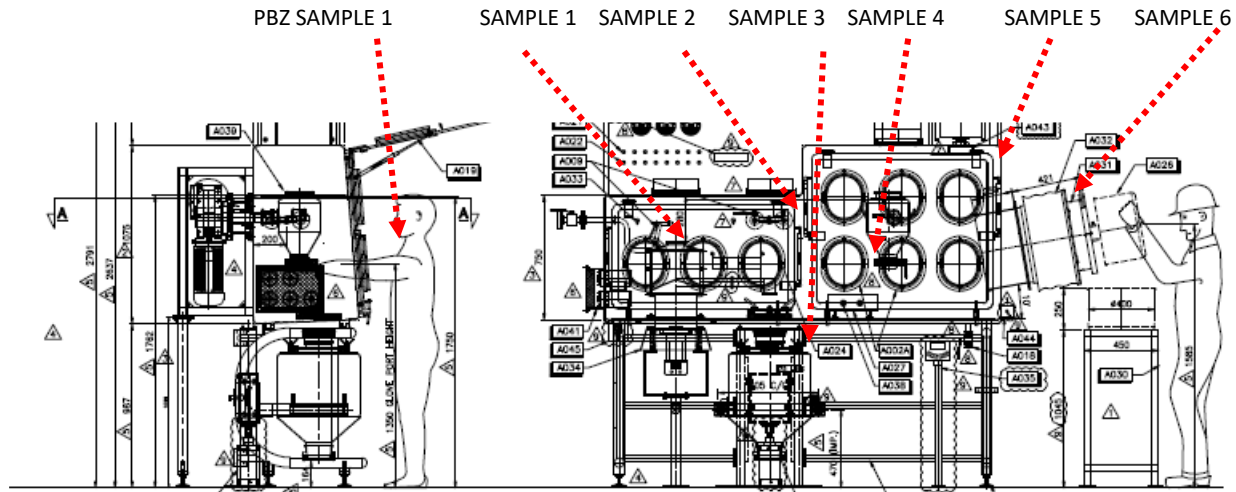




## OPERATOR EXPOSURE LEVEL SAMPLING PLAN

### SAMPLING DISPENSING ISOLATOR



- PBZ SAMPLE 1 – Personal sample on operator (Personal Air Sample).
  - SAMPLE 1 (Back Ground Static Sample) = between centre glove ports on surface of front window on chamber- 1 at 1500 mm above floor level.
  - SAMPLE 2 (Back Ground Static Sample) = on front surface of Chamber -2 at the Gull wing door top(RHS)
  - SAMPLE 3 (Back Ground Static Sample) = directly adjacent to RTP at about 300 mm distance
  - SAMPLE 4 (Back Ground Static Sample) = between centre glove ports on surface of front window on chamber- 1 at 1500mm above floor level.
  - SAMPLE 5 (Back Ground Static Sample) = on front surface of Chamber -2 at the Gull wing door top(RHS)
  - SAMPLE 6 (Back Ground Static sample) = near liner of drum loading port at 300 mm distance
  - SAMPLE 7 (Continuous Static Sample)= on rear of isolator at 2000 mm distance 1500mm from floor level.
- Pre Trial = In front of Isolator at 2000 mm distance at 1500 mm height

Total samples =

Pre trial – 1 no. x 3 iterations = 3 nos.

Personal Air Sample (PBZ) – 1 no. x 3 iterations = 3 nos.

Back ground Static Sample – 6 no.x 3 iterations = 18 nos.

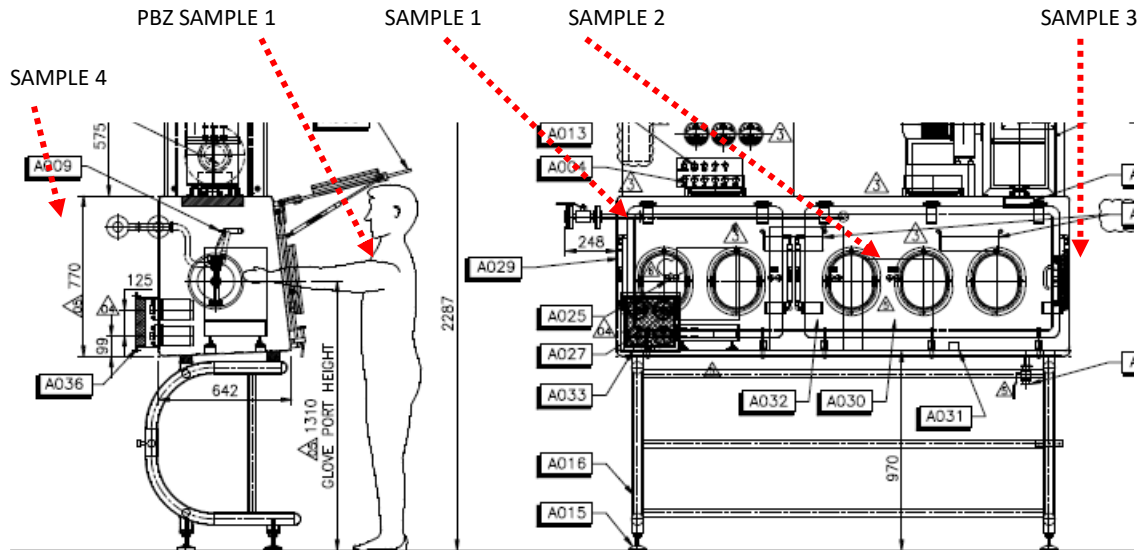
Continuous Static Samples – 1 no.x 3 iterations = 3 nos.

Pre Trial Back ground sample – 1 no. x 3 iterations = 3 nos.



## OPERATOR EXPOSURE LEVEL SAMPLING PLAN

### IPQC ISOLATOR



- PBZ SAMPLE 1 – Personal sample on operator (Personal Air Sample).
- SAMPLE 1 (Back Ground Static Sample) = on front surface of Chamber at the Gull wing door top(LHS)
- SAMPLE 2(Back Ground Static Sample) = between centre glove ports on surface of front window on chamber- 1 at 1500 mm above floor level.
- SAMPLE 3 (Back Ground Static Sample) = directly adjacent to RTP at about 300 mm distance
- SAMPLE 4 (Continuous Static sample)= on rear of isolator 1500mm from floor level.

Pre Trial = In front of Isolator at 2000 mm distance at 1500 mm height

Total samples =

Pre trial – 1 no. x 3 iterations = 3 nos.

Personal Air Sample (PBZ) – 1 no. x 3 Iterations = 3 nos.

Back ground Static Sample – 3 no. x 3 Iterations = 9 nos.

Continuous Static Samples – 1 no. x 3 Iterations = 3 nos.

Pre Trial Back ground sample – 1 no. x 3 Iterations = 3 nos.

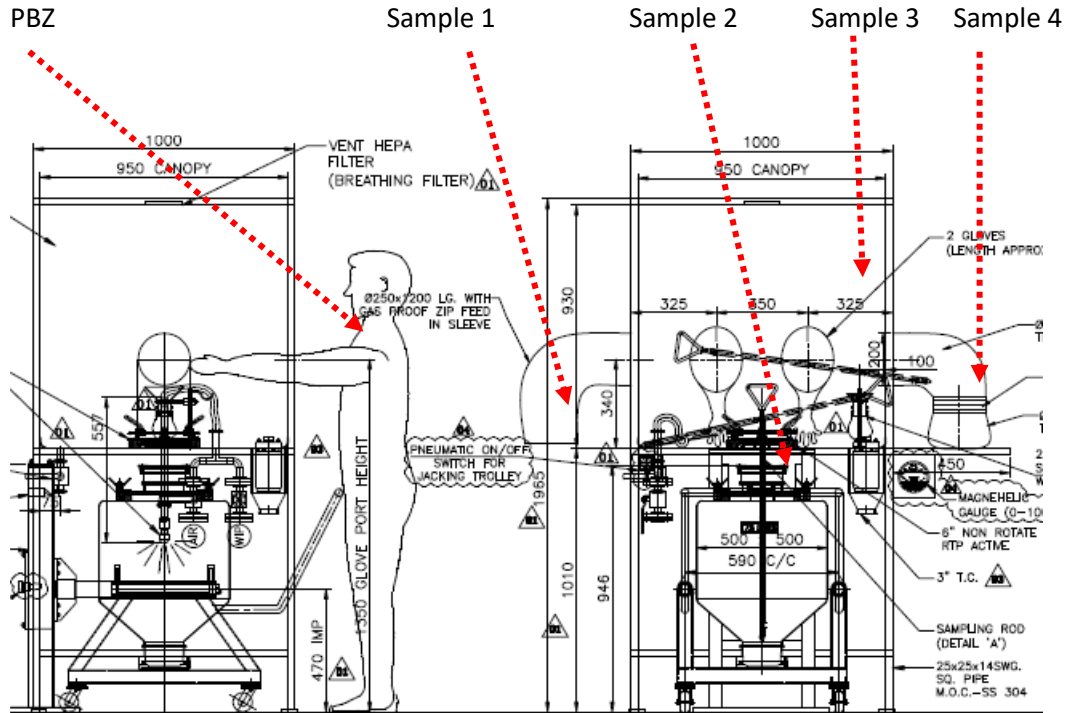


# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## OPERATOR EXPOSURE LEVEL SAMPLING PLAN

### SAMPLING TABLE



- PBZ SAMPLE 1 – Personal sample on operator (Personal Air Sample).
- Sample 1 (Back Ground Static Sample) = On in feed sleeve
- Sample 2 (Back Ground Static Sample) = directly adjacent to RTP at about 300 mm distance
- Sample 3 (Back Ground Static Sample) = on front surface of Canopy at the Zip
- Sample 4 (Back Ground Static Sample) = On out feed sleeve
- SAMPLE 5 (Continuous Static sample) = on rear of isolator 1500mm from floor level.

Pre Trial = In front of Isolator at 2000 mm distance at 1500 mm height

Total samples =

Pre trial – 1 no. x 3 iterations = 3 nos.

Personal Air Sample (PBZ) – 1 no. x 3 Iterations = 3 nos.

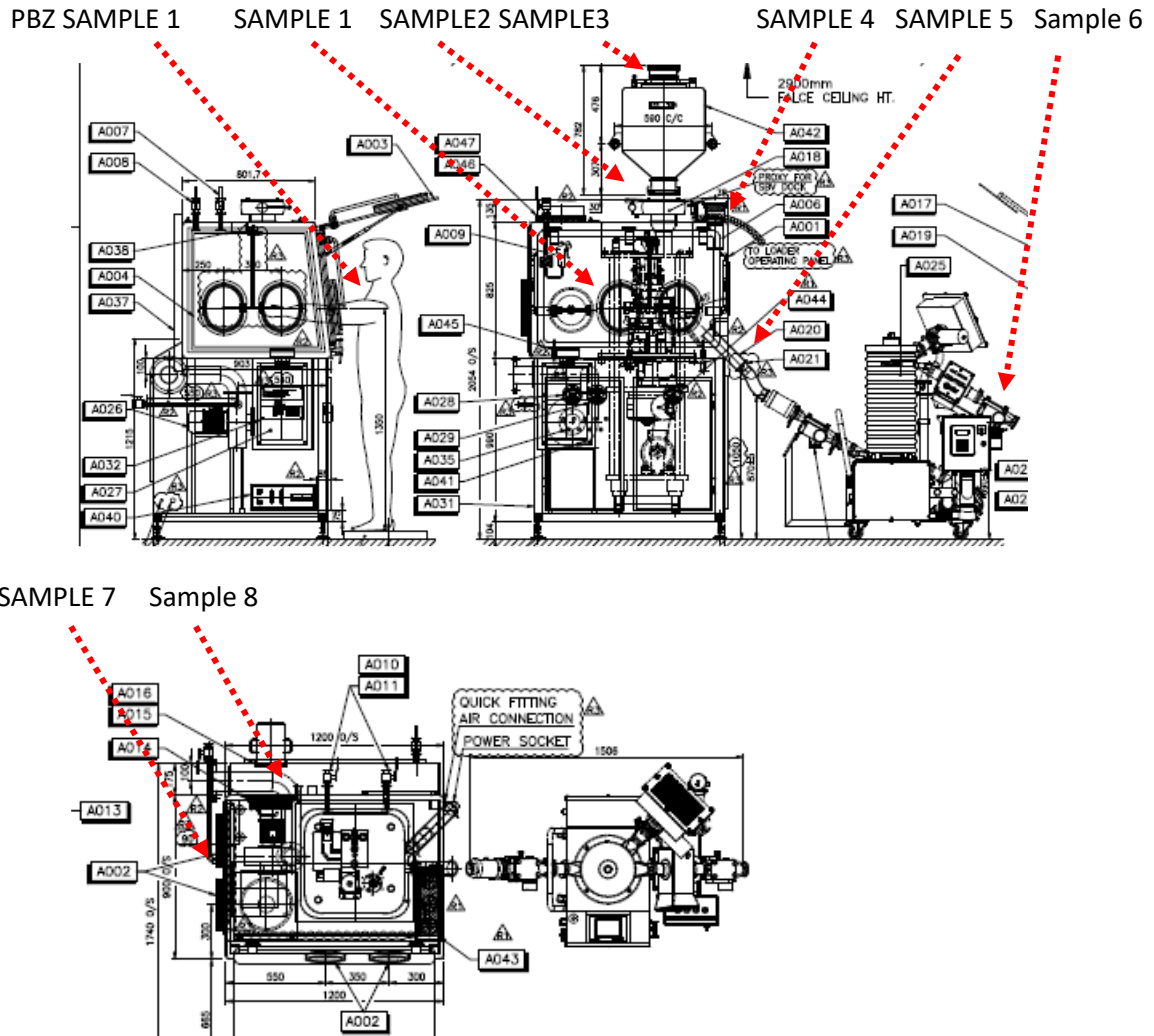
Back ground Static Sample – 4 no. x 3 Iterations = 12 nos.

Continuous Static Samples – 1 no. x 3 Iterations = 3 nos.



**OPERATOR EXPOSURE LEVEL SAMPLING PLAN**

**TABLET PRESS ISOLATOR**



- PBZ Sample 1 – Personal sample on operator (Personal Air Sample).
- Sample 1 (Back Ground Static Sample) = On Glove ports front door
- Sample 2 (Back Ground Static Sample) = Near SBV Active Passive on top of Tab press
- Sample 3 (Back Ground Static Sample) = Near SBV Passive on top of Bin
- Sample 4 (Back Ground Static Sample) = On Gull wing door frame on top RHS
- Sample 5 (Back Ground Static Sample) = On interface between compression and tablet deduster
- Sample 6 (Back Ground Static Sample) = On interface between Tablet deduster and Tablet Glove Box
- Sample 7 (Back Ground Static Sample) = On rear glove ports of Tablet press
- Sample 8 (Back Ground Static Sample) = Near side RTP of Tablet press
- Sample 9 (Back Ground Static Sample) = Near RTP (1) Bag grommet of Tablet Glove Box
- Sample 10 (Back Ground Static Sample) = On RTP (2) Bag grommet of Tablet Glove box
- Sample 11 (Continuous Static sample) = on rear of isolator 1500mm from floor level.



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## OPERATOR EXPOSURE LEVEL SAMPLING PLAN

Pre Trial = In front of Isolator at 2000 mm distance at 1500 mm height (before each Iteration)

Total samples =

Pre trial – 1 no. x 3 iterations = 3 nos.

Personal Air Sample (PBZ) – 1 no. x 3 Iterations = 3 nos.

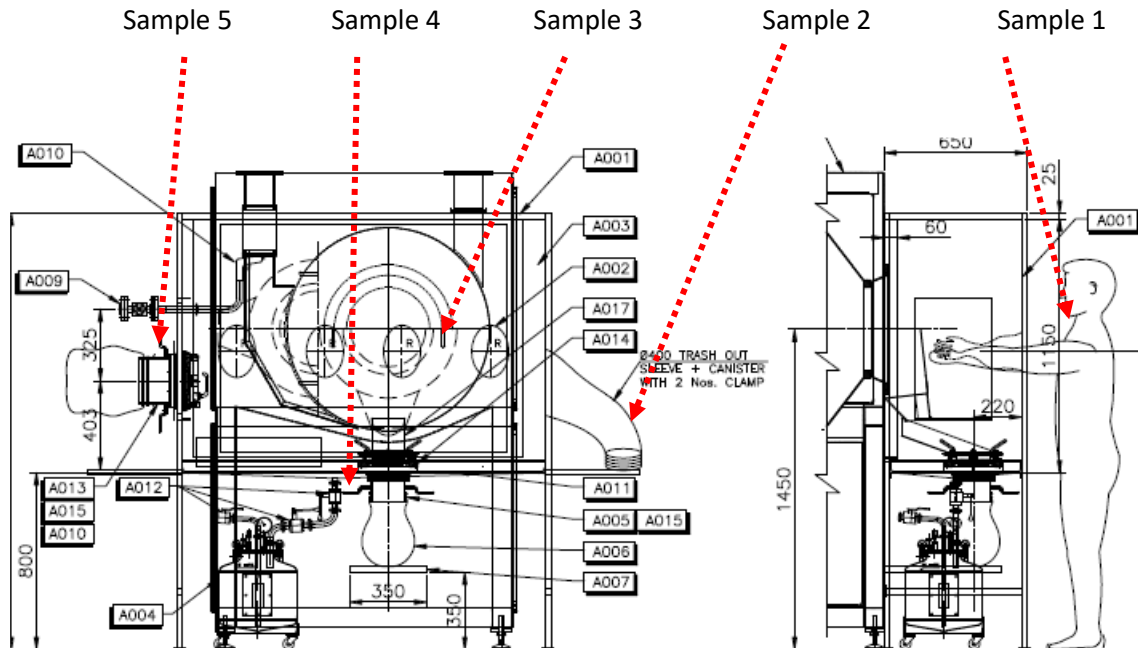
Back ground Static Sample – 10 no. x 3 Iterations = 30 nos.

Continuous Static Samples – 1 no. x 3 Iterations = 3 nos.



## OPERATOR EXPOSURE LEVEL SAMPLING PLAN

### AUTO COATER



- PBZ Sample 1 – Personal sample on Operator (Personal Air Sample).
- Sample 1 (Back Ground Static Sample) = On out feed sleeve
- Sample 2 (Back Ground Static Sample) = On front surface of Canopy at the Zip
- Sample 3 (Back Ground Static Sample) = Directly adjacent to Unloading RTP at about 300 mm distance
- Sample 4 (Back Ground Static Sample) = On out feed sleeve
- Sample 5 (Continuous Static Sample) = On rear of isolator 1500mm from floor level.

Pre Trial = In front of Isolator at 2000 mm distance at 1500 mm height.

Total Samples =

Pre trial – 1 no. x 3 iterations = 3 nos.

Personal Air Sample (PBZ) – 1 no. x 3 iterations = 3 nos.

Back ground Static Sample – 4 no. x 3 iterations = 12 nos.

Continuous Static Samples – 1 no. x 3 iterations = 3 nos.