The Use of Protective Screens to Improve Downflow Booth Performance

The data on the pages that follow describes a procedure and results for Occupational Hygiene Monitoring using a surrogate in an Extract Technology Downflow Booth manufactured by Walker Barrier Systems of New Lisbon, WI. A Downflow Booth is used in the pharmaceutical industry to safeguard operators against harmful dusts generated during many manual powder handling operations. Clean air from the ceiling plenum is distributed evenly across the entire work area pushing any breathable dust generated downward and away from the operators breathing zone. This particular booth included a protective screen with glove ports to further protect the operator from exposure to potent compounds being handled inside the downflow booth.

Surrogate Used

OHC 1- Lactose was used as a surrogate for other API and excipient materials that may be used in the dispensary in the pilot plant.
OEL range for OHC 2 compounds is 100-1000 ug/m^3
OHC 3 compounds 10 –100 ug/m^3
OHC 4 compounds 1–10 ug/m^3
OHC 5 compounds <1 ug/m^3

IH Sampling Locations

Personal breathing zone samples were collected on the “operator” and the “verifier”. Area samples were collected on the left and right sides of the booth at waist height (~ 36” above the ground) and 65 inches back from the inside face of the booth. These left handed and right handed area samples were ~ 6” inside the containment zone established by Walker-Extract with red tape. These area sample locations were chosen to reflect containment at the “edge” of the containment zone as (1) defined by Walker – Extract and (2) confirmed by ECT smoke testing.
A room background sample was also collected outside of the booths

Down Flow Booth with rigid gloved barrier
Surrogate trials for 100 g weighings
The dispensary operator worked deep in the booth and through the gloves on the rigid lexan barrier on a portable stainless steel table in the right hand corner of the booth with the table abutting the inside panel. The dispensary operator dispensed 100 g quantities from a sanitainer (~ 2 Kg) into amber bottles for each of the 100g trials. The dispensary operator performed an “initial clean” of the area following each dispensing. A “verifier” operator was present for each dispensing and primarily observed and assisted when directed by the dispensing operator. A total of three dispensing trials for the 100 g weighings were completed.

Surrogate trials for 1 Kg weighings
The dispensary operator worked deep in the booth and through the gloves on the rigid lexan barrier on a portable stainless steel table in the right hand corner of the booth with the table abutting the inside panel. The dispensary operator dispensed 1 kilogram quantities from a mauser drum (~2 Kg) on the stainless table to sanitainers on the table for each of the 1Kg trials. The dispensary operator performed an “initial clean” of the area following each dispensing. A “verifier” operator was present for each dispensing and primarily observed and assisted when directed by the dispensing operator. A total of two dispensing trials for the 1Kg weighings were completed and one combined weighing and major cleaning was completed.

Personal Sampling Results

Single Pass down flow booth with rigid gloved barrier
Personal sampling results for the single pass downflow booth with the rigid gloved barrier in place are well below the Walker – Extract performance criteria of 10 ug/m3 with operator averages at 0.254 ug/m3 for the 100 g dispensings, and 1.03 ug/m3 for the I kg dispensings, respectively. Verifier averages were 0.651 ug/m3 for the 100 g and 0.154 ug/m3 for the 1kg,respectively.

Area Sampling Results
Area samples for the recirculating booth were all below 0.391 ug/m3 with the majority recorded as non-detectable results at <0.067 ug/m3.
Area samples for the single pass booth were non-detectable at <0.067 ug/m3 with the exception of one room background sample recorded at 0.12 ug/m3. This is an unexpected result but is an order of magnitude lower than the performance criteria of 1.0 ug/m3 for the “booth” and is an adjoining area just outside of the down flow booth.

Conclusion:
The use of the rigid screen improves operator protection inside the booth to levels below 10 ug/m3 on a consistent basis. In this particular example, levels were found in the 1-2 ug/m3 range. Results may vary due to quantities of product and length of operation.

Rigid screens can move front to back, side to side and up/down within a booth. They can also rotate and tilt. Glove ports are an option. Retrofit packages are available to add a screen to an existing downflow booth.