<0.0483

OEL Test Results – Compression Activities

	Air Sampling Results ($\mu\text{g}/\text{m}^3$) <i>Sample Time c. 27 mins</i>		
Sample Location	Iteration 1	Iteration 2	Iteration 3
Personal Sample Breathing Zone	0.083	0.114	0.385
Approx 200mm from the GlovePorts on the High Containment Screen	0.141	0.536	0.329
Approx 200mm inside the Containment Zone	0.102	<0.0513	0.431
Approx 200mm outside the Containment Zone	0.0576	<0.0526	0.325
Collected at the face of the Containment Zone limit	0.114	0.321	0.996
Collected 2m from the Containment Zone line prior to dispensing and weighing activities	0.236	0.395	0.443

OEL Test Results – Milling Activities

	Air Sampling Results ($\mu\text{g}/\text{m}^3$) <i>Sample Time c. 25 mins</i>		
Sample Location	Iteration 1	Iteration 2	Iteration 3
Personal Sample Breathing Zone	0.627	0.607	<0.0714
Approx 200mm from the GlovePorts on the High Containment Screen	0.413	0.464	0.247
Approx 200mm inside the Containment Zone	0.544	0.488	<0.0735
Approx 200mm outside the Containment Zone	0.413	0.346	<0.0717
Collected at the face of the Containment Zone limit	0.457	0.448	0.106
Collected 2m from the Containment Zone line	0.63	0.493	<0.0714

OEL Test Results - Conclusions

Test results demonstrate that the Howorth Downflow Booth provides effective containment of powders to below the CPT of 10 µg/m³. This conclusion is based on the sampling results for the dispensing/weighing, compression, milling, and cleaning events completed in the downflow booth.



Customer References - Pharmaceutical



FOR THE PUREST AIR...

*Safe and secure in
the knowledge that
we deliver*



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