This document provides a rationale for selection of viable environmental monitoring locations for routine monitoring in Block-III facility of Biological E Limited, Pharma Division located at Shameerpet. The locations for routine monitoring in Block-III are selected for monitoring based on the data obtained during area performance qualification and subsequent monitoring performed. The below mentioned criteria are considered for selection of location for routine monitoring.

* **Locations where microbial contamination is likely to have an adverse effect on product quality:**

The locations where microbial contamination is expected due to the nature of the activities performed or position of the sampling site and that microbial contamination is likely to have an adverse effect on the product.

* **Locations that would most likely demonstrate heaviest microbial proliferation during manufacturing activities:**

The locations in the area that are most likely to demonstrate heaviest microbial proliferation such as return air raisers, close to door openings, locations where there is noticeable movement of personnel/material due to the activities in the area are considered during selection of the locations for monitoring.

* **Locations that are most inaccessible or difficult to clean, sanitize or disinfect:**

The locations that are inaccessible or difficult to clean, sanitize or disinfect such as surface of wall behind equipment, machine surfaces that are in direct or indirect contact with the product etc. are considered during the selection for routine monitoring.

* **The probability of the sampling location/methodology to disturb the environment sufficiently to cause erroneous data or that might contribute to contamination of the product process:**

Locations that are in proximity to product process or in the path of man/material movement and if selected for monitoring might have an detrimental impact product quality/ environment are excluded from selection. The equipment’s such as dynamic pass boxes and ceiling suspended LAF (where applicable) are considered for volumetric air sampling and surface monitoring as the exposure of settle plates obstructs the movement of materials.

* **The activities that occur in the area:**

The activities occurring in the area are also considered for selection or exclusion of the monitoring locations depending on the impact on product process and environment.

* **Product contact parts:**

Product contact parts such as filling nozzles, stopper bowl etc. are selected as these are in direct contact with the product. Monitoring of these locations is appropriate to demonstration contamination and sterility assurance of the process.

* **Air flow visualization studies:**

The air flow visualization studies performed through protocol no.: EPQ-PF-HVAC-150/00- are reviewed and considered for selection of viable monitoring locations.

Apart from the above, the below mentioned are also considered for selection of locations for routine monitoring.

* **Recoveries obtained during “At-rest” condition monitoring in area PQ.**
* **Recoveries obtained during the monitoring period.**
* **Maximum counts obtained during the monitoring period.**
* **Viable monitoring excursions reported during the monitoring period.**

**Proposed location numbering for Block-III:**

After selecting the locations, it is proposed to have unique and serial numbering for the environmental monitoring locations in Block-III. This numbering procedure shall be incorporated in the respective environmental monitoring SOP during routine monitoring.

Location number should consist of following details:

* line number (Line-IV for block-III),
* Type of monitoring (P- settle plate, A- Air sampling, R- RODAC, S-swab and C- for contact plate monitoring),
* Grade of the location (A- grade-A; B- Grade –B; C- Grade-C; D- Grade-D),
* location number in sequence for the particular grade.

Example-1: First location in Settle plate monitoring in grade-A shall be number as L4PA1

Example-2: First location in Air sampling in grade-B shall be number as L4AB1

| **AUTOCLAVE AND COMPOUNDING AREA** |
| --- |
| **SETTLE PLATE MONITORING** |

| **Location ID** | **Room ID** | **Description** | **Grade** | **Selected for routine monitoring** | **Proposed Location ID** | **Rationale** |
| --- | --- | --- | --- | --- | --- | --- |
| B3PD1 | B3G019/  Change  room-I | Near return air raiser (EN-AHU-0003/RG/07) Before cross over bench | D | NO | NA | Personnel entering into the autoclave and compounding rooms removes the factory footwear, crosses over the bench for entry into the change room-II. This location is at the return air raiser near to change Room-I entry door, before the cross over bench and is adjacent to controlled unclassified area. Viable monitoring by volumetric air sampling is proposed middle of the room (before cross over bench) which is located nearer to this location to determine the air quality before cross over bench. Hence, this location is not selected for routine monitoring. |
| B3PD2 | B3G019/  Change  room-I | Near return air raiser (EN-AHU-0003/RG/08) After cross over bench | D | YES | L4PD2 | This location is at the return air raiser near to change room-II entry door and after the cross over bench. The personnel entering into Grade-C area sanitizes the hands with disinfectant and used garments are disposed in this zone. The air from the room sweeps through the return air raiser. This location is selected to monitor the quality of the air in the room and to determine contamination due to man movement. |
| B3PC1 | B3G020/  Change room-II | Near return air raiser (EN-AHU-0004/RG/22) | C | YES | L4PC3 | Personnel entering into Grade-C area wear the garments in this zone and crosses over the bench. This location is at the return air raiser before the cross over bench and near to door of Change Room-I (Grade-D). The air from the room sweeps through the return air raiser. This location is selected to monitor the quality of the air in the room and to determine contamination due to man movement. |
| B3PC2 | B3G020/  Change room-II | Near return air raiser (EN-AHU-0004/RG/21) | C | NO | NA | Personnel after wearing the garment crosses over the bench and wears the secondary pair of gloves before entering into Grade-C corridor. This location is at the return air raiser after the cross over bench. Even though OOLs observed in this location, there is no activity near this location except wearing second pair of gloves. Viable monitoring by settle plate method is proposed near return air raiser (EN-AHU-0004/RG/22) volumetric air sampling is proposed middle of the room (before cross over bench) which is located nearer to this location to determine the air quality of this room. Hence, this location is not selected for routine monitoring. |
| B3PC3 | B3G021/ Corridor | Near return air raiser (EN-AHU-0004/RG/10) | C | YES | L4PC4 | This corridor serves as a passage for entry to processing areas such as autoclave room, parts washing room, compounding room, Buffer preparation room and vial wash & tunnel room and hence the movement of man/material is high in this corridor. There were no recoveries observed during “At-Rest and In-Operation” condition monitoring during the area PQ, however this location is at the return air raiser near to door of change room-II where the movement of man/material is high. Monitoring at this location determines the quality of air and contamination due to man/material movement. Hence, this location is selected for monitoring. |
| B3PC4 | B3G021/ Corridor | Near return air raiser (EN-AHU-0004/RG/09) | C | NO | NA | This location is at the return air raiser adjacent to door of janitor room opposite to autoclave entry. Viable monitoring by volumetric air sampling is proposed at location Middle of corridor (in-front of autoclave entry door) and by settle plate monitoring at location near the return air raiser at the entry door to corridor from change room-II which are located nearer to this location to determine the air quality in this area. There were no recoveries observed during the area PQ monitoring and no excursions reported for this location. Hence, this location is not selected for routine monitoring. |
| B3PC5 | B3G021/ Corridor | Near return air raiser (EN-AHU-0004/RG/07) | C | NO | NA | This location is at the return air raiser opposite to compounding room. Viable monitoring by volumetric air sampling is proposed at Middle of the corridor (In front of Compounding room entry) which is adjacent to this location to determine the air quality in this area. There were no recoveries observed during the area PQ monitoring and no excursions reported for this location. Hence, this location is not selected for routine monitoring. |
| B3PC6 | B3G021/ Corridor | Near return air raiser (EN-AHU-0004/RG/08) | C | NO | NA | This location is at the return air raiser between door of compounding and parts washing entry. Microbial recovery is identified during “At-rest “monitoring (max count-01 CFU) and no recoveries observed during “In-Operation” condition monitoring during the area PQ. Viable monitoring by volumetric air sampling is proposed at Middle of the corridor (In front of Compounding room entry) which is adjacent to this location to determine the air quality in this area. Hence, this location is not selected for routine monitoring. |
| B3PC7 | B3G021/ Corridor | Near return air raiser (EN-AHU-0004/RG/05) | C | NO | NA | This location is at the return air raiser adjacent to door of buffer preparation entry. Viable monitoring by volumetric air sampling is proposed at Middle of the corridor, in-front of Compounding room entry and by settle plate is location return air raiser between door of compounding and vial wash and tunnel rooms which are adjacent to this location to determine the air quality in this area. There were no recoveries observed during the area PQ monitoring and no excursions reported for this location. Hence, this location is not selected for routine monitoring. |
| B3PC8 | B3G021/ Corridor | Near return air raiser (EN-AHU-0004/RG/06) | C | YES | L4PC5 | This location is at the return air raiser between door of compounding and vial wash and tunnel rooms. Microbial recovery is identified during “In-operation “monitoring (max count-03 CFU) and no recoveries observed during “At-rest” condition monitoring during the area PQ. Man/material movement is frequent in this zone and hence this location is selected for monitoring to determine the quality of air and contamination due to man/material movement in this zone. |
| B3PC9 | B3G025/  Autoclave room | Near return air raiser  (EN-AHU-0004/RG/20) | C | YES | L4PC6 | The cleaned and dried articles used in the batch manufacturing process are transferred to this room and are loaded into the autoclave for sterilization. The materials that cannot be sterilized and required for performing the activities in aseptic area are transferred from this room to aseptic area through the dynamic pass box located in this room and hence man/material movement is significantly high in this room.  This location is at the return air raiser located in front of the autoclave loading LAF where the materials are loaded into autoclave for sterilization. There were no recoveries identified at this location during the PQ, however an SS table hosting a computer used for operation of autoclave is placed near to this location. Hence, this location is selected to monitor the quality of air and to determine the contamination due to man/material movement. |
| B3PC10 | B3G025/  Autoclave room | Near return air raiser  (EN- AHU-0004/RG/19) | C | NO | NA | This location is at the return air raiser located in front of the autoclave loading LAF where the materials are loaded into autoclave for sterilization. Monitoring by settle plate is proposed at location Near return air raiser (EN-AHU-0004/RG/20) and by volumetric air sampling In-front of Ceiling suspended LAF which are nearer to this location. There were no recoveries observed during the area PQ monitoring and no OOL’s reported for this location during the monitoring period. Hence, this location is not selected for routine monitoring. |
| B3PC11 | B3G025/  Autoclave room | Near return air raiser  (EN- AHU-0004/RG/17) | C | YES | L4PC7 | This location is at the return air raiser and near to the dynamic pass box between autoclave room and cool zone room. The materials that cannot be sterilized and required for performing the activities in aseptic area are transferred from this room to aseptic area through this dynamic pass box, which is adjacent to this location. The air from the room sweeps through the return air raiser. This location selected to monitor the quality of air and to determine the contamination due to man/material movement. |
| B3PC12 | B3G025/  Autoclave room | Near return air raiser  (EN- AHU-0004/RG/16) | C | NO | NA | This location is at the return air raiser and adjacent to the dynamic pass box between autoclave room and cool zone room. Monitoring by settle plate is proposed at Near return air raiser (EN- AHU-0004/RG/17) which is nearer to this location. There were no recoveries observed during the area PQ monitoring and no OOL’s reported for this location during the monitoring period. Hence, this location is not selected for routine monitoring. |
| B3PC13 | B3G025/  Autoclave room | Near return air raiser  (EN- AHU-0004/RG/15) | C | YES | L4PC8 | This location at the return air raiser near to the entry door autoclave room through which the movement of man/material occurs. This location selected for routine monitoring to monitor the contamination due to man/material movement and to determine the quality of air |
| B3PC14 | B3G025/  Autoclave room | Under autoclave loading LAF  (Right side middle of LAF) PF-LAF- 4010 | C | YES | L4PC9 | These location is under the ceiling suspended LAF (right side) where the cleaned and dried accessories/articles used in batch manufacturing are held before sterilization. Hence, this location is selected for routine monitoring to demonstrate the air quality of the LAF. |
| B3PC15 | B3G025/  Autoclave room | Under autoclave loading LAF (Left side middle of LAF) PF-LAF-4010 | C | NO | NA | This location is Under autoclave loading LAF (Left side middle). Monitoring by settle plate is proposed at right side middle of the LAF and by volumetric air sampling at the middle of the ceiling suspended LAF which are nearer to this location. There were no recoveries observed during the area PQ monitoring and no OOL’s reported for this location during the monitoring period. Hence, this location is not selected for routine monitoring. |
| B3PC16 | B3G024/  Parts Washing Room | Near return raiser (EN- AHU-0004/RG/13) | C | YES | L4PC10 | This location is near return air raiser near the door entry through which man/material movement occurs. The articles/accessories used in the batch manufacturing activities are transferred to this room. The dirty articles/accessories are washed and dried in this room. There is significant movement of man/material in this room considering the nature of activities performed in this room. This location is at the return air raiser near to entry door through which man/material movement occurs. This location is selected for monitoring to determine the hair quality in this room and to monitor the contamination due to man/material movement. |
| B3PC17 | B3G024/  Parts Washing Room | Near return raiser (EN- AHU-0004/RG/14) | C | NO | NA | This location is at the return air raiser near to the ceiling suspended LAF (PF-LAF-4003) where the cleaned accessories are dried before they are transferred for storage or sterilization. Monitoring by settle plate is proposed at Near return raiser (EN- AHU-0004/RG/13) and by volumetric air sampling at location middle of the room which are near to this location. There were no recoveries observed during the area PQ monitoring and no OOL’s reported for this location during the monitoring period, hence this location is not selected for routine monitoring. |
| B3PC18 | B3G024/  Parts Washing Room | Near return raiser (EN- AHU-0004/RG/11) | C | NO | NA | This location is at the return air raiser and in the corner of the room adjacent to the dynamic pass box located between parts washing room and airlock (Aseptic area) room. This location obstructs the door of the dynamic pass. Monitoring by volumetric air sampling is proposed at the middle of the room which is near to this location. There were no recoveries observed during the area PQ monitoring and no OOL’s reported for this location during the monitoring period. Hence, this location is not selected for routine monitoring. |
| B3PC19 | B3G024/  Parts Washing Room | Near to parts wash table | C | NO | NA | This location is at the return air raiser near to the parts washing table where the washing of accessories/materials occurs. This location obstructs the activities carried out at this location. Monitoring by volumetric air sampling is proposed at middle of the room which is near to this location. There were no recoveries observed during the area PQ monitoring and no OOL’s reported for this location during the monitoring period. Hence, this location is not selected for routine monitoring. |
| B3PC20 | B3G024/  Parts Washing Room | Near return raiser(EN- ILF-0006/RG/01) | C | YES | L4PC11 | This location is at the return air raiser and near to the utility points, which are used during washing/drying/sampling. This location is selected to monitor the quality of air and to determine the contamination due to man/material movement. |
| B3PC21 | B3G023/  Compounding Room | Near return raiser (EN- AHU-0005/RG/05) | C | YES | L4PC12 | Batch manufacturing activities such as compounding, bulk solution/utility sampling occurs in this room. The compounding process involves the handling of materials that are critical to product manufacturing such as drug product, excipients, and intermediates.  This location is at the return air raiser near to the entry door where there is movement of man/material. This location is selected for routine monitoring based on the recoveries obtained during area PQ and to monitor the quality of air and to determine the contamination due to man/material movement. |
| B3PC22 | B3G023/  Compounding Room | Near return raiser (EN- AHU-0005/RG/04) | C | NO | NA | This location is at the return air raiser near to the control panel for CIP Re-circulation for filtration vessels. Viable monitoring by volumetric air sampling method is proposed at middle of the room which is close to this location and determines the contamination due to man/ material movement. There were no OOL’s reported for this location during the monitoring period, hence this location is not selected for monitoring. |
| B3PC23 | B3G023/  Compounding Room | Near return raiser (EN- AHU-0005/RG/02) | C | NO | NA | This location at the return air raiser and toward the back side of the 200 Ltrs vessel and in the corner of the room. Viable monitoring by volumetric air sampling method is proposed at Back Side Mixing vessels (near to view panel between compounding and vial washing room) which is close to this location and determines the contamination due to man/ material movement. There were no OOL’s reported for this location during the monitoring period, hence this location is not selected for monitoring. Hence, this location is not selected for routine monitoring. |
| B3PC24 | B3G023/  Compounding Room | Near return raiser (EN- AHU-0005/RG/01) | C | NO | NA | This location is at back side of the 50 Ltrs vessel near to view panel between compounding and vial washing room and obstructs the movement of personnel. Viable monitoring by volumetric air sampling method is proposed at Back Side Mixing vessels (near to view panel between compounding and vial washing room) which is close to this location and determines the contamination due to man/ material movement. There were no OOL’s reported for this location during the monitoring period, hence this location is not selected for monitoring. Hence, this location is not selected for routine monitoring. |
| B3PC25 | B3G023/  Compounding Room | Near return raiser (EN- AHU-0005/RG/06) | C | YES | L4PC13 | This location is at the return air raiser and near to the Utility and drain point. The utility points are frequently accessed by the personnel to perform batch related activities and sampling. Considering the recoveries obtained during are PQ, this location is selected for routine monitoring to monitor the quality of air and to determine the contamination due to man/material movement. |
| B3PC26 | B3G022/  Vial Wash and Tunnel Room | Near return raiser (EN- AHU-0006/RG/07) | C | NO | NA | The activities such as vial washing and depyrogenation of vials that are related to batch manufacturing occurs in this room. This location is at the return air raiser and near the visual inspection hood which is used for inspection of washed vials during batch manufacturing. Monitoring by volumetric air sampling is proposed at Right side of Tunnel and by settle plate Near return raiser (EN- AHU-0006/RG/08) which are near to this location. There were no recoveries observed during the area PQ monitoring and no OOL’s reported for this location during the monitoring period, hence this location is not selected for monitoring. |
| B3PC27 | B3G022/  Vial Wash and Tunnel Room | Near return raiser (EN- AHU-0006/RG/08) | C | YES | L4PC14 | This location is at the return air raiser and near the visual inspection hood, which is used for inspection of washed vials during batch manufacturing.  This location is considered for routine monitoring to monitor the air quality and to determine the contamination due to man/material movement. |
| B3PC28 | B3G022/  Vial Wash and Tunnel Room | Near return raiser (EN- AHU-0006/RG/09) | C | NO | NA | This location is at the return air raiser towards the right side of the tunnel There were no recoveries observed during the area PQ and no viable monitoring excursions were reported for this location during the monitoring period. Monitoring by volumetric air sampling is proposed at Right side of Tunnel and by settle plate Near return raiser (EN- AHU-0006/RG/08) which are near to this location. There were no OOL’s reported for this location during the monitoring period, hence this location is not selected for monitoring. |
| B3PC29 | B3G022/  Vial Wash and Tunnel Room | Near return raiser (EN- AHU-0006/RG/10) | C | YES | L4PC15 | This location is at the return air raiser and in the corner of the room and near to the view panel of filling machine through which the personnel observes/tracks the filling activity in the aseptic area. This location is selected for routine monitoring considering the movement of personnel and to monitor the quality of air and to determine the contamination due to man/material movement. |
| B3PC30 | B3G022/  Vial Wash and Tunnel Room | Near return raiser (EN- AHU-0006/RG/01) | C | NO | NA | This location is near to the utility points which are accessed during sampling activity. There were no recoveries observed during the area PQ and no viable monitoring excursions were reported for this location during the monitoring period. Man/material movement is minimal at this location. Monitoring by volumetric air sampling is proposed at Left side of the Tunnel which is near to this location and determines the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PC31 | B3G022/  Vial Wash and Tunnel Room | Near return raiser (EN- AHU-0006/RG/02) | C | NO | NA | This location is at the return air raiser towards the left side of tunnel. There were no recoveries observed during the area PQ and no viable monitoring excursions were reported for this location during the monitoring period. Monitoring by volumetric air sampling is proposed at right and left side of the tunnel and settle plate monitoring is proposed at Near return raiser (EN- AHU-0006/RG/08) and Near return raiser (EN- AHU-0006/RG/10) in this room which determines the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PC32 | B3G022/  Vial Wash and Tunnel Room | Near return raiser (EN- AHU-0006/RG/03) | C | NO | NA | This location is towards the left side of tunnel. There were no recoveries observed during the area PQ and no viable monitoring excursions were reported for this location during the monitoring period. Monitoring by volumetric air sampling is proposed at right and left side of the tunnel and settle plate monitoring is proposed at Near return raiser (EN- AHU-0006/RG/08) and Near return raiser (EN- AHU-0006/RG/10) in this room which determines the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PC33 | B3G022/  Vial Wash and Tunnel Room | Near return raiser (EN- AHU-0006/RG/04) | C | No | NA | This location is at the return air raiser and towards the left side of tunnel. Viable monitoring by settle plate method is proposed at the location near return air raiser which is considered as worst location for routine monitoring. There were no recoveries and OOLs observed in this locations during PQ and routine monitoring. Hence, this location is not selected for routine monitoring. |
| B3PC34 | B3G022/  Vial Wash and Tunnel Room | Near return raiser (EN- AHU-0006/RG/05) | C | No | NA | This location is at the return air raiser and located near to the swing conveyor and vial washing HMI. Viable monitoring by settle plate method is proposed at the location near return air raiser which is considered as worst location for routine monitoring. There were no recoveries observed during the area PQ and no viable monitoring excursions were reported for this location during the monitoring period. Hence, this location is not selected for routine monitoring. |
| B3PC35 | B3G022/  Vial Wash and Tunnel Room | Near return raiser (EN- AHU-0006/RG/06) | C | YES | L4PC16 | This location is at the return air raiser and near to the entry door of vial washing and tunnel room. This location is selected for routine monitoring considering the movement of personnel and to monitor the quality of air and to determine the contamination due to man/material movement. |
| B3PC36 | B3G027/  Janitor Room | Near return raiser (EN- ILF-0004/RG/02) | C | YES | L4PC17 | This room is used for storage of area cleaning accessories and materials. This location is at the return air raiser and towards the entry door where man/material movement occurs. This location is selected for routine monitoring considering the maximum counts obtained, to monitor the quality of air and to determine the contamination due to man/material movement. |
| B3PC37 | B3G027/  Janitor Room | Near return raiser (EN- ILF-0004/RG/01) | C | No | NA | This location is in the corner of the room where the cleaning accessories are stored. There were no recoveries obtained during area PQ and No OOL’s were observed for this location. Monitoring by settle plate is proposed at the return air raiser near the door entry and by volumetric air sampling at middle of the room which effectively demonstrates the air quality of the room. Hence, this location is not selected for routine monitoring. |
| B3PC38 | B3G017/  Compounding room-2 | Near return raiser (EN- AHU-0004/RG/03) | C | YES | L4PC18 | This location is at the return air raiser and near to entry door where man/material movement occurs. This location is selected for routine monitoring considering the recoveries obtained, to monitor the quality of air and to determine the contamination due to man/material movement. |
| B3PC39 | B3G017/  Compounding room-2 | Near return raiser (EN- AHU-0004/RG/02) | C | YES | L4PC19 | This location is at the return air raiser and towards the back of the room and near the return air raiser. This location is selected for routine monitoring considering the recoveries obtained, to monitor the quality of air and to determine the contamination due to man/material movement. |
| B3PC40 | B3G017/  Compounding room-2 | Near return raiser (EN- AHU-0004/RG/01) | C | NO | NA | This location is at the return air raiser towards the back left side corner of the room. There were no recoveries obtained during area PQ and No OOL’s were observed for this location. Monitoring by settle plate is proposed at the Near return raisers EN- AHU-0004/RG/02 and EN- AHU-0004/RG/03 and by volumetric air sampling at Middle of the room which demonstrates the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PC41 | B3G017/  Compounding room-2 | Near return raiser (EN- AHU-0004/RG/04) | C | NO | NA | This location is at the return air raiser and near to the utility points which are accessed for sampling and near return air raiser. Hence there are chances of splashing of water during routine monitoring. Additionally, monitoring by settle plate is proposed at the Near return raisers EN- AHU-0004/RG/02 and EN- AHU-0004/RG/03 and by volumetric air sampling at Middle of the room which demonstrates the air quality in this room. Hence, this location is not selected for routine monitoring. |

| **VOLUMETRIC AIR SAMPLING** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Location ID** | **Room ID** | **Description** | **Grade** | **Selected for sampling** | **Proposed Location ID** | **Rationale** |
| B3AD1 | B3G019/  Change room-I | Middle of the room (before cross over bench) | D | YES | L4AD2 | This is a common change room for entry and exit to Grade-C processing areas and is adjacent to controlled unclassified area. Personnel entering into the Grade- C area, removes the factory foot wear in this room, sanitizes the hands and enters into the change room-2. The used garments during exit are disposed in this room. The location for volumetric air sampling is selected in the middle of the room to monitor the air quality and to determine the contamination due to personnel movement. |
| B3AC1 | B3G020/  Change room-II | Middle of the room (before cross over bench) | C | YES | L4AC3 | Gowning of the personnel entering into Grade-C processing areas occurs in this room. The location for volumetric air sampling is selected in the middle of the room to monitor the air quality and to determine the contamination due to personnel movement. |
| B3AC2 | B3G021/ Corridor | Middle of the corridor, in-front of autoclave entry | C | YES | L4AC4 | This corridor serves as a passage for entry to processing areas such as autoclave room, parts washing room, compounding room, Buffer preparation room and vial wash & tunnel room and hence the movement of man/material is high in this corridor. This location is in between autoclave room and janitor room entry. This location is selected to monitor the quality of air and to determine the contamination due to man/material movement. |
| B3AC3 | B3G021/ Corridor | Middle of the corridor, in-front of Compounding room entry | C | YES | L4AC5 | This location is in front of compounding entry and middle of the corridor. This location selected to monitor the quality of air and to determine the contamination due to man/material movement. |
| B3AC4 | B3G021/ Corridor | In front of Dynamic Pass box (PF-DPB-4001) | C | NO | NA | Materials are transferred into and out of Grade-C areas through the pass box. This location is in front of the pass box which is between material air lock and corridor. Viable monitoring by volumetric air sampling method in middle of the dynamic pass box is proposed to determine the air quality of the dynamic pass box. There were no OOLs observed in this location during PQ and routine monitoring. Hence, this location not selected for monitoring. |
| B3AC5 | B3G021/ Corridor | Middle of Dynamic Pass box (PF-DPB-4001) | C | YES | L4AC6 | The pass box is located between material air lock and corridor. The pass box is used for transfer of articles into and out of the Grade-C processing areas. Monitoring inside the pass box determines the air quality inside the dynamic pass box. |
| B3AC6 | B3G025/Autoclave room | Middle of the room (near to autoclave loading LAF) | C | YES | L4AC7 | The cleaned and dried articles used in the batch manufacturing process are transferred to this room and are loaded into the autoclave for sterilization. The materials that could not be sterilized and required for performing the activities in aseptic area are transferred from this room to aseptic area through the dynamic pass box located in this room and hence man/material movement is significantly high in this room.  This location is in the middle of the room and near to autoclave loading LAF. Monitoring at this location demonstrates the quality of air and contamination due to man/material movement. |
| B3AC7 | B3G025/Autoclave room | Middle of the Ceiling suspended LAF (PF-LAF-4010) | C | YES | L4AC8 | Cleaned accessories and articles are held under this LAF before sterilization, Monitoring under this LAF demonstrates the air quality of the LAF. |
| B3AC8 | B3G025/Autoclave room | In front of Dynamic Pass box (PF-DPB-4002) | C | NO | NA | This location is in front of dynamic pass box between autoclave room and cool zone room. Viable monitoring by volumetric air sampling method in middle of the dynamic pass box is proposed to determine the air quality of the dynamic pass box. There were no OOLs observed in this location during PQ and routine monitoring. Hence, this location not selected for monitoring. |
| B3AC9 | B3G025/Autoclave room | Right side corner of the room (In-front of Ceiling suspended LAF) | C | YES | L4AC9 | This location is in right side corner of the room in front of autoclave loading LAF (PF-LAF-4010). Monitoring at this location demonstrates the quality of air and contamination due to man/material movement. |
| B3AC10 | B3G024/ Parts Washing Room | Middle of the room | C | YES | L4AC10 | The articles/accessories used in the batch manufacturing activities are transferred to this room. The dirty articles/accessories are washed and dried in this room. There is significant movement of man/material in this room considering the nature of activities performed.  This location is in the middle of the room and is selected to demonstrate the quality of air and contamination due man/material movement. |
| B3AC11 | B3G024/ Parts Washing Room | Middle of the Ceiling suspended LAF (PF-LAF-4008) | C | YES | L4AC11 | Cleaned accessories and articles are held under this LAF for wrapping before sterilization. Monitoring under this LAF demonstrates the air quality of the LAF. |
| B3AC12 | B3G024/ Parts Washing Room | In front of Dynamic Pass box (PF-DPB-4003) | C | NO | NA | The monitoring location is located in front of dynamic pass box located between parts washing room and air lock (Aseptic area). Viable monitoring by volumetric air sampling method in middle of the dynamic pass box is proposed to determine the air quality of the dynamic pass box. There were no OOLs observed in this location during PQ and routine monitoring. Hence, this location not selected for monitoring. |
| B3AC13 | B3G023/  Compounding Room | Near to the Mixing vessel (500 Ltrs) (Near to the view panel between the compounding room & filtration room) | C | NO | NA | The monitoring location is located in front of near mixing vessel 500 lts. There were no excursions observed in this location during routine monitoring. Viable monitoring by volumetric air sampling is proposed near the middle of the room which effectively demonstrates the air quality of the room and the proposed location is in between the two mixing vesssels and hence can determine any contamination generated during the activities at any of the mixing vessel. Hence, this location is not selected for routine monitoring. |
| B3AC14 | B3G023/  Compounding Room | Near to the Mixing vessel (50 Ltrs) | C | YES | L4AC12  (Middle of the room between 50lts and 200lts mixing vessel) | This location is near to the mixing vessel (50 Ltrs) where there is movement of personnel/materials. This location is selected to demonstrate the quality of air and contamination due man/material movement. However, considering the worst case location for volumetric air sampling, it is proposed to move this location slightly towards the middle of the room between 50lts and 200lts mixing vessel as the contamination due to man movement near any of the vessels can be determined during routine operations. |
| B3AC15 | B3G023/  Compounding Room | Back side Mixing vessels near to view panel between compounding and vial washing room | C | YES | L4AC13 | This location is towards the left side of the room (middle), backside of mixing vessel near to wall between compounding and vial washing rooms. This location is selected to demonstrate the quality of air and contamination due man/material movement. |
| B3AC16 | B3G022/  Vial Wash and Tunnel Room | Near to the Vial washing Turn table (Near to the HMI) | C | NO | NA | The activities such as vial washing and depyrogenation of vials that are related to batch manufacturing occurs in this room. However, there were no OOLs observed in this location during PQ and routine monitoring. Viable monitoring by volumetric air sampling method is proposed at right and left side of the tunnel which are critical and effectively demonstrates the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3AC17 | B3G022/  Vial Wash and Tunnel Room | Right side of Tunnel (PF-DIS-4001) | C | YES | L4AC14 | This location is towards the right side of tunnel and near to the view panel of filling through which the person tracks the filling activity. This location is selected to demonstrate the quality of air and contamination due man/material movement. |
| B3AC18 | B3G022/  Vial Wash and Tunnel Room | Left side of the Tunnel (PF-DIS-4001) | C | YES | L4AC15 | This location is towards the left side of tunnel near to view panel between vial washing room and general corridor. Considering the man and material movement near this location, this location is selected for routine monitoring. |
| B3AC19 | B3G027/  Janitor Room | Middle of the room | C | YES | L4AC16 | This room is used for storage of area cleaning accessories and materials.  This location is selected for monitoring to determine the air quality and to monitor the contamination due to man movement in this room. |
| B3AC20 | B3G017/  Compounding room-2 | Middle of the room | C | YES | L4AC17 | This location is selected for monitoring to determine the air quality and to monitor the contamination due to man movement in this room. |

| **AUTOCLAVE AND COMPOUNDING AREA** |
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| **SURFACE MONITORING** |

| **Location ID** | **Room ID** | **Description** | **Grade** | **Method of sampling** | **Selected for routine monitoring** | **Proposed Location ID** | **Rationale** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| B3SC1 | B3G020/  Change room-II | On surface of push plate of door towards corridor | C | RODAC | YES | L4RC4 | The personnel after wearing the garments pushes open the door and enters into the corridor to access the relevant areas. This location is selected to determine the cleaning and sanitization practices. |
| B3SC2 | B3G021/ Corridor | On Surface of Dynamic pass box door handle (PF-DPB-4001) | C | SWAB | NO | NA | The surface of the door knob is selected for sampling to determine the cleaning and sanitization practices. There were no recoveries obtained for this location during the area PQ and no excursions were reported during the monitoring period and hence this location is not selected for routine monitoring. |
| B3SC3 | B3G021/ Corridor | On bottom Surface of Dynamic pass box (PF-DPB-4001) (inside) | C | RODAC | YES | L4RC5 | This location is selected to monitor the surface cleanliness of Dynamic pass box. |
| B3SC4 | B3G021/ Corridor | On Surface of door push plate towards Autoclave room | C | RODAC | YES | L4RC6 | The Personnel uses push plate to push open the door to enter into room. These locations are frequently accessed by the personnel and hence selected for sampling to monitor the cleaning and sanitization practices. |
| B3SC23 | B3G021/ Corridor | On Surface of door push plate towards vial washing & tunnel room | C | RODAC | YES | L4RC7 | The Personnel uses push plate to push open the door to enter into room. These locations are frequently accessed by the personnel and hence selected for sampling to monitor the cleaning and sanitization practices. |
| B3SC14 | B3G021/ Corridor | On Surface of door push plate towards compounding room | C | RODAC | YES | L4RC8 | The Personnel uses push plate to push open the door to enter into room. These locations are frequently accessed by the personnel and hence selected for sampling to monitor the cleaning and sanitization practices. |
| B3SC5 | B3G025/ Autoclave room | On Surface of door handle towards corridor | C | SWAB | NO | NA | The Personnel uses door the handle to pull open the door to exit from the room. This location is selected during initial qualification to assess the cleaning and sanitization practices. However, there are no excursions observed during the PQ and routine monitoring. As the locations like HMI, View panel locations selected for routine monitoring which are easy to monitor and also effectively demonstrates the sanitization practices of personnel in the respective area this location is not considered for routine monitoring. |
| B3SC6 | B3G025/ Autoclave room | On Surface of wall (Near entry door) | C | RODAC | YES | L4RC9 | This location is selected to monitor the cleaning and sanitization practices. |
| B3SC7 | B3G025/ Autoclave room | On Surface of Dynamic Pass box door handle (PF-DPB-4002) | C | SWAB | NO | NA | This dynamic pass box is used for transfer articles between autoclave and cool zone rooms. The pass box is frequently accessed by the personnel for transfer of articles but frequent sanitization of gloved hands while transferring the articles takes place which reduces the risk of contamination. There are no excursions observed during the PQ and routine monitoring. Monitoring by volumetric air sampling is proposed inside the dynamic passbox any contamination generated during handling of passbox can be determined. Hence, this location is not considered for routine monitoring. |
| B3SC8 | B3G025/ Autoclave room | On Surface of Extended LAF flaps (outside) | C | RODAC | YES | L4RC10 | This location is selected to monitor the cleaning and sanitization practices. |
| B3SC9 | B3G025/ Autoclave room | On Surface of Autoclave loading trolley handle | C | SWAB | NO | NA | This location is selected to monitor the Surface cleanliness of the trolley and to cover the personnel sanitization practices. There are no excursions observed during the PQ and routine monitoring. As the locations like HMI, View panel locations selected for routine monitoring which are easy to monitor and also effectively demonstrates the sanitization practices of personnel in the respective area this location is not considered for routine monitoring. |
| B3SC10 | B3G025/ Autoclave room | On Surface of Autoclave HMI | C | RODAC | YES | L4RC11 | This HMI is accessed by the personnel for operation of autoclave. This location is selected to monitor the cleaning and sanitization practices of the personnel. |
| B3SC11 | B3G024/ Parts Washing Room | On Surface view panel between compounding and parts wash room | C | RODAC | YES | L4RC12 | This location is near to the parts washing table and is selected to monitor the cleaning and sanitization practices. |
| B3SC12 | B3G024/ Parts Washing Room | On Surface of Dynamic Pass box door handle (PF-DPB-4003) | C | SWAB | NO | NA | The used machine parts are transferred through the dynamic pass box from aseptic processing area to parts washing room. The pass box is frequently accessed by the personnel for transfer of articles but frequent sanitization of gloved hands while transferring the articles takes place which reduces the risk of contamination. There are no excursions observed during the PQ and routine monitoring. Monitoring by volumetric air sampling is proposed inside the dynamic passbox any contamination generated during handling of passbox can be determined. Hence, this location is not considered for routine monitoring. |
| B3SC13 | B3G024/ Parts Washing Room | On Surface table under LAF (PF-LAF-4008) (Inside) | C | RODAC | YES | L4RC13 | The table is used for wrapping of articles after completion of washing, This location are considered for surface monitoring to monitor the Surface cleanliness and cover the personnel practices. |
| B3SC15 | B3G023/ Compounding Room | On Surface of door handle towards corridor | C | SWAB | NO | NA | The Personnel uses the door handle to pull open the door to exit from the room. There are no excursions observed during the PQ and routine monitoring. As the locations like surface wall of the compounding vessels are selected for routine monitoring which are easy to monitor and also effectively demonstrates the sanitization practices of personnel in the respective area this location is not considered for routine monitoring. |
| B3SC16 | B3G023/ Compounding Room | On surface wall (backside of 500L compounding vessels, beside solenoid junction box of 500L vessel) | C | RODAC | YES | L4RC14 | This location is selected to monitor the cleaning and sanitization practices. |
| B3SC17 | B3G023/ Compounding Room | On surface of compounding vessel on top of lid (50 Ltrs) | C | RODAC | YES | L4RC15 | This location is selected to monitor the cleaning and sanitization practices. |
| B3SC18 | B3G023/ Compounding Room | On surface of compounding vessel on top of lid (200 Ltrs) | C | RODAC | YES | L4RC16 | This location is selected to monitor the cleaning and sanitization practices. |
| B3SC19 | B3G023/ Compounding Room | On surface of compounding vessel on top of lid (500 Ltrs) | C | RODAC | YES | L4RC17 | This location is selected to monitor the cleaning and sanitization practices. |
| B3SC20 | B3G023/ Compounding Room | On surface of mixing vessel IPC (Junction box) | C | RODAC | YES | L4RC18 | This location is selected to monitor the cleaning and sanitization practices. |
| B3SC21 | B3G027/  Janitor Room | On Surface of floor (Near entry door) | C | RODAC | YES | L4RC19 | This location is selected to monitor the cleaning and disinfection practices. |
| B3SC22 | B3G017/  Compounding room-2 | On Surface of wall (Near utility lines) | C | RODAC | YES | L4RC20 | This location is at the corner of the room near to utility lines and is selected to monitor the cleaning and disinfection practices. |
| B3SC24 | B3G022/  Vial Wash and Tunnel Room | On Surface of door handle towards corridor | C | SWAB | NO | NA | The Personnel uses the door handle to pull open the door to exit from the room. There are no excursions observed during the PQ and routine monitoring. As the locations like HMI, vial washing machine door are selected for routine monitoring which are easy to monitor and also effectively demonstrates the sanitization practices of personnel in the respective area this location is not considered for routine monitoring. |
| B3SC25 | B3G022/  Vial Wash and Tunnel Room | On top surface of visual inspection hood | C | RODAC | YES | L4RC21 | The visual inspection hood is used for inspection of washed vials during batch manufacturing. This location is selected to monitor the cleaning and disinfection practices. |
| B3SC26 | B3G022/  Vial Wash and Tunnel Room | On Surface of vial washing machine HMI | C | RODAC | YES | L4RC22 | Operators touch the HMI screen frequently during operation. This location is selected for surface monitoring to determine the contamination due to personnel practices and to demonstrate the effectiveness of cleaning and disinfection process. |
| B3SC27 | B3G022/  Vial Wash and Tunnel Room | On Surface of swing conveyor | C | RODAC | YES | L4RC23 | The conveyer is used for the transfer of vials to infeed turn table for vial washing. Monitoring of the surface of conveyer demonstrates the cleaning and disinfection process. |
| B3SC28 | B3G022/  Vial Wash and Tunnel Room | On Surface of vial washing machine door | C | RODAC | YES | L4RC24 | This location is selected for surface monitoring to determine the contamination due to personnel practices and to demonstrate the effectiveness of cleaning and disinfection process. |
| B3SD2 | B3G019/  Change room-I | On surface of cross over bench | D | RODAC | YES | L4RD2 | The person crosses over the bench and moves into change room-2. This location is selected to monitor the cleaning and sanitization practices. |

| **ASEPTIC PROCESSING AREA** |
| --- |
| **SETTLE PLATE MONITORING** |

| **Location ID** | **Room ID** | **Description** | **Grade** | **Selected for routine monitoring** | **Proposed Location ID** | **Rationale** |
| --- | --- | --- | --- | --- | --- | --- |
| B3PD9 | B3G033/ APA  Change Room-I | Near return air raiser (EN- AHU-0007/RG/01) | D | NO | NA | This is room is adjacent to the controlled unclassified area and serves as a common change room for entry and exit of aseptic processing area.  This monitoring location is at the return air raiser near to entry door of change room-I. This location is not considered for routine monitoring as there is no activity near this location. Viable monitoring by settle plate method is proposed Near return air raiser (EN- AHU-0007/RG/03) where the personnel entering wears factory foot wear and that location is considered critical. Hence, this location is not selected for routine monitoring. |
| B3PD10 | B3G033/ APA  Change Room-I | Near return air raiser (EN- AHU-0007/RG/03) | D | YES | L4PD1 | The personnel entering into the aseptic area removes the factory footwear, wears the sterilized booties in this room crosses over the bench for entry to change room-II.  This monitoring location is at the return air raiser. This location is considered for routine monitoring considering the recoveries obtained during “At-rest” condition during area PQ. Monitoring at this location determines the contamination due to man/material movement and to monitor the air quality in this room. |
| B3PD11 | B3G033/ APA  Change Room-I | Near return air raiser (EN- AHU-0007/RG/02) | D | NO | NA | The personnel exiting the aseptic processing area disposes off the removed sterile garments in the bin near to this location.  This monitoring location is at the return air raiser. There were no recoveries obtained in at-rest condition monitoring and no excursions were reported during the monitoring period at this location. Monitoring by settle plate is proposed Near return air raiser (EN- AHU-0007/RG/03) and by volumetric air sampling Middle of the room to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PC42 | B3G034/APA  Change room-II | Near return air raiser (EN- AHU-0008/RG/01) | C | NO | NA | This room is next to the change room-I and the person entering into aseptic processing area wears the sterile primary garments and moves to change room-III. The location is near return air raiser which is adjacent to door opening and there are no gowning activities near this location. There were no recoveries obtained in at-rest condition monitoring and no excursions were reported during the monitoring period at this location. Viable monitoring by settle plate method near return air raiser (EN- AHU-0008/RG/02) Before cross over bench and volumetric air sampling near Middle of the room (Before cross over bench) to determine the contamination due to gowning practices and to monitor the air quality in this room. Hence, this location is not considered for routine monitoring. |
| B3PC43 | B3G034/APA  Change room-II | Near return air raiser (EN- AHU-0008/RG/02) Before cross over bench | C | YES | L4PC1 | This location is at the return air raiser near to cross over bench where the person wears the primary sterile garment and crosses over the bench for entry to change room-III. This location is considered for routine monitoring considering the recoveries obtained during “At-rest” condition during area PQ. Monitoring at this location determines the contamination due to gowning practices and man/material movement and to monitor the air quality in this room. |
| B3PC44 | B3G034/APA  Change room-II | Near return air raiser (EN- AHU-0008/RG/03) After cross over bench | C | NO | NA | This location is at the return air raiser near to door opening towards change room-III after cross over bench. The person after wearing the garment crosses over the bench, sanitizes the hands and enters into change room-III. There were no recoveries obtained in at-rest condition monitoring and no excursions were reported during the monitoring period at this location. Viable monitoring by settle plate method near return air raiser (EN- AHU-0008/RG/02) Before cross over bench and volumetric air sampling near Middle of the room (Before cross over bench) to determine the contamination due to gowning practices and to monitor the air quality in this room. Hence, this location is not considered for routine monitoring. |
| B3PB1 | B3G035/APA  Change room-III | Near return air raiser (EN- AHU-0009/RG/14) | B | NO | NA | The person enters into this room with sterile primary garment. In this room, the person wears the sterile secondary garment secondary pair of gloves and moves to the aseptic processing area for performing relevant activities.  This location is at the return air raiser beside garment cubicle and opposite to door between change room-III and change room-II. There were no recoveries obtained in at-rest condition monitoring and no excursions were reported during the monitoring period at this location. Monitoring by settle plate is proposed at the Near return air raiser (EN- AHU-0009/RG/15) and by volumetric air sampling at middle of the room before cross over bench to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB2 | B3G035/APA  Change room-III | Near return air raiser (EN- AHU-0009/RG/15) | B | YES | L4PB1 | This location is at the return air raiser towards the corner of the room near to cross over bench. Personnel movement occurs at this location to don the sterile secondary garment. The air in the room sweeps out through this return air raiser and monitoring at this location determines the quality of air and the contamination due to man movement. Hence, this location is selected for monitoring. |
| B3PB3 | B3G035/APA  Change room-III | Near return air raiser (EN- AHU-0009/RG/13) | B | NO | NA | This location is at the return air raiser near to door opening towards buffer room. The personnel after crossing over the bench wears second pair of sterile gloves and enters into aseptic area. There were no recoveries obtained in at-rest condition monitoring and no excursions were reported during the monitoring period at this location. Monitoring by settle plate is proposed at the Near return air raiser (EN- AHU-0009/RG/15) and by volumetric air sampling at middle of the room before cross over bench to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB4 | B3G036/  Buffer Room | Near return air raiser (EN- AHU-0009/RG/12) | B | YES | L4PB2 | The personnel after wearing sterile secondary garments enters into this room and moves into APA corridor. The microbiology accessories used for monitoring are held under the ceiling suspended LAF in this room where activities such as inspection, labelling of unused plates and wrapping of sampled plates occur. This room is frequently accessed by man to perform activities. This location is at the return air raiser near to door between buffer room and change room-III. The air in the room sweeps out through these return air raisers and monitoring at these locations determines the quality of air and hence these locations are selected for monitoring. |
| B3PB5 | B3G036/  Buffer Room | Near return air raiser (EN- AHU-0009/RG/11) | B | NO | NA | This location is at the return air raiser near to door towards sterile corridor and in-front of ceiling suspended LAF. There were no recoveries obtained in area PQ monitoring and no excursions were reported during the monitoring period at this location. Monitoring by settle plate is proposed Near return air raiser (EN- AHU-0009/RG/12) and by volumetric air sampling at the Middle of the room to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB6 | B3G036/  Buffer Room | Left side middle of the Ceiling suspended LAF | B | YES | L4PB3 | The Ceiling suspended LAF is used for holding and labelling of viable environmental monitoring accessories. There were no recoveries obtained in at-rest condition monitoring and no excursions were reported during the monitoring period at this location. This LAF is solely used for labelling of plates and do not pose any direct impact on the product quality. This location is selected for routine monitoring to monitor the air quality under the LAF. |
| B3PB7 | B3G036/  Buffer Room | Right side middle of the ceiling suspended LAF | B | NO | NA | There were no recoveries obtained in at-rest condition monitoring and no excursions were reported during the monitoring period at this location. Monitoring by volumetric air sampling at Middle of the ceiling suspended LAF and by settle plate towards the left side of the ceiling suspended LAF, to monitor the air quality, to determine the contamination due to activities performed under the LAF and to evaluate the personnel practices. This LAF is solely used for labelling of plates and do not pose any direct impact on the product quality. Hence, these location is not selected for routine monitoring. |
| B3PB8 | B3G037/APA corridor | Near return air raiser (EN- AHU-0009/RG/10) | B | NO | NA | APA corridor is the common area for all the personnel who enters in to the different areas of the aseptic area like filtration room, filling room, sealing room and Lyo loading and unloading areas. There were no recoveries obtained in area during PQ monitoring and no excursions were reported during the monitoring period at this location. Monitoring by volumetric air sampling is proposed at the location Middle of the corridor (In between the change room-IV & Cool zone) is adjacent to this location for routine monitoring. Hence, this location is not selected for routine monitoring. |
| B3PB9 | B3G037/APA corridor | Near return air raiser (EN- AHU-0009/RG/09) | B | NO | NA | This location is at the return air raiser near to door opening towards air lock through which the used articles for cleaning are transferred to Grade-C processing areas. There were no recoveries obtained in area during PQ monitoring and no excursions were reported during the monitoring period at this location. Monitoring by settle plate is proposed Near return air raisers EN- AHU-0009/RG/05 and EN- AHU-0009/RG/08 and volumetric air sampling at locations at the middle of the corridor between the change room-IV & Cool zone and middle of the corridor towards lyo loading and filtration rooms to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB10 | B3G037/APA corridor | Near return air raiser (EN- AHU-0009/RG/07) | B | NO | NA | This location is at the return air raiser near to door towards filtration room and opposite to Lyo loading and unloading room. There were no recoveries obtained in area during PQ monitoring and no excursions were reported during the monitoring period at this location. Monitoring by settle plate is proposed Near return air raisers EN- AHU-0009/RG/05 and EN- AHU-0009/RG/08 and volumetric air sampling at locations at the middle of the corridor between the change room-IV & Cool zone and middle of the corridor towards lyo loading and filtration rooms to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB11 | B3G037/APA corridor | Near return air raiser (EN- AHU-0009/RG/04) | B | NO | NA | There were no recoveries obtained in area during PQ monitoring and no excursions were reported during the monitoring period at this location. Monitoring by settle plate is proposed Near return air raisers EN- AHU-0009/RG/05 and EN- AHU-0009/RG/08 and volumetric air sampling at locations at the middle of the corridor between the change room-IV & Cool zone and middle of the corridor towards lyo loading and filtration rooms to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB12 | B3G037/APA corridor | Near return air raiser (EN- AHU-0009/RG/05) | B | YES | L4PB4 | This location is at the door towards filling room where the movement of man/material is frequent. This location is selected for routine monitoring based on the recoveries during the monitoring period to determine the contamination due to man/material movement and to monitor the air quality in this room. |
| B3PB13 | B3G037/APA corridor | Near return air raiser (EN- AHU-0009/RG/06) | B | NO | NA | This location is at the return air raiser near to door opening towards lyo loading and unloading room There were no recoveries obtained in area during PQ monitoring and no excursions were reported during the monitoring period at this location. Monitoring by settle plate is proposed Near return air raisers EN- AHU-0009/RG/05 and EN- AHU-0009/RG/08 and volumetric air sampling at locations at the middle of the corridor between the change room-IV & Cool zone and middle of the corridor towards lyo loading and filtration rooms to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB14 | B3G037/APA corridor | Near return air raiser (EN- AHU-0009/RG/08) | B | YES | L4PB5 | This location is at the return air raiser opposite to material air lock. This location is selected for routine monitoring based on the recoveries during the monitoring period to determine the contamination due to man/material movement and to monitor the air quality in this room. |
| B3PB15 | B3G038/Cool Zone | Near return air raiser (EN- AHU-0010/RG/01) | B | YES | L4PB6 | The sterilized articles are unloaded and stored under the LAF’s in this room. The sanitized accessories are transferred through the pass box between cool zone and autoclave room. Man/material movement is high and frequent in this room.  This location is at the return air raiser near to door of cool zone opposite autoclave unloading LAF. This location is selected for monitoring considering its location and based on the recovery obtained during the monitoring period to determine the quality of air and the contamination due to man movement in this room. |
| B3PB16 | B3G038/Cool Zone | Near return air raiser (EN- BMU-0001/RG/01) | B | NO | NA | This location is at the return air raiser opposite to autoclave unloading LAF. The air in the room seeps through this return air raiser and is supplied to the ceiling suspended LAF.  There were no recoveries obtained in area PQ monitoring and no excursions were reported during the monitoring period at this location. Monitoring by settle plate is proposed at the Near return air raisers EN- AHU-0010/RG/01 and EN- AHU-0010/RG/02 which are near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB17 | B3G038/Cool Zone | Near return air raiser (EN- BMU-0001/RG/02) | B | YES | L4PB7 | The air in the room seeps through this return air raiser and is supplied to the ceiling suspended LAF. This location is at the return air towards the corner of the room.  This location is selected for monitoring considering its location and based on the recovery obtained during the monitoring period to determine the quality of air and the contamination due to man movement in this room. |
| B3PB18 | B3G038/Cool Zone | Near return air raiser (EN- AHU-0010/RG/02) | B | NO | NA | This location is at the return air raiser near to autoclave unloading LAF. There were no recoveries obtained in area PQ monitoring and no excursions were reported during the monitoring period at this location. Monitoring by one settle plate is proposed at this return air raiser and by volumetric air sampling at location In-front of unloading LAF which are near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB19 | B3G038/Cool Zone | Near return air raiser (EN- BMU-0001/RG/09) | B | NO | NA | This location is at the return air raiser near to cool zone door and parts storage ceiling suspended LAF. There were no recoveries obtained in area PQ monitoring and no excursions were reported during the monitoring period at this location. Monitoring by volumetric air sampling is proposed at location In-front of Parts storage LAF which is near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB20 | B3G038/Cool Zone | Under cool zone unloading LAF (Front left corner of the LAF) (PF-LAF-4004) | B | YES | L4PB8 | The sterilized articles used during the product manufacturing process are unloaded and transferred to mobile LAF under this LAF. This location is under the ceiling suspended LAF (cool zone unloading LAF) and is selected for routine monitoring considering the recoveries obtained during the monitoring period to monitor the air quality and to determine the practices of the personnel working under this LAF. |
| B3PB21 | B3G038/Cool Zone | Under cool zone unloading LAF (Front right corner of the LAF) (PF-LAF-4004) | B | NO | NA | This location is under the ceiling suspended LAF (cool zone unloading LAF). There were no recoveries obtained in area PQ monitoring and no excursions were reported during the monitoring period at this location. Monitoring by settle plate is proposed at the Front left corner of the LAF and Towards autoclave right corner of the LAF and by volumetric air sampling at the middle of the LAF which determines the contamination due to man/material movement and to monitor the air quality under this LAF. Hence this location is not selected for routine monitoring. |
| B3PB22 | B3G038/Cool Zone | Under cool zone unloading LAF (Towards autoclave left corner of the LAF) (PF-LAF-4004) | B | NO | NA | This location is under the ceiling suspended LAF (cool zone unloading LAF). There were no recoveries obtained in area PQ monitoring and no excursions were reported during the monitoring period at this location. Monitoring by settle plate is proposed at the Front left corner of the LAF and Towards autoclave right corner of the LAF and by volumetric air sampling at the middle of the LAF which determines the contamination due to man/material movement and to monitor the air quality under this LAF. Hence this location is not selected for routine monitoring. |
| B3PB23 | B3G038/Cool Zone | Under cool zone unloading LAF (Towards autoclave right corner of the LAF) (PF-LAF-4004) | B | YES | L4PB9 | This location is under the ceiling suspended LAF (cool zone unloading LAF) and is selected for routine monitoring to monitor the air quality and to determine the practices of the personnel working under this LAF. |
| B3PB24 | B3G038/Cool Zone | Under cool zone Parts Storage LAF  (Front left corner of the LAF) | B | YES | L4PB10 | The sterilized articles used during the product manufacturing process are transferred in mobile LAF and are stored under this LAF. This location is under the ceiling suspended LAF and is selected for routine monitoring considering the recoveries obtained during the monitoring period to monitor the air quality and to determine the practices of the personnel working under this LAF. |
| B3PB25 | B3G038/Cool Zone | Under cool zone Parts Storage LAF (Front right corner of the LAF) | B | NO | NA | This location is under the ceiling suspended LAF (cool zone unloading LAF). There were no recoveries obtained in area PQ monitoring and no excursions were reported during the monitoring period at this location. Monitoring by settle plate is proposed at the Front left corner of the LAF and Back right corner of the LAF and by volumetric air sampling at the middle of the LAF which determines the contamination due to man/material movement and to monitor the air quality under this LAF. Hence this location is not selected for routine monitoring. |
| B3PB26 | B3G038/Cool Zone | Under cool zone Parts Storage LAF (Back left corner of the LAF) | B | NO | NA | This location is under the ceiling suspended LAF (cool zone unloading LAF). There were no recoveries obtained in area PQ monitoring and no excursions were reported during the monitoring period at this location. Monitoring by settle plate is proposed at the Front left corner of the LAF and Back right corner of the LAF and by volumetric air sampling at the middle of the LAF which determines the contamination due to man/material movement and to monitor the air quality under this LAF. Hence this location is not selected for routine monitoring. |
| B3PB27 | B3G038/Cool Zone | Under cool zone Parts Storage LAF (Back right corner of the LAF) | B | YES | L4PB11 | The sterilized articles used during the product manufacturing process are transferred in mobile LAF and are stored under this LAF. This location is under the ceiling suspended LAF and is selected for routine monitoring considering the recoveries obtained during the monitoring period to monitor the air quality and to determine the practices of the personnel working under this LAF. |
| B3PB28 | B3G039/  Air Lock | Near return air raiser (EN- AHU-0009/RG/03) | B | No | NA | This air lock is used for the transferring of used machine parts and other materials to parts washing room through the dynamic pass box located in this room. Man/material movement is frequent in this room. This location is at the return air raiser near to door of material air lock. There were no recoveries obtained in area PQ monitoring and no excursions were reported during the monitoring period at this location. Considering the recovery rate at this location and proposal for monitoring by settle plate Near return air raiser (EN- AHU-0009/RG/02) and volumetric air sampling at middle of the room which are near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room this location is not selected for routine monitoring. |
| B3PB29 | B3G039/  Air Lock | Near return air raiser (EN- AHU-0009/RG/02) | B | YES | L4PB12 | This location is at the return air raiser in-front of dynamic pass box through which the articles are transferred to Grade-C processing area. Considering the recovery rate this location is selected for routine monitoring determine the quality of air and the contamination due to man/material movement in this room. |
| B3PB30 | B3G039/  Air Lock | Near return air raiser (EN- AHU-0009/RG/01) | B | No | NA | This location is at the return air raiser near to dynamic pass box through which the articles are transferred to Grade-C processing area. There were no recoveries obtained in area PQ monitoring and no excursions were reported during the monitoring period at this location. Considering the recovery rate at this location and proposal for monitoring by settle plate Near return air raiser (EN- AHU-0009/RG/02) and volumetric air sampling at middle of the room which are near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room this location is not selected for routine monitoring. |
| B3PB31 | B3G040/  Filtration Room | Near return air raiser (EN- BMU-0002/RG/01) | B | NO | NA | This location is at the return air raiser near to door of filtration room. There were no recoveries obtained during area PQ and no excursions were reported during the monitoring period. Monitoring by settle plate is proposed at Near return air raiser (EN- BMU-0002/RG/02) and by volumetric air sampling at Middle of the room which are near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence this location is not selected for routine monitoring. |
| B3PB32 | B3G040/  Filtration Room | Near return air raiser (EN- BMU-0002/RG/02) | B | YES | L4PB13 | After completion of compounding, the product is transferred to this room through the product transfer lines. Primary filtration of the product occurs in this room and the filtered product is held in the filtration vessels under ceiling suspended LAF for further processing. The activities are performed in closed conditions in this room. The man movement is frequent in this room. Manual activities such as connections for filtration and sampling of bulk solution occurs in this room.  This location is at the return air raiser in-front of ceiling suspended LAF (PF-LAF-4002). The air in the room seeps through this return air raiser and is supplied to the ceiling suspended LAF. This location is selected for monitoring considering its location and based on the recovery obtained during the monitoring period to determine the quality of air and the contamination due to man movement in this room. |
| B3PB33 | B3G040/  Filtration Room | Near return air raiser (EN- BMU-0002/RG/03) | B | NO | NA | This location is at the return air raiser near ceiling suspended LAF (PF-LAF-4007). The air in the room seeps through this return air raiser and is supplied to the ceiling suspended LAF. There were no excursions were reported during the monitoring period. Monitoring by settle plate is proposed at Near return air raiser (EN- BMU-0002/RG/02) and by volumetric air sampling at Middle of the room which are near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence this location is not selected for routine monitoring. |
| B3PB34 | B3G040/  Filtration Room | Near return air raiser (EN- AHU-0011/RG/02) | B | NO | NA | This location is at the return air raiser near to of door of filtration room. The air in the room seeps through this return air raiser. There were no excursions were reported during the monitoring period. Monitoring by settle plate is proposed at Near return air raiser (EN- BMU-0002/RG/02) and by volumetric air sampling at Middle of the room which are near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence this location is not selected for routine monitoring. |
| B3PB35 | B3G040/  Filtration Room | Middle of the ceiling suspended LAF –between the 500 Ltrs & 200 Ltrs filtration vessel | B | YES | L4PB14 | This LAF is used for filtration activity of bulk solution and the personnel intervention is required during preparatory works like connection, removal / fixing of filters & clamps and sampling of bulk solution. The activities occur in closed condition under this LAF. The Filtered bulk solution is held in filtration vessels under this LAF in closed condition. This location is selected for routine monitoring to monitor the air quality of the LAF and to determine the contamination due activities performed under this LAF. |
| B3PB36 | B3G044/  Vial Sealing Room-I | Near return air raiser (EN- BMU-0005/RG/10) | B | YES | L4PB15 | After completion of lyophilization process, lyophilized product vials are sealed under LAF in this room. The movement of the personnel for performing sealing activities, transferring and loading of seals and sealed vials occurs in this room.  This location is at the return air raiser in-front of door of sealing Room-I. This location is selected for monitoring considering its location and based on the recovery obtained during area PQ monitoring to determine the quality of air and the contamination due to man movement in this room. |
| B3PB37 | B3G044/  Vial Sealing Room-I | Near return air raiser (EN- BMU-0005/RG/11) | B | NO | NA | This location is at the return air raiser near to extended LAF for seals addition. The air in the room seeps through this return air raiser and is supplied to ceiling suspended LAF.  There were no recoveries obtained during area PQ and no excursions were reported during the monitoring period. Monitoring by settle plate is proposed Near return air raiser (EN- BMU-0005/RG/10) and by volumetric air sampling at Middle of the room (Near to the HMI) which are near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB38 | B3G044/  Vial Sealing Room-I | Near return air raiser (EN- BMU-0005/RG/12) | B | NO | NA | This location is at the return air raiser near to extended LAF for sealing machine. There were no recoveries obtained during area PQ and no excursions were reported during the monitoring period. Monitoring by settle plate is proposed Near return air raiser (EN- BMU-0005/RG/10) and by volumetric air sampling at Middle of the room (Near to the HMI) which are near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB39 | B3G044/  Vial Sealing Room-I | Near return air raiser (EN- BMU-0005/RG/13) | B | NO | NA | This location is at the return air raiser at the corner of the room. Monitoring by settle plate is proposed Near return air raiser (EN- BMU-0005/RG/10) and by volumetric air sampling at Middle of the room (Near to the HMI) which are near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB40 | B3G044/  Vial Sealing Room-I | Near return air raiser (EN- AHU-0014/RG/04) | B | NO | NA | This location is at the return air raiser beside door of sealing room. There were no recoveries obtained during area PQ and no excursions were reported during the monitoring period. Monitoring by settle plate is proposed Near return air raiser (EN- BMU-0005/RG/10) and by volumetric air sampling at Middle of the room (Near to the HMI) which are near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB41 | B3G044/  Vial Sealing Room-I | Near return air raiser (EN- BMU-0005/RG/09) | B | YES | L4PB16 | This location is at the return air raiser at the corner of the room. The air in the room seeps through this return air raiser and is supplied to ceiling suspended LAF. This location is selected for monitoring considering its location and based on the recovery obtained during area PQ monitoring to determine the quality of air and the contamination due to man movement in this room |
| B3PB42 | B3G043/  Lyo Loading & Unloading Room | Near return air raiser (EN- BMU-0005/RG/07) | B | YES | L4PB17 | Loading of held- stoppered vials for lyophilization and unloading of full stoppered lyophilized products for sealing activity occurs under the LAF in this room. This location is at the return air raiser near to entry door of lyo loading and unloading room (right side of door). This location is selected for monitoring considering its location and based on the recovery obtained during monitoring period to determine the quality of air and the contamination due to man movement in this room. |
| B3PB43 | B3G043/  Lyo Loading & Unloading Room | Near return air raiser (EN- BMU-0005/RG/08) | B | NO | NA | This location is at the return air raiser near to extended LAF of outfeed turn table. Man movement is frequent in this room during manufacturing activity. There were no recoveries obtained during area PQ and no excursions were reported during the monitoring period. Monitoring by settle plate is proposed at Near return air raiser (EN- BMU-0005/RG/07) and by volumetric air sampling at location Near to the ALUS Pusher unit and Beside ALUS-2 HMI which is middle of the lyo loading and unloading room and determine the contamination due to man/material movement and to monitor the air quality in this room. Hence this location is not selected for routine monitoring. |
| B3PB44 | B3G043/  Lyo Loading & Unloading Room | Near return air raiser (EN- BMU-0005/RG/06) | B | NO | NA | This location is at the return air raiser near to entry door of lyo loading and unloading room (left side of door). There were no recoveries obtained during area PQ and no excursions were reported during the monitoring period. Monitoring by settle plate is proposed at Near return air raiser (EN- BMU-0005/RG/07) and by volumetric air sampling at location Near to the ALUS Pusher unit and Beside ALUS-2 HMI which is middle of the lyo loading and unloading room and determine the contamination due to man/material movement and to monitor the air quality in this room. Hence this location is not selected for routine monitoring. |
| B3PB45 | B3G043/  Lyo Loading & Unloading Room | Near return air raiser (EN- BMU-0005/RG/05) | B | NO | NA | This location is at the return air raiser. There were no recoveries obtained during area PQ and no excursions were reported during the monitoring period. Monitoring by settle plate is proposed at Near return air raiser (EN- BMU-0005/RG/07) and by volumetric air sampling at location Near to the ALUS Pusher unit and Beside ALUS-2 HMI which is middle of the lyo loading and unloading room and determine the contamination due to man/material movement and to monitor the air quality in this room. Hence this location is not selected for routine monitoring. |
| B3PB46 | B3G043/  Lyo Loading & Unloading Room | Near return air raiser (EN- BMU-0005/RG/04) | B | YES | L4PB18 | This location is at the return air raiser. This location is selected for monitoring considering its location to determine the quality of air and the contamination due to man movement in this room. |
| B3PB47 | B3G043/  Lyo Loading & Unloading Room | Near return air raiser (EN- BMU-0005/RG/03) | B | NO | NA | This location is at the return air raiser. The air in the room seeps through this return air raiser. There were no recoveries obtained during area PQ and no excursions were reported during the monitoring period. Monitoring by settle plate is proposed at Near return air raiser (EN- BMU-0005/RG/04) and by volumetric air sampling at Near to the ALUS Pusher unit and Beside ALUS-2 HMI which is middle of the lyo loading and unloading room and the selected locations are near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB48 | B3G043/  Lyo Loading & Unloading Room | Near return air raiser (EN- BMU-0005/RG/02) | B | NO | NA | This location is at the return air raiser. There were no recoveries obtained during area PQ and no excursions were reported during the monitoring period. Monitoring by volumetric air sampling at Near to the ALUS HMI (ID No.: PF-ALU-4001) and in-front of ALUS-I Loading side which is near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB49 | B3G043/  Lyo Loading & Unloading Room | Near to ALUS-1 HMI | B | NO | NA | This location is at the HMI of ALUS-1. There were no recoveries obtained during area PQ and no excursions were reported during the monitoring period. Monitoring by volumetric air sampling at Near to the ALUS HMI (ID No.: PF-ALU-4001) and in-front of ALUS-I Loading side which is near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence this location is not selected for routine monitoring. |
| B3PB70 | B3G043/  Lyo Loading & Unloading Room | Under the extended LAF near ALUS in-feed conveyer | B | NO | NA | This location is under the extended LAF. There were no excursions were reported during the monitoring period. Monitoring by volumetric air sampling is proposed Under the Extended LAF - In front of Lyophilizer-2 and Under the Extended LAF - In between the ALUS Infeed conveyor and corner of the in-feed conveyor which are near to this location to determine the contamination and to monitor the air quality in this room. Hence this location is not selected for routine monitoring. |
| B3PB50 | B3G041/  Vial Filling Room | Near return air raiser (EN- BMU-0003/RG/07) | B | YES | L4PB19 | During aseptic filling of product solution, personnel involves in various filling interventions, operation of filling and stoppering stations through HMI’s and movement of personnel to vial sealing room-II for online sealing activities and thus increases the personnel movement in this room. The required accessories for filling and movement of stoppered vials from filling room to sealing for sealing occurs in this room and thus increases the material movement in this room. This location is besides door entry of filling room. This location is selected for routine monitoring considering the man/material movement and to monitor the air quality in this room. Monitoring at this location determines the contamination due to man/material movement. |
| B3PB51 | B3G041/  Vial Filling Room | Near return air raiser (EN- BMU-0003/RG/08) | B | NO | NA | This location is at the return air raiser opposite to stopper addition. There were no recoveries obtained during area PQ and no excursions were reported during the monitoring period. Monitoring by settle plate is proposed at Near return air raiser (EN- BMU-0003/RG/07) by volumetric air sampling at In-front of door of filling room and middle of the room which are near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB52 | B3G041/  Vial Filling Room | Near return air raiser (EN- BMU-0003/RG/09) | B | NO | NA | This location is at the return air raiser and is near to the stopper loading station. There were no excursions were reported during the monitoring period. Monitoring by settle plate is proposed at Near return air raiser (EN- BMU-0003/RG/07) by volumetric air sampling at In-front of door of filling room and middle of the room which are near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB53 | B3G041/  Vial Filling Room | Near return air raiser (EN- AHU-0012/RG/02) | B | YES | L4PB20 | This location is at the return air raiser opposite to filling station. Based on the recoveries obtained during area PQ, and the documentation activities performed near this location, this location is considered for routine monitoring. |
| B3PB54 | B3G041/  Vial Filling Room | Near return air raiser (EN- AHU-0012/RG/01) | B | NO | NA | This location is at the return air raiser opposite to vial in-feed turn table and towards corner of the room. Recoveries were observed at this location due to documentation activities being performed this location. However, considering the worst case locations of the room, monitoring by settle plate is proposed at Near return air raiser (EN- BMU-0003/RG/02) and by volumetric air sampling at In-front of door of filling room and middle of the room which are near to this location and near to door entry to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB55 | B3G041/  Vial Filling Room | Near return air raiser (EN- BMU-0003/RG/06) | B | NO | NA | This location is at the return air raiser near to door of filling room (right side). There were no recoveries obtained during area PQ and no excursions were reported during the monitoring period. Monitoring by settle plate is proposed at Near return air raiser (EN- BMU-0003/RG/05) and by volumetric air sampling at In-front of door of filling room and middle of the room which are which determines the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB56 | B3G041/  Vial Filling Room | Near return air raiser (EN- BMU-0003/RG/05) | B | YES | L4PB21 | This location is at the return air raiser. Man/material movement towards sealing room-II occurs through this path. This location is adjacent to door entry. Based on the recoveries obtained at this location and considering the man/material movement near this location, it is proposed to select this location for routine monitoring. |
| B3PB57 | B3G041/  Vial Filling Room | Near return air raiser (EN- BMU-0003/RG/04) | B | NO | NA | This location is at the return air raiser. towards sealing room-II. There were no recoveries obtained during area PQ and no excursions were reported during the monitoring period. Monitoring by settle plate is proposed at Near return air raiser (EN- BMU-0003/RG/05) and by volumetric air sampling at In-front of door of filling room and middle of the room which are which determines the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB58 | B3G041/  Vial Filling Room | Near return air raiser (EN- BMU-0003/RG/03) | B | NO | NA | This location is at the return air raiser near to swing conveyer toward lyo loading and unloading room. There were no recoveries obtained during area PQ and no excursions were reported during the monitoring period. Monitoring by settle plate is proposed at Near return air raiser (EN- BMU-0003/RG/05) and by volumetric air sampling at In-front of door of filling room and middle of the room which are which determines the contamination due to man/material movement and to monitor the air quality in this room. Hence, this location is not selected for routine monitoring. |
| B3PB59 | B3G041/  Vial Filling Room | Near return air raiser (EN- BMU-0003/RG/02) | B | YES | L4PB22 | This location is at the return air raiser opposite to swing conveyer towards back side of filling LAF. This location is selected for routine monitoring considering the recoveries obtained during the monitoring period, to determine the contamination due man/material movement and to monitor the air quality in this room. |
| B3PB60 | B3G041/  Vial Filling Room | Near return air raiser (EN- BMU-0003/RG/01) | B | YES | L4PB23 | This location is at the return air raiser at the corner of the room towards back side of filling LAF. This location is selected for routine monitoring considering the recoveries obtained during the monitoring period, to determine the contamination due man/material movement and to monitor the air quality in this room. |
| B3PB61 | B3G042/  Vial Sealing Room-II | Near return air raiser (EN- BMU-0004/RG/05) | B | YES | L4PB24 | After completion of filling process, stoppered vials are sealed under LAF. The movement of the personnel while performing sealing activities and transferring of sealed vials is high and thus increases the men and material movement in this room.  This location is at the return air raiser towards right side corner of the room. This location is selected for routine monitoring considering the recoveries obtained during the monitoring period, to determine the contamination due man/material movement and to monitor the air quality in this room. |
| B3PB62 | B3G042/  Vial Sealing Room-II | Near return air raiser (EN- BMU-0004/RG/04) | B | NO | NA | This location is at the return air raiser. There were no recoveries obtained during area PQ and no excursions were reported during the monitoring period. Monitoring by settle plate is proposed at Near return air raiser (EN- BMU-0004/RG/05) and by volumetric air sampling at middle of the room which are near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence this location is not selected for routine monitoring. |
| B3PB63 | B3G042/  Vial Sealing Room-II | Near return air raiser (EN- AHU-0013/RG/02) | B | NO | NA | This location is at the return air raiser near to mouse hole between sealing room-2 and vial collection room-2. There were no recoveries obtained during area PQ and no excursions were reported during the monitoring period. Monitoring by volumetric air sampling is proposed at middle of the room which is near to this location to determine the contamination due to man/material movement and to monitor the air quality in this room. Hence this location is not selected for routine monitoring. |
| B3PB64 | B3G042/  Vial Sealing Room-II | Near return air raiser (EN- BMU-0004/RG/01) | B | NO | NA | This location is at the return air raiser towards left side corner of the room near to sealing infeed conveyer operating side. There were no excursions observed in this location during monitoring period. Viable monitoring by settle plate method is proposed at Near return air raiser (EN- BMU-0004/RG/03) which is near to this location and any man / material movement to this location shall pass through the selected settle plate location which effectively demonstrates the contamination due to man/material movement. Hence, this location is not considered for routine monitoring. |
| B3PB65 | B3G042/  Vial Sealing Room-II | Near return air raiser (EN- BMU-0004/RG/02) | B | NO | NA | This location is at the return air raiser opposite to sealing station. There were no recoveries obtained during monitoring period and no excursions were reported during the monitoring period. Viable monitoring by settle plate method is proposed at Near return air raiser (EN- BMU-0004/RG/03) which is near to this location and any man / material movement to this location shall pass through the selected settle plate location which effectively demonstrates the contamination due to man/material movement. Hence, this location is not considered for routine monitoring. |
| B3PB66 | B3G042/  Vial Sealing Room-II | Near return air raiser (EN- BMU-0004/RG/03) | B | YES | L4PB25 | This location is at the return air raiser. Man movement occurs through this path for operation of sealing machine. This location is selected for routine monitoring considering the recoveries obtained during the area PQ monitoring, to determine the contamination due man/material movement and to monitor the air quality in this room.. |
| B3PB67 | B3G045/  Change Room-IV | Near return air raiser (EN- AHU-0009/RG/17) | B | NO | NA | Personnel exiting the aseptic area moves through the change room-IV to change Room-V. Exit monitoring of the personnel exiting the aseptic area occurs in this room.  There were no recoveries obtained during area PQ monitoring and no excursions were reported during the monitoring period. Monitoring by settle plate is proposed Near return air raiser (EN- AHU-0009/RG/16) and by volumetric air sampling at middle of the room to monitor the air quality in this room and to determine the contamination due to man/material movement and hence this location is not selected for routine monitoring. |
| B3PB68 | B3G045/  Change Room-IV | Near return air raiser (EN- AHU-0009/RG/16) | B | YES | L4PB26 | This location is at the return air raiser in-front of door towards change Room-V. This location is selected for routine monitoring considering the recoveries obtained during the monitoring period to determine the contamination due to man/material movement and to monitor the air quality in this room. |
| B3PB69 | B3G045/  Change Room-IV | Near return air raiser (EN- AHU-0009/RG/18) | B | NO | NA | This location is at the return air raiser near to door towards change Room-V. There were no recoveries obtained during area PQ monitoring and no excursions were reported during the monitoring period. Monitoring by settle plate is proposed Near return air raiser (EN- AHU-0009/RG/16) and by volumetric air sampling at middle of the room to monitor the air quality in this room and to determine the contamination due to man/material movement and hence this location is not selected for routine monitoring. |
| B3PC45 | B3G046/  Change Room-V | Near return air raiser (EN- AHU-0008/RG/04) | C | NO | NA | Personnel exiting from the aseptic area and remove the sterile area garments in this room. This location is at the return air raiser near to door between change room-IV and change room-V. Monitoring by settle plate is proposed Near return air raiser (EN- AHU-0008/RG/05) and by volumetric air sampling at middle of the room to monitor the air quality in this room and to determine the contamination due to man/material movement and hence this location is not selected for routine monitoring. |
| B3PC46 | B3G046/  Change Room-V | Near return air raiser (EN- AHU-0008/RG/05) | C | YES | L4PC2 | This location is at the return air raiser near to door towards change room-I. This location is selected for routine monitoring considering the recoveries obtained during the PQ of area and in monitoring period. Monitoring at this location determines the quality of air and the contamination due to man movement and hence this location is selected for monitoring. |

| **FILLING AREA** |
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| **SETTLE PLATE MONITORING- GRADE-A** |

| **Location ID** | **Room ID** | **Description** | **Grade** | **Selected for routine monitoring** | **Proposed Location ID** | **Rationale** |
| --- | --- | --- | --- | --- | --- | --- |
| B3PA1 | B3G041/Vial Filling room | In-feed turn table (Operating side) | A | YES | L4PA1 | Empty vials after vial washing and depyrogenation are moved from tunnel to in-feed turn table. Personnel intervention is required for clearing any jammed condition and removing the fallen vials. Monitoring in this location demonstrates the air quality and hence selected for routine monitoring. |
| B3PA2 | B3G041/Vial Filling room | In front of the filling nozzle (In between the weighing loading cells (Tare weight & gross weight) (Operating side) | A | YES | L4PA2 | Filling of product solution in to vials occurs in this location and there is personnel intervention for removal of jammed vials, centering the filling nozzle, filled vials are exposed to environment and under continuous movement, product solution is also exposed. Monitoring in this location demonstrates the air quality and hence selected for routine monitoring |
| B3PA3 | B3G041/Vial Filling room | Near to the Stopper bowl | A | YES | L4PA3 | Filled vials are stoppered (fully/ partially) in this location and personnel intervention is required for addition of sterile stoppers to stopper bowl, replenishing the Vibratory bowl with stoppers and clearing the stopper jams in the rubber stopper chute. Monitoring in this location demonstrates the air quality and hence selected for routine monitoring |
| B3PA4 | B3G041/Vial Filling room | Outfeed conveyor near to rejection station (Non-Operating side) | A | YES | L4PA4 | This is the conveyor where the stoppered / half stoppered vials moved from stoppering station and are exposed to the environment. Personnel intervention is required for clearing any jammed condition. Monitoring in this location demonstrates the air quality and hence selected for routine monitoring |
| B3PA5 | B3G041/Vial Filling room | Near to the NT-2 Disk wheel (NT-2 Conveyor) (operating side) | A | YES | L4PA5 | All stoppered / half stoppered vials are exposed to the environment in this zone. Monitoring in this location demonstrates the air quality and hence selected for routine monitoring. |
| B3PA6 | B3G041/Vial Filling room | Near to the NT-5 swing conveyor (Before ALUS In-feed conveyor) | A | YES | L4PA6 | There is personnel movement at this location as the operator moves through the conveyor. All stoppered / half stoppered vials are exposed to the environment. Monitoring in this location demonstrates the air quality and hence selected for routine monitoring. |
| B3PA7 | B3G044/Vial Capping Machine-I | Near to capping machine-I | A | YES | L4PA7 | Lyophilized and full-stoppered vials are sealed in this zone. Interventions such as clearing of any jams, Star wheel adjustment, rejects removal occurs in this zone. Monitoring in this location demonstrates the air quality and hence selected for routine monitoring. |
| B3PA8 | B3G043/Lyo Loading and Unloading Room | Near to the ALUS In-feed conveyor | A | YES | L4PA8 | Product filled and half-stoppered vials are transferred to loading station of lyophilizer and are exposed to environment. Personnel intervention is required for clearing any jammed vials. Monitoring in this location demonstrates the air quality and hence selected for routine monitoring. |
| B3PA9 | B3G043/Lyo Loading and Unloading Room | In-front of ALUS-1 slot door (Near to the star wheel) in loading side | A | YES | L4PA9 | Product filled vials are loaded (half-stoppered) and unloaded (full stoppered) to and from the lyophilizer in this zone. Personnel intervention is required for removal of fallen vials, loading & unloading activities. Monitoring in this location demonstrates the air quality and hence selected for routine monitoring. |
| B3PA10 | B3G043/Lyo Loading and Unloading Room | In-front of ALUS-2 slot door (Near to the star wheel) in loading side | A | YES | L4PA10 | Product filled vials are loaded (half-stoppered) and unloaded (full stoppered) to and from the lyophilizer in this zone. Personnel intervention is required for removal of fallen vials, loading & unloading activities. Monitoring in this location demonstrates the air quality and hence selected for routine monitoring. |
| B3PA11 | B3G043/Lyo Loading and Unloading Room | Near to the ALUS Out feed turn table | A | YES | L4PA11 | Lyophilized product vials are transferred to capping station through this turn table and personnel intervention is required for clearing any jammed vials. Monitoring in this location demonstrates the air quality and hence selected for routine monitoring. |
| B3PA12 | B3G042/ Vial Capping Machine-II | Near to the Capping machine-II | A | YES | L4PA12 | Capping of Lyophilized product vials occurs in this zone and personnel intervention is required to clear any fallen vials. Monitoring in this location demonstrates the air quality and hence selected for routine monitoring. |

| **FILLING AREA** |
| --- |
| **VOLUMETRIC AIR SAMPLING** |

| **Location ID** | **Room ID** | **Description** | **Grade** | **Selected for routine monitoring** | **Proposed Location ID** | **Rationale** |
| --- | --- | --- | --- | --- | --- | --- |
| B3AD5 | B3G033/  Change Room-I | Middle of the room | D | YES | L4AD1 | This is room is adjacent to the controlled unclassified area and serves as a common change room for entry and exit of aseptic processing area. The personnel entering into the aseptic area removes the factory foot wear, wears the sterilized booties in this room and enters into change room-II.  The personnel exiting the aseptic processing area disposes off the removed sterile garments in the bin located in this room and wears the factory foot wear. Monitoring in this location determines the air quality in the room and contamination due to man/material movement and hence considered for routine monitoring. |
| B3AC21 | B3G034/  Change room-II | Middle of the room (before cross over bench) | C | YES | L4AC1 | This room is next to the change Room-I and the person entering into aseptic processing area wears the sterile primary garments and moves to change room-III.  Monitoring in this location determines the air quality in the room and contamination due to man/material movement. and hence considered for routine monitoring. |
| B3AB1 | B3G035/  Change room-III | Middle of the room (before cross over bench) | B | YES | L4AB1 | The person enters into this room with sterile primary garment. In this room, the person takes the sterile secondary garment form the garment cubicle, wears the garment and moves to the aseptic processing area for performing relevant activities.  Monitoring in this location determines the air quality in the room and contamination due to man/material movement and hence considered for routine monitoring. |
| B3AB2 | B3G036/  Buffer Room | Middle of the room | B | YES | L4AB2 | The personnel after wearing sterile secondary garments enters into this room and moves into APA corridor. The microbiology accessories used for monitoring are held under the ceiling suspended LAF in this room where activities such as inspection, labelling of unused plates and wrapping of sampled plates occur. This room is frequently accessed by man to perform activities.  Monitoring in this location determines the air quality in the room and contamination due to man/material movement. |
| B3AB3 | B3G036/  Buffer Room | Middle of the ceiling suspended LAF  (PF-LAF-4009) | B | YES | L4AB3 | The Ceiling suspended LAF is used for holding and labelling of viable environmental monitoring accessories. Monitoring in this location determines the air quality under the LAF and practices of the personnel working under the LAF and hence considered for routine monitoring. |
| B3AB4 | B3G037/APA corridor | Middle of the corridor (In between the change room-IV & Cool zone) | B | YES | L4AB4 | APA corridor is the common area for all the personnel who enters in to the different areas of the aseptic area like filtration room, filling room, sealing room and Lyo loading and unloading areas. The movement of men and material movement through this room is high. Monitoring in this location determines the air quality in the room and contamination due to man/material movement and hence considered for routine monitoring. |
| B3AB5 | B3G037/APA corridor | In-front of Filling room (In-between Lyo Loading & Unloading room(Room No.: B3G043) and Filtration room (Room No.: B3G040) | B | YES | L4AB5 | The Movement of the personnel into and out of the filling area occurs through this room, this monitoring location is located In-front of Filling room, In-between Lyo Loading & Unloading room and Filtration room. Viable particulate generation will be more due to the frequent opening and closing of the entry door for personnel movement. Monitoring in this location determines the air quality in the room and contamination due to man/material movement and hence considered for routine monitoring. |
| B3AB6 | B3G037/APA corridor | Inside the Garment Cubicle (Middle) (ID. No.: PF-GCU-4001) | B | YES | L4AB6 | Sterilized secondary garments are held in this garment cubicle. The personnel operate the garment cubicle to access the garments for wearing and placing of sterilized garments. This location is selected for monitoring to monitor the quality of the air inside the garment cubicle and the practices of personnel and hence considered for routine monitoring. |
| B3AB7 | B3G038/Cool Zone | In-front of the unloading LAF | B | NO | NA | The sterilized articles are unloaded and stored under the unloading LAF. The sanitized accessories are transferred through the passbox between cool zone and autoclave room. Even though recoveries were observed in this location during monitoring and PQ, there were no excursions observed in this locations. Volumetric air sampling location is proposed at the middle of the room infront of parts storage LAF to monitor the quality of the air and the practices of personnel which is near to this location. Hence, this location is not selected for routine monitoring. |
| B3AB8 | B3G038/Cool Zone | In-front of the Parts storage LAF | B | YES | L4AB7  (middle of the cool zone) | The sterilized articles are unloaded and stored under part storage LAF’s in this room. The sanitized accessories are transferred through the passbox between cool zone and autoclave room. Man/material movement is high and frequent in this room.  As this location is in the middle of the room in-front of parts storage LAF. This location is selected to monitor the quality of air and to assess the practices of personnel working in the room and hence considered for routine monitoring. |
| B3AB9 | B3G038/Cool Zone | Middle of the Dynamic pass box (ID No.: PF-DPB-4002) | B | YES | L4AB8 | The Dynamic pass box is located between cool zone and Autoclave room. The pass box is used for transfer of articles into and out of the aseptic processing area. Monitoring of the pass box determines the contamination due to article transfer and the air quality insides the dynamic passbox and hence considered for routine monitoring. |
| B3AB10 | B3G038/Cool Zone | Under cool zone unloading LAF (Right side middle of the LAF) | B | NO | NA | The sterilized articles used during the product manufacturing process are unloaded and transferred to mobile LAF under this LAF. This location is under the ceiling suspended LAF. This location is at the right side middle of the LAF. There were no recoveries obtained for this location during the monitoring period and no excursions were reported. Monitoring by settle plate is proposed at location front left corner and right corner towards autoclave and by volumetric air sampling at location middle of the LAF to monitor the quality of air under this LAF. Hence, this location is not selected for routine monitoring. |
| B3AB11 | B3G038/Cool Zone | Under cool zone unloading LAF (Middle of the LAF) | B | YES | L4AB9 | This location is in the middle of the LAF. There were no recoveries obtained for this location during the area PQ monitoring and no excursions were reported. Monitoring at this location determines the quality of air under the LAF and demonstrates the practices of the personnel working under the LAF. |
| B3AB12 | B3G038/Cool Zone | Under cool zone unloading LAF (Left side middle of the LAF) | B | NO | NA | This location is at the left side middle of the LAF and is considered for routine monitoring considering the recoveries obtained during the monitoring period. settle plate is proposed at location front left corner and right corner towards autoclave and by volumetric air sampling at location middle of the LAF to monitor the quality of air under this LAF. Hence, this location is not selected for routine monitoring. |
| B3AB13 | B3G038/Cool Zone | Under cool zone Parts Storage LAF (Right side middle of the LAF) | B | NO | NA | The sterilized articles used during the product manufacturing process are transferred in mobile LAF and are stored under this LAF. There were no excursions observed in this location during monitoring period Monitoring by settle plate is proposed at location front left corner and back right corner of the LAF and by volumetric air sampling at middle of the LAF to monitor the quality of air under this LAF. Hence, this location is not selected for routine monitoring. |
| B3AB14 | B3G038/Cool Zone | Under cool zone Parts Storage LAF (Middle of the LAF) | B | YES | L4AB10 | This location is at the middle of the LAF. There were no recoveries obtained for this location during the area PQ monitoring and no excursions were reported. This location is under the ceiling suspended LAF and is selected for routine monitoring considering the recoveries obtained during area PQ, to monitor the air quality and to determine the practices of the personnel working under this LAF. |
| B3AB15 | B3G038/Cool Zone | Under cool zone Parts Storage LAF (Left side middle of the LAF) | B | NO | NA | This location is at the left side middle of the LAF. There were no recoveries obtained for this location during the area PQ monitoring and no excursions were reported. Monitoring by settle plate is proposed at location front left corner and back right corner of the LAF and by volumetric air sampling at middle of the LAF to monitor the quality of air under this LAF. Hence, this location is not selected for routine monitoring. |
| B3AB16 | B3G039/  Air Lock | Middle of the room | B | YES | L4AB11 | This air lock is used for the transferring of used machine parts and other materials to parts washing room through the dynamic pass box located in this room. Man/material movement is frequent in this room. Monitoring in this location determines the air quality in the room and contamination due to man/material movement and hence considered for routine monitoring. |
| B3AB17 | B3G039/  Air Lock | Middle of the Dynamic pass box (ID No.: PF-DPB-4003) | B | YES | L4AB12 | Dynamic pass box is used to transfer of used articles to parts washing room. Monitoring of the pass box determines the contamination due to article transfer and also the air quality of the pass box and hence considered for routine monitoring. |
| B3AB18 | B3G040/  Filtration Room | Middle of the room | B | YES | L4AB13 | After completion of compounding, the product is transferred to this room through the product transfer lines. Primary filtration of the product occurs in this room and the filtered product is held in the filtration vessels under ceiling suspended LAF for further processing. The activities are performed in closed conditions in this room. The man movement is frequent in this room. Manual activities such as connections for filtration and sampling of bulk solution occurs in this room.  This location is in the middle of the room and is selected for monitoring to determine the quality of air and contamination due to man/material movement and hence considered for routine monitoring. |
| B3AB19 | B3G040/  Filtration Room | Under the ceiling suspended LAF (In between the 500 Ltrs & 200 Ltrs Filtration vessel) | B | YES | L4AB14 | This LAF is used for filtration activity of bulk solution and the personnel intervention is required during preparatory works like connection, removal / fixing of filters & clamps and sampling of bulk solution. The activities occur in closed condition under this LAF. The Filtered bulk solution is held in filtration vessels under this LAF in closed condition. This location is in the front middle of the LAF and is selected for monitoring to determine the quality of air and contamination due to man/material movement. Hence considered for routine monitoring. |
| B3AB20 | B3G040/  Filtration Room | Middle of the ceiling suspended LAF (ID No.: PF-LAF-4007) | B | YES | L4AB15 | This LAF shall be used for storage of articles, which are used for filtration. This location is selected to monitor the quality of air and to determine contamination due to man/material movement and hence considered for routine monitoring. |
| B3AB21 | B3G044/  Vial Sealing Room-I | Middle of the room (Near to the HMI) | B | YES | L4AB16 | After completion of lyophilization process, lyophilized product vials are sealed under LAF in this room. The movement of the personnel for performing sealing activities, transferring and loading of seals and sealed vials occurs in this room.  This location is in the middle of the room and is selected to monitor the quality of air and to determine contamination due to man/material movement. Hence considered for routine monitoring. |
| B3AB22 | B3G044/  Vial Sealing Room-I | Under the Extended LAF – In-front of capping station | B | YES | L4AB17 | Personnel intervention is required to clear the jammed vials, Star wheel adjustment, samples collection & rejects removal.  Monitoring in this location determines the air quality in the room and contamination due to man/material movement. Hence considered for routine monitoring. |
| B3AB23 | B3G044/  Vial Sealing Room-I | Under the Extended LAF – In-front of sealing bowl | B | NO | NA | Personnel intervention is required to replenish the Vibratory bowl with seals. The product filled vial are fully stoppered in this room and are not exposed to the room environment. No critical activities which might impact the product quality occurs at this zone. There were no recoveries obtained for this location during the area PQ and hence this location is not selected for routine monitoring. |
| B3AB48 | B3G044/  Vial Sealing Room-I | Under the extended LAF near to seals loading | B | YES | L4AB18 | This location is selected to monitor the quality of air under the LAF and to determine the contamination due to man/material movement. Hence this location is selected for routine monitoring. |
| B3AB49 | B3G044/  Vial Sealing Room-I | Under the extended LAF near to in-feed conveyer | B | NO | NA | This location is under the extended LAF near to in-feed conveyer. The product filled vial are fully stoppered in this room and are not exposed to the room environment. No critical activities which might impact the product quality occurs at this zone and hence this location is not selected for routine monitoring. |
| B3AB24 | B3G043/  Lyo Loading & Unloading Room | Near to the ALUS HMI (ID No.: PF-ALU-4001) and in-front of ALUS-I Loading side | B | YES | L4AB19 | Loading of half-stopered vials for lyophilization and unloading of lyophilized products for sealing activity occurs in this room. Personnel activities such as operation of ALUS systems and Lyophilizer HMI’s occurs in this room.  This location is near to ALUS HMI where there is movement of personnel for operation of ALUS and Lyophilizer. Monitoring at this location determines the air quality in the room and contamination due to man/material movement, hence this location is selected for routine monitoring. |
| B3AB25 | B3G043/  Lyo Loading & Unloading Room | Near to the ALUS Pusher unit and Beside ALUS-2 HMI (ID No.: PF-ALU-4002) | B | YES | L4AB20 | This location is near to ALUS HMI where there is movement of personnel for operation of ALUS and Lyophilizer. Monitoring at this location determines the air quality in the room and contamination due to man/material movement, hence this location is selected for routine monitoring. |
| B3AB26 | B3G043/  Lyo Loading & Unloading Room | Under the Extended LAF, near ALUS Infeed conveyor | B | YES | L4AB21 | This location is selected to monitor the air quality under the LAF and contamination due to man/material movement and hence selected for routine monitoring. |
| B3AB27 | B3G043/  Lyo Loading & Unloading Room | Under the Extended LAF - In front of Lyophilizer-1 | B | NO | NA | This location is in front of lyophilizer-1, activities such as assembling and manual interventions occurs at this zone. There were no recoveries obtained during the monitoring period and no excursions were reported for this location. Man/material movement is minimal at this location and monitoring by volumetric air sampling is proposed Under the Extended LAF - In front of Lyophilizer-2 which is centre of the extended LAF and the movement of man is minimal at this location and the critical zone (Grade-A) is continuously monitored by settle plate monitoring to determine the contamination due to activities performed by the personnel. There were no recoveries obtained during the area PQ and no excursions were reported for this location and hence this location is not selected for routine monitoring, hence this location is not selected for routine monitoring. |
| B3AB28 | B3G043/  Lyo Loading & Unloading Room | Under the Extended LAF - In front of Lyophilizer-2 | B | YES | L4AB22 | This location is in front of lyophilizer-2, activities such as assembling and manual interventions occurs at this zone. The movement of man is minimal at this location and the critical zone (Grade-A) is continuously monitored by settle plate monitoring to determine the contamination due to activities performed by the personnel. As this location is centre of the extended LAF between lyophilizer-1 and 2, monitoring at this location determines the contamination due to any activities performed. Hence, this location is considered for routine monitoring. |
| B3AB29 | B3G043/  Lyo Loading & Unloading Room | Under the Extended LAF - between lyophilizer-2 and outfeed turn table. | B | NO | NA | This location is between lyophilizer-2 and outfeed turn table, manual interventions occurs at this zone. The product filled vials will be in full stoppered condition at this location and the critical zone (Grade-A) at the loading side of Lyophilizer -2 is continuously monitored by settle plate monitoring to determine the contamination due to activities performed by the personnel. No excursions were reported for this location and considering the recoveries obtained during the monitoring period this location is not selected for routine monitoring. |
| B3AB46 | B3G043/  Lyo Loading & Unloading Room | In-front of door of lyo loading and unloading room | B | NO | NA | Man/material movement into and out of the lyo loading and unloading occurs through the door. Monitoring by settle plate proposed near the return air raiser at door entry which is nearer to this location and determines the air quality due to man / material movement. Hence, this location is not considered for routine monitoring. |
| B3AB47 | B3G043/  Lyo Loading & Unloading Room | Under extended LAF, In front of door of ALUS out feed turntable | B | YES | L4AB23 | This location is under the extended LAF of ALUS outfeed turntable and is selected for routine monitoring to monitor the air quality of the extended LAF. |
| B3AB30 | B3G041/  Vial Filling Room | Middle of the room (operating side) between stopper addition and NVPC HMI. | B | YES | L4AB24 | The monitoring location is located near to NVPC HMI. The movement of the personnel near the filling machine/stopper addition were aseptic manipulations are carried out during the filling operation. Monitoring at this location determines the contamination due to movement of personnel and also the air quality of the room, hence this location is selected for routine monitoring. |
| B3AB31 | B3G041/  Vial Filling Room | In-front of door of filling room | B | YES | L4AB25 | The monitoring location is in-front of door of filling room. Man/material movement occurs in this zone. Monitoring at this location determines the contamination due to movement of man/material and also the air quality of the room, hence this location is selected for routine monitoring. |
| B3AB32 | B3G041/  Vial Filling Room | Under the Extended LAF (In-front of filling nozzle station & stoppering station) in operating side | B | YES | L4AB26 | This location is near to filling station under the extended LAF towards operating side. Aseptic manipulations are performed during batch manufacturing near to this location. Monitoring at this location determines the air quality under the LAF and contamination due to movement of personnel, hence this location is selected for routine monitoring. |
| B3AB33 | B3G041/  Vial Filling Room | Under the Extended LAF (In-front of NT-1 Swing conveyor and stoppering station) in operating | B | NO | NA | The monitoring location is Under the Extended LAF (In-front of NT-1 Swing conveyor) towards operating side. There were no excursion reported for this location and monitoring by volumetric air sampling is proposed at In-front of filling nozzle station & stoppering station to monitoring the air quality in the room and to determine the contamination due to man/material movement and hence this location is not selected for routine monitoring. |
| B3AB34 | B3G041/  Vial Filling Room | Under the Extended LAF (In-front of NT-2 disk wheel or In-between the NT-3 Conveyor & NT-5 swing conveyor) | B | YES | L4AB27 | The monitoring location is Under the Extended LAF (In-front of NT-5 Swing conveyor). There is personnel movement at this location as the operator moves towards sealing room to perform the activities. Monitoring at this location determines the air quality under the LAF and contamination due to movement of personnel, hence this location is selected for routine monitoring. |
| B3AB35 | B3G041/  Vial Filling Room | Under the Extended LAF - Near to the SIP & CIP Skid (Back side of the main star wheel) | B | YES | L4AB28 | The monitoring location is located Under the Extended LAF – Near to the SIP & CIP Skid (back side of filling machine). The personnel perform aseptic manipulations during batch manufacturing. This location is selected to determine the contamination due to movement of personnel and the air quality of the LAF, hence this location is selected for routine monitoring. |
| B3AB36 | B3G041/  Vial Filling Room | Under the Extended LAF - Near to the NT-3 Conveyor (Back side of NT-2 Disk wheel or Near to the power cable entry tray) Non-operating side | B | NO | NA | This location is under the extended LAF and near to NT-3 conveyer. There is minimal man activity at this zone. There were no excursions reported at this location and considering the recoveries obtained during the monitoring period, this location is not selected for routine monitoring. |
| B3AB37 | B3G041/  Vial Filling Room | Near to the Control panel of the filling area back side of filling machine. | B | NO | NA | This location is in the middle of the room opposite to operating side of the filling machine. As this location is there at the backside of the filling machine, there were less activities and viable monitoring by settle plate was proposed at Near return air raiser EN- BMU-0003/RG/01 and EN- BMU-0003/RG/02 that determines the contamination due to activities performed. Hence, this location is not considered for routine monitoring. |
| B3AB42 | B3G041/  Vial Filling Room | Under extended LAF Near to stopper addition | B | YES | L4AB29 | Manual interventions are performed by the personnel during stoppering addition which might have an impact on the quality of product. Monitoring at this location determines the quality of air and contamination due to man/material movement, hence selected for routine monitoring. |
| B3AB43 | B3G041/  Vial Filling Room | Under extended LAF Near to outfeed conveyer (non-operating side) | B | NO | NA | This location under the extended LAF near to out feed conveyer. The critical zone (Grade-A) is monitored continuously by settle plate during batch manufacturing activity near to this location. There were no excursion reported for this location and As this location is there at the backside of the filling machine, there were less activities and viable monitoring by settle plate was proposed at Near return air raiser EN- BMU-0003/RG/01 and EN- BMU-0003/RG/02 that determines the contamination due to activities performed. Hence, this location is not considered for routine monitoring. |
| B3AB38 | B3G042/  Vial Sealing Room-II | Middle of the room (In-between the conveyor and seals loading entry) | B | YES | L4AB30 | This location is in the middle of the room and monitoring at this location determines the air quality and covers the Personnel movement in the sealing room, hence this location is selected for routine monitoring. |
| B3AB39 | B3G042/  Vial Sealing Room-II | Under the Extended LAF Near to the capping station | B | YES | L4AB31 | The monitoring location is located under Extended LAF – Near to the capping station. The personnel movement occurs to operate the sealing machine. Monitoring at this location determines the contamination due to movement of personnel and also the air quality of the LAF, hence selected for routine monitoring. |
| B3AB40 | B3G042/  Vial Sealing Room-II | Under the Extended LAF – Near to the HMI of capping machine | B | YES | L4AB32 | The monitoring location is located Under the Extended LAF-Near to the HMI of capping machine. The personnel movement occurs at this location for operation of sealing machine HMI. Monitoring at this location determines the contamination due to movement of personnel and also the air quality of the LAF, hence selected for routine monitoring. |
| B3AB44 | B3G042/  Vial Sealing Room-II | Under the Extended LAF – Near to entry door of vial sealing room-2 | B | NO | NA | This location is under the extended LAF and there is no activities near this location. There were no excursions during the monitoring period. Hence this location is not selected for routine monitoring, |
| B3AB45 | B3G042/  Vial Sealing Room-II | Under the Extended LAF – Near to seals loading | B | NO | NA | The product filled vial are in full stoppered condition in this room and there were no recoveries reported during monitoring period and no excursions were reported for this location. Hence, this location is not selected for monitoring. |
| B3AB41 | B3G045/  Change Room-IV | Middle of the room | B | YES | L4AB33 | Personnel exiting the aseptic area moves through the change room-IV to change room-V. Exit monitoring of the personnel exiting the aseptic area occurs in this room and hence man movement is high in this room.  Monitoring at this location determines the contamination due to movement of personnel, hence selected for routine monitoring. |
| B3AC22 | B3G046/  Change Room-V | Middle of the room | B | YES | L4AC2 | Personnel exiting from the aseptic area disposes off the used sterile area garments in this room. Monitoring at this location determines the contamination due to movement of personnel, hence selected for routine monitoring.. |

| **Filling area** |
| --- |
| **Volumetric air sampling** |

| **Location ID** | **Room ID** | **Description** | **Grade** | **Selected for routine monitoring** | **Proposed Location ID** | **Rationale** |
| --- | --- | --- | --- | --- | --- | --- |
| B3AA1 | B3G041/Vial Filling room | In-feed turn table (Non-Operating side) | A | YES | L4AA1 | The monitoring location is located at In-feed turn table (Non-operating side). This location is selected to monitor the air quality of the critical area, where the dehydrogenated containers are moved from tunnel to the in feed turn table. There is personnel intervention for removing the fallen vials. Hence this location is selected for routine monitoring. |
| B3AA2 | B3G041/Vial Filling room | Near In-feed star wheel (Operating side) | A | YES | L4AA2 | The monitoring location is located Near In-feed star wheel (Operating side) and this location is selected to monitor the air quality of the critical area, where the vials are exposed to the environment before filling, clearing of jams, Star wheel adjustment. Hence this location is selected for routine monitoring. |
| B3AA3 | B3G041/Vial Filling room | In front of the filling nozzle (In between the weighing loading cells( Tare weight & gross weight) (Operating side) | A | YES | L4AA3 | The monitoring location is located In front of the filling nozzle. There is personnel intervention for removal of jammed vials, centering the filling nozzle, and this sites is selected to monitor the air quality of the critical area, where the vials are exposed and under continuous movement, product solution is exposed hence this location is consider as the worst case location for viable monitoring. Hence this location is selected for routine monitoring. |
| B3AA4 | B3G041/Vial Filling room | Near to the Stopper bowl | A | YES | L4AA4 | This location is selected to monitor the air quality of the critical area, where there is Personnel intervention for replenishing the Vibratory bowl with stoppers and clearing the stopper jams in the rubber stopper chute. Hence this location is selected for routine monitoring. |
| B3AA5 | B3G041/Vial Filling room | In-front of stoppering station (non-operating side) | A | YES | L4AA5 | The monitoring location is located at the stoppering station or Near to the Discharge vacuum star wheel (non-operating side), where the stoppered / half stoppered vials moving to the outfeed conveyor and are exposed to the critical environment and clearing of jams, samples collection for fill volume checks & rejects removal performed at rejection station near to the monitoring location of stoppering station. Hence this location is selected for routine monitoring. |
| B3AA6 | B3G041/Vial Filling room | Near to the NT-3 Disk wheel (NT-3 Conveyor) (Non-operating side) | A | NO | NA | The monitoring location is located Near to the NT-3 Disk wheel (non-operating side). Volumetric air sampling in this location shall be performed by introducing air sampler in to the filling line from non-operating side which interferes with the filling process. There are no critical operations performed near this location from non-operating side except interventions caused by microbiological sampling. There were no OOLs observed in this location during routine monitoring period and during PQ. Hence, this location is not considered for routine monitoring. |
| B3AA7 | B3G041/Vial Filling room | Near to the NT-5 swing conveyor (Before ALUS In-feed conveyor) | A | NO | NA | The monitoring location is located Near to the NT-5 swing conveyor (Before ALUS In-feed conveyor). There is no activity performed near this location by the production personnel except the microbiological monitoring. Even though OOLs observed in this location, monitoring by settle plate method in L4PA6 appropriately determines the air quality in this location. Hence, this location is not considered for routine monitoring. |
| B3AA8 | B3G044/Vial Sealing room-I | Near to the capping machine-I | A | YES | L4AA6 | This location is selected to monitor the air quality near the capping machine, where the stoppered product filled vials are exposed to the environment. Hence this location is selected for routine monitoring. |
| B3AA9 | B3G043/ Lyo Loading and Unloading Room | In-front of ALUS-1 Slot door | A | YES | L4AA7 | The monitoring location is In-front of ALUS-1 Slot door (Near to the ALUS-1 Star wheel). The half-stoppered product filled vials are loaded and full stoppered product filled unloaded to and from the Lyophilizer (ALUS-1) in this zone. Hence, this location is selected for routine monitoring. |
| B3AA10 | B3G043/ Lyo Loading and Unloading Room | In-front of ALUS-2 Slot door | A | YES | L4AA8 | The monitoring location is In-front of ALUS-2 Slot door (Near to the ALUS-2 Star wheel). The half-stoppered product filled vials are loaded and full stoppered product filled unloaded to and from the Lyophilizer (ALUS-2) in this zone. Hence this location is selected for routine monitoring. |
| B3AA11 | B3G042/ Vial sealing room-II | Near to the capping machine-II | A | YES | L4AA9 | This location is near the capping machine, where the stoppered product filled vials are exposed to the environment. Hence this location is selected for routine monitoring. |
| B3AA12 | Mobile LAF’s | Middle of the Mobile LAF ( ID. No.: PF-MBL-4001) | A | YES | L4AA10 | Mobile LAF is used for transfer of sterilized articles form cool zone unloading LAF to parts storage LAF and parts storage LAF to filling LAF. Hence this monitoring location is considered as critical to monitor the air quality of the mobile LAF and is selected for routine monitoring. |
| B3AA13 | Mobile LAF’s | Middle of the Mobile LAF  (ID. No.: PF-MBL-4002) | A | YES | L4AA11 | Mobile LAF is used for transfer of sterilized articles form cool zone unloading LAF to parts storage LAF and parts storage LAF to filling LAF. Hence this monitoring location is considered as critical to monitor the air quality of the mobile LAF and is selected for routine monitoring. |
| B3AA14 | Mobile LAF’s | Middle of the Mobile LAF  (ID. No.: PF-MBL-4003) | A | YES | L4AA12 | Mobile LAF is used for transfer of sterilized articles form cool zone unloading LAF to parts storage LAF and parts storage LAF to filling LAF. Hence this monitoring location is considered as critical to monitor the air quality of the mobile LAF and is selected for routine monitoring. |
| B3AA15 | Mobile LAF’s | Middle of the Mobile LAF  (ID. No.: PF-MBL-4004) | A | YES | L4AA13 | Mobile LAF is used for transfer of sterilized articles form cool zone unloading LAF to parts storage LAF and parts storage LAF to filling LAF. Hence this monitoring location is considered as critical to monitor the air quality of the mobile LAF and is selected for routine monitoring. |
| B3AA16 | Mobile LAF’s | Middle of the Mobile LAF  (ID. No.: PF-MBL-4005) | A | YES | L4AA14 | Mobile LAF is used for transfer of sterilized articles form cool zone unloading LAF to parts storage LAF and parts storage LAF to filling LAF. Hence this monitoring location is considered as critical to monitor the air quality of the mobile LAF and is selected for routine monitoring. |

| **WAREHOUSE** |
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| **SETTLE PLATE MONITORING** |

| **Location ID** | **Room ID** | **Description** | **Grade** | **Selected for routine monitoring** | **Proposed Location ID** | **Rationale** |
| --- | --- | --- | --- | --- | --- | --- |
| B3WPD1 | B3G085/  Men Entry for Sampling area | Near return air raiser (EN-AHU-0019/RG/01) | D | YES | B3WHPD1 | Personnel entering into the sampling area removes the factory footwear, wears the garment and crosses over the bench for entry into the sampling area.  This location is at the return air raiser opposite to change room-I entry door, before the cross over bench and is adjacent to controlled unclassified area. The air from the room sweeps through the return air raiser. This location is selected for routine monitoring considering the recoveries obtained during the are PQ to monitor the quality of the air in the room and to determine the contamination due to man movement. |
| B3WPD2 | B3G085/  Men Entry for Sampling area | Near return air raiser (EN-AHU-0019/RG/02) | D | NO | NA | The personnel after crossing over the bench, wears the secondary pair of gloves and enters into sampling area. The sampling location is at the return air raiser opposite to sampling room entry door. No excursions were reported for this location during monitoring period and there was no gowning activity near this location except wearing secondary pair of gloves. Monitoring by settle plate method in location B3WHPD1 and volumetric air sampling is proposed at location B3WHAD1 determines the air quality in this area. Hence, this location is not selected for routine monitoring. |
| B3WPD3 | B3G086/  Sampling Area | Near return air raiser (EN-AHU-0019/RG/03) | D | YES | B3WHPD2 | The location is at the entry door adjacent to change room-I through which man movement occurs. This location is selected for routine monitoring considering the recoveries obtained during the are PQ to monitor the quality of the air in the room and to determine the contamination due to man movement. |
| B3WPD4 | B3G086/  Sampling Area | Near return air raiser (EN-AHU-0019/RG/04) | D | YES | B3WHPD3 | The monitoring location is located at the return air raiser between sampling LAF and dynamic pas box. The articles required for performing activities are transferred through this passbox. This location is selected for routine monitoring considering the recoveries obtained during the are PQ to monitor the quality of the air in the room and to determine the contamination due to man movement. |
| B3WPD5 | B3G086/  Sampling Area | Near return air raiser (EN-AHU-0019/RG/05) | D | NO | NA | This location is near to entry door of wash area and adjacent to sampling LAF where there is movement of man/material. There were no recoveries obtained during the area PQ and monitoring period. No excursions were reported for this location during the monitoring period. Monitoring by volumetric air sampling is proposed at location B3WHAD5 to monitoring the air quality ion this area and hence this location is not selected for routine monitoring. |
| B3WPD6 | B3G086/  Sampling Area | Middle Left side of the RLAF  (ID No.: WH-RLF-0002) | D | YES | B3WHPD4 | This LAF is used for sampling of materials such as drug product, excipients, intermediates.  This location is in the left side middle of the RLAF and is selected for routine monitorng considering the recoveries observed during area PQ, to monitor the air quality and to determine the contamination due to activities carried out under this LAF. |
| B3WPD7 | B3G086/  Sampling Area | Middle Right side of the RLAF  (ID No.: WH-RLF-0002) | D | NO | NA | This location is in the right middle of the LAF. There were no recoveries obtained during the area PQ and monitoring period. No excursions were reported for this location during the monitoring period. Monitoring by volumetric air sampling is proposed at location B3WHAD4 and by settle plate monitoring at location B3WHPD4 to monitor the air quality under this RLAF and hence this location is not selected for routine monitoring. |
| B3WPD8 | B3G087/ Wash for Sampling Area | Near to the Door entry (EN-ILF-0009/RG/01) | D | YES | B3WHPD5 | The articles used during sampling are washed, dried and held in this room. This location is near to entry door of wash area and where there is movement of man/material.  This location is selected for routine monitoring to monitor the quality of the air in the room and to determine the contamination due to man/material movement. |
| B3WPD9 | B3G088/Men Entry for Dispensing area | Near return air raiser (EN-AHU-0020/RG/01) | D | YES | B3WHPD6 | Personnel entering into the dispensing area removes the factory footwear, wears the garment and crosses over the bench for entry into the dispensing area. This location is at the return air raiser, near to entry door, before the cross over bench and is adjacent to controlled unclassified area. This location is selected for routine monitoring considering the recoveries obtained during area PQ and monitoring period to monitor the quality of the air in the room and to determine the contamination due to man movement. |
| B3WPD10 | B3G088/Men Entry for Dispensing area | Near return air raiser (EN-AHU-0020/RG/02) | D | YES | B3WHPD7 | The personnel after crossing over the bench, wears the secondary pair of gloves and enters into dispensing area. The sampling location is at the return air raiser near to dispensing room entry door. This location is selected for routine monitoring considering the recoveries obtained during area PQ and monitoring period to monitor the quality of the air in the room and to determine the contamination due to man movement. |
| B3WPD11 | B3G089/  Dispensing area | Near return air raiser (EN-AHU-0020/RG/03) | D | YES | B3WHPD8 | This location is at the return air raiser beside dispensing entry door through which personnel enters into the room. The air from the room sweeps through the return air raiser. This location is selected for routine monitoring considering the recoveries obtained during area PQ to monitor the quality of the air in the room and to determine the contamination due to man movement. |
| B3WPD12 | B3G089/  Dispensing area | Near return air raiser (EN-AHU-0020/RG/05) | D | YES | B3WHPD9 | This location is at the return air raiser in front of dynamic passbox through which the materials are transferred into and out of dispensing area. The air from the room sweeps through the return air raiser. This location is selected for routine monitoring considering the recoveries obtained during area PQ to monitor the quality of the air in the room and to determine the contamination due to man movement. |
| B3WPD13 | B3G089/  Dispensing area | Near return air raiser (EN-AHU-0020/RG/04) | D | NO | NA | This location is at the return air raiser between dispensing LAF and dynamic pass box (WH-DPB-0008) through which the dispensed materials are transferred to production. There were no recoveries obtained during area PQ and no excursions were reported for this location. Monitoring by volumetric air sampling is proposed at the location B3WHAD11 to monitoring the air quality in this area and hence this location is not selected for routine monitoring. |
| B3WPD14 | B3G089/  Dispensing area | Middle Left side of the RLAF (ID No.: WH-RLF-0001) | D | YES | B3WHPD10 | This LAF is used for dispensing of materials such as drug product, excipients, intermediates.  This location is in the left side middle of the LAF and is selected for routine monitoring considering the maximum count obtained for this location to monitor the air quality and to determine the contamination due to activities carried out under this RLAF. |
| B3WPD15 | B3G089/  Dispensing area | Middle Right side of the RLAF (ID No.: WH-RLF-0001) | D | NO | NA | This location is in the middle right side of the LAF. There were no recoveries obtained during area PQ and no excursions were observed for this location. Monitoring by settle plate is proposed at the location B3WHPD11 and by volumetric air sampling at the location B3WHAD10 to monitor the contamination and to determine the contamination due to activities carried out under this LAF. Hence, this location is not selected for routine monitoring. |
| B3WPD16 | B3G090/ Wash for Dispensing area | Near return air raiser (EN-ILF-0010/RG/01) | D | YES | B3WHPD11 | The monitoring location is at the return air raiser near to entry door of wash area. Washing and drying of articles used in the dispensing activity occurs in this room. This location is selected for routine monitoring to monitor the quality of the air in the room and to determine the contamination due to man movement. |

| **WAREHOUSE** |
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| **VOLUMETRIC AIR SAMPLING** |

| **Location ID** | **Room ID** | **Description** | **Grade** | **Selected for routine monitoring** | **Proposed Location ID** | **Rationale** |
| --- | --- | --- | --- | --- | --- | --- |
| B3WAD1 | B3G085/  Men Entry for Sampling area | Middle of the room before cross over bench | D | YES | B3WHAD1 | Personnel entering into the sampling area removes the factory footwear, wears the garment and crosses over the bench and enters into the sampling area. This location is in the middle of the room before cross over bench. Monitoring at this location determines the quality of air and contamination due to man movement and hence selected for routine monitoring. |
| B3WAD2 | B3G086/  Sampling Area | Middle of the room | D | YES | B3WHAD2 | The articles used for sampling are transferred to this room through the dynamic passbox. Sampling of materials occurs under the RLAF and Man/ Material movement is high in this room. This location is in the middle of the room between entry door of sampling room and RLAF. Monitoring at this location determines the quality of air and contamination due to man/material movement and hence selected for routine monitoring. |
| B3WAD3 | B3G086/  Sampling Area | Middle of the Dynamic pass box (WH-DPB-0006) | D | YES | B3WHAD3 | This passbox is used for transfer of articles form controlled unclassified area to sampling room. Monitoring at this location determines the quality of air inside the dynamic pass.box and hence selected for routine monitoring. |
| B3WAD4 | B3G086/  Sampling Area | Middle Left side of the RLAF (ID No.: WH-RLF-0002) | D | YES | B3WHAD4 | This LAF is used for sampling of materials such as drug product, excipients, intermediates.  This location is in the left side middle of the LAF and is selected for routine monitoring considering the recoveries obtained during the monitoring period to determine the contamination due to activities carried out under this LAF. |
| B3WAD5 | B3G086/  Sampling Area | Middle Right side of the RLAF (ID No.: WH-RLF-0002) | D | NO | NA | This location is in the right side middle of the LAF and there were no recoveries obtained during area PQ and no excursion reported for this location during the monitoring period. Monitoring by volumetric air sampling is proposed at location B3WHAD4 and by settle plate monitoring at location B3WHPD5 to monitor the air quality under this RLAF and hence this location is not selected for routine monitoring. |
| B3WAD15 | B3G086/  Sampling Area | Near entry door of wash area beside sampling LAF | D | YES | B3WHAD5 | This location is near to entry door of wash room. Personnel and material movement occurs at this area. This location is selected to monitoring the quality of air and to determine the contamination due to man/material movement and hence selected for routine monitoring. |
| B3WAD6 | B3G087/ Wash for Sampling Area | Middle of the room | D | YES | B3WHAD6 | The articles used during sampling are washed, dried and held in this room. This location is in the middle of the room and is selected to monitor the air quality and to determine the contamination due to activities carried out in this room and hence selected for routine monitoring. |
| B3WAD7 | B3G088/Men Entry for Dispensing area | Middle of the room before cross over bench | D | YES | B3WHAD7 | Personnel entering into the dispensing area removes the factory footwear, wears the garment and crosses over the bench and enters into the dispensing area. This location is in the middle of the room before cross over bench. Monitoring at this location determines the quality of air and contamination due to man movement and hence selected for routine monitoring. |
| B3WAD8 | B3G089/  Dispensing area | Middle of the Dynamic pass box (WH-DPB-0007) | D | YES | B3WHAD8 | This passbox is used for transfer of articles between unclassified area and dispensing room. Monitoring at this location determines the quality of air inside the dynamic passbox and hence selected for routine monitoring. |
| B3WAD9 | B3G089/  Dispensing area | Middle of the Dynamic pass box (WH-DPB-0008) | D | YES | B3WHAD9 | This passbox is used for transfer of dispensed materials between dispensing room and production. Monitoring at this location determines the quality of air inside the dynamic passbox and hence selected for routine monitoring. |
| B3WAD10 | B3G089/  Dispensing area | Middle Left side of the RLAF (ID No.: WH-RLF-0001) | D | YES | B3WHAD10 | This LAF is used for dispensing of materials such as drug product, excipients, intermediates. This location is in the left side middle of the LAF and is selected for routine monitoring considering the maximum count obtained for this location to monitor the air quality and to determine the contamination due to activities carried out under this RLAF. |
| B3WAD11 | B3G089/  Dispensing area | Middle Right side of the RLAF (ID No.: WH-RLF-0001) | D | NO | NA | This location is in the middle right side of the LAF. There were no recoveries obtained during area PQ and no excursions were observed for this location. Monitoring by settle plate is proposed at at the location B3WHPC11 and by volumetric air sampling at the location B3WHAD10 to monitor the contamination and to determine the contamination due to activities carried out under this LAF, hence this location is not selected for routine monitoring. |
| B3WAD12 | B3G089/  Dispensing area | Middle of the room | D | YES | B3WHAD11 | The articles used for dispensing are transferred to this room through the dynamic passbox. Dispesning of materials occurs under the RLAF and Man/ Material movement is high in this room. This location is in the middle of the room between entry door of dispensing room and RLAF. Monitoring at this location determines the quality of air and contamination due to man/material movement and hence selected for routine monitoring. |
| B3WAD16 | B3G089/  Dispensing area | In-front of dynamic pass box | D | NO | NA | This location is in-front of dynamic passbox between dispensing area and production corridor. Man/material movement occurs at this location and this location is very near to the volumetric air sampling location in the middle of the room. As monitoring by volumetric air sampling at the location B3WHAD11 determines the contamination due to activities carried out under this LAF, this location is not selected for routine monitoring. |
| B3WAD13 | B3G090/ Wash for Dispensing area | Middle of the room | D | YES | B3WHAD12 | The articles used during dispensing are washed, dried and held in this room. This location is in the middle of the room and is selected to monitor the air quality and to determine the contamination due to activities carried out in this room and hence selected for routine monitoring. |
| B3WAD14 | NA | Middle of Mobile LAF | D | YES | B3WHAD13 | The LAF is used for transfer of articles between warehouse areas. This location is in the middle of the LAF and is selected to monitor the air quality of the LAF and hence selected for routine monitoring. |

| **VIAL COLLECTION LAF** |
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| **VOLUMETRIC AIR SAMPLING** |

| **Location ID** | **Room ID** | **Description** | **Grade** | **Selected for routine monitoring** | **Proposed location ID** | **Rationale** |
| --- | --- | --- | --- | --- | --- | --- |
| B3AD6 | B3G048/Vial collection room-1 | Vial collection LAF-I | D | YES | L4AD3 | The product filled and sealed vials are transferred from sealing room to vial collection area. The vial collection room is a controlled and unclassified and the vial collection LAF serves as buffer between sealing room (classified area) and vial collection room. The monitoring is in the middle of the LAF and monitoring at this location determines the quality of air under the LAF. |
| B3AD7 | B3G057/Vial collection room-2 | Vial collection LAF-II | D | YES | L4AD4 |

| **ASEPTIC AREA** |
| --- |
| **SURFACE MONITORING** |

| **Location ID** | **Room ID** | **Description** | **Grade** | **Method of sampling** | **Rationale** |
| --- | --- | --- | --- | --- | --- |
| B3SD1 | B3G033/  Change room-I | On surface of cross over bench towards change room-II | D | Contact plate using RODAC | This is room is adjacent to the controlled unclassified area and serves as a common change room for entry and exit of aseptic processing area. This location is selected for routine monitoring to determine the cleaning and sanitization practices. |
| B3SC29 | B3G034/  Change room-II | On the surface of cross over bench | C | Contact plate using RODAC | Personnel in change room-II performs gowning activity by sitting on the bench. This location is selected for routine monitoring to evaluate the personnel sanitization practices and to determine the effectiveness of cleaning and sanitization process. |
| B3SC30 | B3G034/  Change room-II | On the surface of push plate of door towards change room-III | C | Contact plate using RODAC | Personnel in change room-2 pushes the door using the push plate and enters into change room-III. This location is selected for routine monitoring to monitor the sanitization practices of personnel moving towards the critical areas. |
| B3SB1 | B3G035/  Change room-III | On surface of cross over bench | B | Contact plate using RODAC | The Personnel in change room-III performs gowning activity by sitting on the bench. This location is selected for routine monitoring to monitor the personnel sanitization practices and to determine the effectiveness of cleaning and sanitization process. |
| B3SB2 | B3G035/  Change room-III | On the surface of door handle of garment cubicle (PF-GCU-4001) | B | SWAB | Surface monitoring of the door handle of garment cubicle from the sterile corridor is recommended for routine monitoring to determine the personnel sanitization and cleaning practices of the garment cubicle and hence this location is selected for routine monitoring. |
| B3SB3 | B3G035/  Change room-III | On the surface of Wall | B | Contact plate using RODAC | This location is selected for routine monitoring to evaluate the surface cleanliness of wall, and to demonstrate the cleaning and sanitization practices. |
| B3SB4 | B3G036/  Buffer Room | On the surface of push plate of door towards sterile corridor | B | Contact plate using RODAC | The personnel pushes open the door and enters into sterile corridor to access relevant areas. This location is selected for routine monitoring to demonstrate the cleaning and sanitization practices of the personnel. |
| B3SB5 | B3G036/  Buffer Room | On the surface of SS table under ceiling suspended LAF | B | Contact plate using RODAC | The table is under for holding of environmental monitoring accessories. This location is selected for routine monitoring to demonstrate the cleaning and sanitization practices and determine contamination due to activities performed under this LAF. |
| B3SB6 | B3G037/APA corridor | On the surface of push plate of door towards cool zone | B | Contact plate using RODAC | This location is on the push plate of the door towards cool zone. The surface monitoring of push plate of filling room entry door selected for routine monitoring provides an representation to demonstrate the cleaning and sanitization practices and hence this location is not selected for routine monitoring. |
| B3SB7 | B3G037/APA corridor | On the surface of door handles of garment cubicle (PF-GCU-4001) | B | Swab | The garment cubicle is accessed for placing of sterilized garments. This location is selected for routine monitoring to evaluate the cleaning and sanitization practices. |
| B3SB8 | B3G037/APA corridor | On surface of Garment cubicle lower shelf (PF-GCU-4001) | B | Contact plate using RODAC | The sterilized garments are placed inside garment cubicle for usage. This location is selected for routine monitoring to demonstrate the quality of air and the cleaning and sanitization practices. |
| B3SB9 | B3G037/APA corridor | On the surface of push plate of door towards filling room | B | Contact plate using RODAC | The personnel pushes open the door and enters into filling. The filling room is frequently accessed for performing routine activities and for movement towards sealing room-2 This location is selected for routine monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB10 | B3G038/  Cool Zone | On the surface of Wall (Near entry door) | B | Contact plate using RODAC | This location is on the walls surface in the cool zone room near to entry door. The surface sampling of the wall in the filling room selected for routine monitoring as it provides an representation to determine the cleaning and disinfection practices and hence this location is selected for routine monitoring. |
| B3SB11 | B3G038/  Cool Zone | On outer surface of cool zone unloading LAF Flaps (PF-LAF-4004) | B | Contact plate using RODAC | The location is on the outer surface of flaps of cool zone unloading LAF. The surface monitoring of cool zone parts storage LAF provides a representation to determine the cleaning and disinfection practices and demonstrate the personnel practices and hence it is selected for routine monitoring. This location is selected for routine monitoring to determine the cleaning and disinfection practices and demonstrate the personnel practices. |
| B3SB12 | B3G038/  Cool Zone | On bottom surface of dynamic pass box (Inside) | B | Contact plate using RODAC | The dynamic passbox is used for transfer of articles into an out of aseptic processing area. This location is selected for routine monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB13 | B3G038/  Cool Zone | On surface of cool zone parts storage LAF Flaps (Outside) (PF-LAF-4003) | B | Contact plate using RODAC | This location is on the surface of parts storage LAF. And is selected for routine monitoring considering the recoveries obtained during the monitoring to determine the cleaning and disinfection practices and demonstrate the personnel practices. |
| B3SB14 | Mobile LAF’s | On the surface of Mobile LAF Door handles (PF-MBL-4001) | B | Swab | The door handle mobile LAF’s are frequently accessed by the personnel for placing or removal of sterilized articles. These locations are selected to demonstrate the cleaning and sanitization practices. |
| B3SB15 | On the surface of Mobile LAF Door handles (PF-MBL-4002) | B | Swab |
| B3SB16 | On the surface of Mobile LAF Door handles (PF-MBL-4003) | B | Swab |
| B3SB17 | On the surface of Mobile LAF Door handles (PF-MBL-4004) | B | Swab |
| B3SB18 | On the surface of Mobile LAF Door handles (PF-MBL-4005) | B | Swab |
| B3SB19 | B3G039/  Air Lock | On surface of door handles of dynamic pass box | B | Swab | This dynamic pass box is used for transfer of used articles to parts wash room for washing. The door handle is accessed by personnel for opening and placing of articles inside the dynamic pass box. Considering the activities performed this location is selected for routine monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB20 | B3G039/  Air Lock | On bottom surface of dynamic pass box (Inside) | B | Contact plate using RODAC | This dynamic pass box is used for transfer of used articles to parts wash room for washing. The materials transferred are placed on this surface. This location is selected for monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB21 | B3G040/  Filtration Room | On outer surface of ceiling suspended LAF flaps (ID No.: PF-LAF-4007) | B | Contact plate using RODAC | These locations are selected for routine monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB22 | B3G040/  Filtration Room | surface of wall (Inside filtration ceiling suspended LAF) | B | Contact plate using RODAC |
| B3SB23 | B3G040/  Filtration Room | On surface of filtration vessel (500 Ltrs. FV2) (ID No.: PF-FVL-4002) | B | Contact plate using RODAC | The filtration vessels are used for holding of bulk solution prior to filling. This location is selected for routine monitoring considering the size of the vessel which is difficult to clean and to demonstrate the cleaning and sanitization practices. |
| B3SB24 | B3G040/  Filtration Room | On surface of filtration vessel (200 Ltrs. FV1) (ID No.: PF-FVL-4001) | B | Contact plate using RODAC | This location is on the surface of the 200Ltrs filtration vessel. The filtration vessels are used for holding of bulk solution prior to filling. This location is selected for routine monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB25 | B3G040/  Filtration Room | On surface of filtration vessel IPC (500 Ltrs. FV2) | B | Contact plate using RODAC | The filtration vessel IPC is used for connections and transfer of product for filling. This location is selected for monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB26 | B3G040/  Filtration Room | On surface of filtration vessel IPC (200 Ltrs. FV1) | B | Contact plate using RODAC | This location is on the surface of the 200Ltrs filtration vessel. The filtration vessels are used for holding of bulk solution prior to filling. This location is selected for routine monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB27 | B3G044/  Vial Sealing Room-1 | On the surface of handle of door towards APA corridor. | B | Swab | The personnel pulls open the door to enter into sterile corridor. This location is selected for routine monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB28 | B3G044/  Vial Sealing Room-1 | On the surface of vial capping machine-I HMI | B | Contact plate using RODAC | The HMI of vial capping machine is accessed frequently during batch manufacturing activity. This location is selected for routine monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB29 | B3G044/  Vial Sealing Room-1 | On Surface of door handles in-front of seals loading (Under extended LAF) | B | Swab | The door infront of seals loading is accessed frequently during batch manufacturing activity for addition of seals. This location is selected for routine monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB30 | B3G043/  Lyoloading and unloading room | On the surface of Wall (Near entry door) | B | Contact plate using RODAC | This location is on the wall surface near to entry door. The surface sampling of the wall in the filling room selected for routine monitoring provides an representation to determine the cleaning and disinfection practices and hence this location is selected for routine monitoring. |
| B3SB31 | B3G043/  Lyoloading and unloading room | On the surface of ALUS-1 HMI | B | Contact plate using RODAC | The surface sampling of the HMI is selected for routine monitoring as it provides a representation to determine the cleaning and disinfection practices and hence this location is selected for routine monitoring. |
| B3SB32 | B3G043/  Lyoloading and unloading room | On the surface of Lyo-1 HMI | B | Contact plate using RODAC |
| B3SB33 | B3G043/  Lyoloading and unloading room | On the surface of ALUS-2 HMI | B | Contact plate using RODAC |
| B3SB34 | B3G043/  Lyoloading and unloading room | On the surface of Lyo-2 HMI | B | Contact plate using RODAC |
| B3SB35 | B3G043/  Lyoloading and unloading room | On surface of online NVPC HMI | B | Contact plate using RODAC |
| B3SB36 | B3G041/  Vial Filling Room | On the surface of Wall (Near entry door) | B | Contact plate using RODAC | This location is selected for monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB37 | B3G041/  Vial Filling Room | On surface of Balance touch screen | B | Contact plate using RODAC | The balance is used for checking of fill volume during batch manufacturing. This location is selected for monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB38 | B3G041/  Vial Filling Room | On surface of online NVPC HMI | B | Contact plate using RODAC | The HMI of filling machine and NVPC are accessed frequently during batch manufacturing activity. These locations are selected for monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB39 | B3G041/  Vial Filling Room | On surface of Filling machine HMI | B | Contact plate using RODAC |
| B3SB40 | B3G041/  Vial Filling Room | On surface of door knobs of filling cabinet (in front of filling nozzles) | B | Swab | The door infront of filling station is accessed frequently during batch manufacturing activity for performing interventions. This location is selected for monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB41 | B3G041/  Vial Filling Room | On surface of door knobs in front of filling nozzles (under extended LAF) | B | Swab |
| B3SB42 | B3G041/  Vial Filling Room | On surface of clean room telephone | B | Contact plate using RODAC | The clean room telephone is used for communication with the personnel in other areas and is accessed frequently. This location is selected for monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB43 | B3G041/  Vial Filling Room | On surface of SS trolley handle | B | Swab | The SS trolley is used for holding and transfer of accessories during routine and batch manufacturing activity. This location is selected for routine monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB44 | B3G042/  Sealing Room-2 | On Surface of door handles in-front of seals loading (Under extended LAF) | B | Swab | The door infront of seals loading is accessed frequently during batch manufacturing activity for addition of seals. This location is selected for routine monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB45 | B3G042/  Sealing Room-2 | On the surface of vial capping machine-II HMI | B | Contact plate using RODAC | The HMI of vial capping machine is accessed frequently during batch manufacturing activity. This location is selected for routine monitoring to demonstrate the cleaning and sanitization practices. |
| B3SB46 | B3G045/  APA Change Room-IV | On the surface of push plate of door towards sterile corridor | B | Contact plate using RODAC | Personnel monitoring of the personnel exiting the aseptic are occurs in this room. This location is selected for routine monitoring to monitor the cleaning and sanitization practices of the personnel coming back into the aseptic area for performing relevant activities. |
| B3SB47 | B3G045/  APA Change Room-IV | On surface of wall near door towards change room-V | B | Contact plate using RODAC | There were no recoveries obtained during the monitoring period and no excursions were reported for this location. The surface sampling of the wall in the filling room selected for routine monitoring provides an representation to determine the cleaning and disinfection practices and hence this location is not selected for routine monitoring. |
| B3SC31 | B3G046/  APA Change Room-V | On the surface of return air raiser grill (EN- AHU-0008/RG/04) | C | Contact plate using RODAC | This location is selected for routine monitoring to demonstrate the cleaning and disinfection practices. |

| **SURFACE MONITORING- GRADE-A** |
| --- |

| **Location ID** | **Room ID** | **Description** | **Grade** | **Method of sampling** | **Rationale** |
| --- | --- | --- | --- | --- | --- |
| B3SA1 | B3G041/  Vial Filling Room | On Surface of In-feed turn table | A | Contact plate using RODAC | The depyrogenated vials are transferred onto the in-feed turntable and are held prior to filling. This location is in the product filling path and if contaminated may have an impact on the sterility assurance of the product and hence this location is selected for monitoring |
| B3SA2 | On Surface of conveyor near to the filling nozzle | A | Contact plate using RODAC | The conveyer belt lies in the product filling path and is difficult to clean. If contaminated may have an impact on the sterility assurance of the product and hence this location is selected for monitoring. |
| B3SA3 | On Surface of Filling nozzles | A | Swab | The filling nozzles are used for filling of sterile drug product into the vial. The surface monitoring is performed on the outer surface of the nozzles, if contaminated it has an impact on the sterility assurance of the product and hence this location is selected for monitoring. |
| B3SA4 | On Surface of filling nozzles barrier  (Above the filling nozzle) | A | Contact plate using RODAC | This location is selected to determine the cleaning and disinfection practices. |
| B3SA5 | On Surface of Rubber stopper bowl | A | Contact plate using RODAC | The sterilized/sterile rubber stoppers are added into the rubber stopper bowl. The stoppers comes into direct contact with the sterile drug product and if contaminated has an impact on the sterility assurance of the product. This location is selected for monitoring to determine the sterilization effectiveness and demonstrate the practices of the personnel. |
| B3SA6 | B3G041/  Vial Filling Room | On Surface of Rubber stopper chute | A | Swab | The rubber stoppers from the stopper bowl are transferred through the stopper chute for stoppering of product filled vials . The stoppers comes into direct contact with the sterile drug product and if contaminated has an impact on the sterility assurance of the product. This location is selected for monitoring to determine the sterilization effectiveness and demonstrate the practices of the personnel. |
| B3SA7 | On Surface of Forceps near to the Tare weight | A | Swab | These forceps are used to pick the vials for fill volume verification, clearing of rubber stopper jams. These forceps are considered as representative for all forceps present in filling zone (operating side & Non-operating side). If contaminated it may lead to breach in sterility of the product hence considered for sampling. |
| B3SA8 | On Surface of Forceps near to the Gross weight | A | Swab |
| B3SA9 | On Surface of Forceps near to the Rubber stopper bowl | A | Swab |
| B3SA10 | On finger dab surface of glove port glove  (In front of In-feed turn table) | A | Contact plate using 90mm plate | To monitor the Surface cleanliness of Glove port, which are used for the handling of various aseptic manipulation for removing of fallen vials and clearing the jams on the conveyer. |
| B3SA11 | On finger dab surface of glove port glove (In front of In-feed Star wheel) | A | Contact plate using 90mm plate |
| B3SA12 | B3G041/  Vial Filling Room | On finger dab surface of glove port glove (Left side of filling nozzles) | A | Contact plate using 90mm plate | The glove port gloves are used for manual interventions during routine operations by operator. Monitoring of the glove port gloves determines the contamination due to the activity performed. |
| B3SA13 | On finger dab surface of glove port glove (Right side filling nozzles) | A | Contact plate using 90mm plate |
| B3SA14 | On finger dab surface of glove port glove (Left side Rubber stopper bowl) | A | Contact plate using 90mm plate | To monitor the Surface cleanliness of Glove port, which are used for the handling of various aseptic manipulation for adjustment of rubber stoppers and manual interventions. |
| B3SA15 | On finger dab surface of glove port glove (Right side Rubber stopper hopper) | A | Contact plate using 90mm plate |
| B3SA16 | On finger dab surface of glove port glove ( Left side near to the rubber stoppers loading tray) | A | Contact plate using 90mm plate |
| B3SA17 | On finger dab surface of glove port glove( Right side near to the rubber stoppers loading tray) | A | Contact plate using 90mm plate |
| B3SA18 | B3G041/  Vial Filling Room | On finger dab surface of glove port glove( Opposite to the rubber stopper bowl) | A | Contact plate using 90mm plate | To monitor the Surface cleanliness of Glove port, which are used for the handling of various aseptic manipulation for adjustment of rubber stoppers and manual interventions. |
| B3SA19 | On finger dab surface of glove port glove( Near to the out feed conveyor or stoppering station) | A | Contact plate using 90mm plate | The glove port gloves are used for manual interventions during routine operations by operator. Monitoring of the glove port gloves determines the contamination due to the activity performed near the stoppering station. |
| B3SA20 | On finger dab surface of glove port glove(Left side near to the NT-1 Swing conveyor) | A | Contact plate using 90mm plate | The glove port gloves are used for manual interventions during routine operations by operator. Monitoring of the glove port gloves determines the contamination due to the activity performed. |
| B3SA21 | On finger dab surface of glove port glove( Right side near to the NT-1 Swing conveyor) | A | Contact plate using 90mm plate | The glove port gloves are used for manual interventions during routine operations by operator. Monitoring of the glove port gloves determines the contamination due to the activity performed. |
| B3SA22 | On finger dab surface of glove port glove( Left side near to the NT-2 conveyor) | A | Contact plate using 90mm plate | The glove port gloves are used for manual interventions during routine operations by operator. Monitoring of the glove port gloves determines the contamination due to the activity performed. |
| B3SA23 | On finger dab surface of glove port glove  (Right side near to the NT-2 conveyor) | A | Contact plate using 90mm plate |
| B3SA24 | B3G041/  Vial Filling Room | On finger dab surface of glove port glove  ( Near to the NT-3 conveyor) | A | Contact plate using 90mm plate | The glove port gloves are used for manual interventions during routine operations by operator. Monitoring of the glove port gloves determines the contamination due to the activity performed. |
| B3SA25 | On finger dab surface of glove port glove -1  ( Left side door left glove port of NT-5 conveyor) | A | Contact plate using 90mm plate | The glove port gloves are used for manual interventions during routine operations by operator. Monitoring of the glove port gloves determines the contamination due to the activity performed. |
| B3SA26 | On finger dab surface of glove port glove -2  (Left side door right glove port of NT-5 conveyor) | A | Contact plate using 90mm plate |
| B3SA27 | On finger dab surface of glove port glove -1  ( Right side door left glove port of NT-5 conveyor) | A | Contact plate using 90mm plate |
| B3SA28 | On finger dab surface of glove port glove -2 (Right side door right glove port of NT-5 conveyor) | A | Contact plate using 90mm plate |
| B3SA29 | On surface of Buffer tank (Non operation side) | A | Contact plate using RODAC | The sterile product solution is transferred for filling through the buffer tank. This location is selected to demonstrate the cleanliness and sanitization practices. |
| B3SA30 | B3G041/  Vial Filling Room | On finger dab surface of glove port glove(Opposite to the in-feed turn table) (Non operation side) | A | Contact plate using 90mm plate | The glove port gloves are used for manual interventions during routine operations by operator. Monitoring of the glove port gloves determines the contamination due to the activity performed. |
| B3SA31 | On finger dab surface of right side glove port glove(Opposite to the in-feed star wheel) (Non operation side) | A | Contact plate using 90mm plate |
| B3SA32 | On finger dab surface of left side glove port glove (Opposite to the in-feed star wheel) (Non operation side) | A | Contact plate using 90mm plate |
| B3SA33 | On finger dab surface of right side glove port glove(Back side of the filling pumps) (Non operation side) | A | Contact plate using 90mm plate |
| B3SA34 | On finger dab surface of left side glove port glove(Back side of the filling pumps) (Non operation side) | A | Contact plate using 90mm plate |
| B3SA35 | B3G041/  Vial Filling Room | On finger dab surface of right side glove port glove Near to the Buffer tank) (Non operation side) | A | Contact plate using 90mm plate | The glove port gloves are used for manual interventions during routine operations by operator. Monitoring of the glove port gloves determines the contamination due to the activity performed. |
| B3SA36 | On finger dab surface of left side glove port glove (Near to the Buffer tank) (Non operation side) | A | Contact plate using 90mm plate |
| B3SA37 | On finger dab surface of glove port glove  (Opposite to the rejection conveyor) (Non operation side) | A | Contact plate using 90mm plate |
| B3SA38 | On finger dab surface of right side glove port glove (Opposite to the NT-1 Swing conveyor) (Non operation side) | A | Contact plate using 90mm plate | The glove port gloves are used for manual interventions during routine operations by operator. Monitoring of the glove port gloves determines the contamination due to the activity performed. |
| B3SA39 | On finger dab surface of left side glove port glove (Opposite to the NT-1 Swing conveyor) (Non operation side) | A | Contact plate using 90mm plate |
| B3SA40 | B3G041/  Vial Filling Room | On finger dab surface of glove port glove (Near to the NT-2 disk wheel) (Non operation side) | A | Contact plate using 90mm plate | The glove port gloves are used for manual interventions during routine operations by operator. Monitoring of the glove port gloves determines the contamination due to the activity performed. |
| B3SA41 | On finger dab surface of right side glove port glove (Opposite to the NT-3 conveyor Disk) (Non operation side) | A | Contact plate using 90mm plate |
| B3SA42 | On finger dab surface of left side glove port glove (Opposite to the NT-3 conveyor Disk) (Non operation side) | A | Contact plate using 90mm plate |
| B3SA43 | B3G042/  Vial Sealing  Room-II  B3G042/  Vial Sealing  Room-II  B3G042/  Vial Sealing  Room-II | On surface of sealing bowl | A | Contact plate using RODAC | The sterilized/sterile seals are added into the sealing sealing bowl. This location is selected for monitoring to determine the sterilization effectiveness and demonstrate the practices of the personnel. |
| B3SA44 | On surface of seals hopper (Inside) | A | Contact plate using RODAC | This location is selected for surface monitoring to demonstrate the cleaning and sanitization practices. |
| B3SA45 | On surface of seals loading tray | A | Contact plate using RODAC |
| B3SA46 | On finger dab surface of glove port glove  (Opposite to the NT-4 conveyor) | A | Contact plate using 90mm plate | The glove port gloves are used for manual interventions during routine operations by operator. Monitoring of the glove port gloves determines the contamination due to the activity performed. |
| B3SA47 | On finger dab surface of Left side glove port glove  (Opposite to the seals in-feed conveyor) | A | Contact plate using 90mm plate |
| B3SA48 | On finger dab surface of Right side glove port glove  (Opposite to the seals in-feed conveyor) | A | Contact plate using 90mm plate |
| B3SA49 | On finger dab surface of Left side glove port glove  (Seals loading side) | A | Contact plate using 90mm plate |
| B3SA50 | On finger dab surface of Right side glove port glove  (Seals loading side) | A | Contact plate using 90mm plate |
| B3SA51 | On finger dab surface of glove port glove  (Near to the seals bowl) | A | Contact plate using 90mm plate | The glove port gloves are used for manual interventions during routine operations by operator. Monitoring of the glove port gloves determines the contamination due to the activity performed. |
| B3SA52 | On finger dab surface of Left side glove port glove(Out feed star wheel) | A | Contact plate using 90mm plate |
| B3SA53 | On finger dab surface of Right side glove port glove (Out feed star wheel) | A | Contact plate using 90mm plate |
| B3SA54 | On finger dab surface of glove port glove (Opposite to the seal station) (non-operating side) | A | Contact plate using 90mm plate | The glove port gloves are used for manual interventions during routine operations by operator in non-operating side. Monitoring of the glove port gloves determines the contamination due to the activity performed. |
| B3SA55 | On finger dab surface of glove port glove (Opposite to infeed warm wheel)  (non-operating side) | A | Contact plate using 90mm plate |
| B3SA56 | On finger dab surface of glove port glove (Opposite to the NT-4 conveyor)  (non-operating side) | A | Contact plate using 90mm plate |
| B3SA57 | B3G044/  Vial Sealing  Room-I  B3G044/  Vial Sealing  Room-I | On surface of sealing bowl | A | Contact plate using RODAC | The sterilized/sterile seals are added into the sealing sealing bowl. This location is selected for monitoring to determine the sterilization effectiveness and demonstrate the practices of the personnel. |
| B3SA58 | On surface of seals hopper (Inside) | A | Contact plate using RODAC | These locations are selected for surface monitoring to demonstrate the cleaning and sanitization practices. |
| B3SA59 | On surface of seals loading tray | A | Contact plate using RODAC |
| B3SA60 | On finger dab surface of glove port glove (Near to the seal bowl) | A | Contact plate using 90mm plate | The glove port gloves are used for manual interventions during routine operations by operator. Monitoring of the glove port gloves determines the contamination due to the activity performed. |
| B3SA61 | On finger dab surface of Left side glove port glove  (Near Rejection conveyor) | A | Contact plate using 90mm plate |
| B3SA62 | On finger dab surface of Right side glove port glove  (Near Rejection conveyor) | A | Contact plate using 90mm plate |
| B3SA63 | On finger dab surface of Left side glove port glove  (Near sealing station) | A | Contact plate using 90mm plate | The glove port gloves are used for manual interventions during routine operations by operator. Monitoring of the glove port gloves determines the contamination due to the activity performed. |
| B3SA64 | On finger dab surface of Right side glove port glove  (Near sealing station) | A | Contact plate using 90mm plate |
| B3SA65 | On finger dab surface of Left side glove port glove  (Seals loading side) | A | Contact plate using 90mm plate |
| B3SA66 | On finger dab surface of Right side glove port glove  (Seals loading side) | A | Contact plate using 90mm plate |
| B3SA67 | On finger dab surface of Left side glove port glove (Near to the infeed conveyor) | A | Contact plate using 90mm plate |
| B3SA68 | On finger dab surface of Right side glove port glove (Near to the infeed conveyor) | A | Contact plate using 90mm plate |
| B3SA69 | B3G043/  Lyo Loading & Unloading Room  B3G043/  Lyo Loading & Unloading Room  B3G043/  Lyo Loading & Unloading Room | On surface of infeed conveyor | A | Contact plate using RODAC | The half-stoppered product filled vials are transferred for lyophilization. This location is hard to clean ad is selected to demonstrate the cleaning and disinfection process. |
| B3SA70 | On surface of Lyo-1 bridge plate | A | Contact plate using RODAC | The bridge plate is used for transfer of half-stoppered product filled vials into the lyophilizer for lyophilization and is difficult to clean surface. This location is selected to determine the cleaning and disinfection practices. |
| B3SA71 | On surface of Lyo-1 loading star wheel | A | Swab | The product filled half stoppered vials are transferred by the star wheel onto lyophilizer conveyer. This location is difficult to clean and is selected to determine the cleaning and disinfection practices. |
| B3SA72 | On surface of Lyo-2 bridge plate | A | Contact plate using RODAC | The bridge plate is used for transfer of half-stoppered product filled vials into the lyophilizer for lyophilization and is difficult to clean surface. This location is selected to determine the cleaning and disinfection practices. |
| B3SA73 | On surface of Lyo-2 loading star wheel | A | Swab | The product filled half stoppered vials are transferred by the star wheel onto lyophilizer conveyer. This location is difficult to clean and is selected to determine the cleaning and disinfection practices. |
| B3SA74 | On finger dab surface of glove port glove (Left side of the Lyo infeed conveyor) | A | Contact plate using 90mm plate | To monitor the Surface cleanliness of glove port, which are used for the handling of varies aseptic manipulation for removing of fallen vials and clearing the jams on the conveyer. The glove port gloves are used for manual interventions during routine operations by operator. Monitoring of the glove port gloves determines the contamination due to the activity performed. |
| B3SA75 | On finger dab surface of glove port glove (Right side of the Lyo infeed conveyor) | A | Contact plate using 90mm plate |
| B3SA76 | On finger dab surface of glove port glove (Near conveyor-2) | A | Contact plate using 90mm plate | The glove port gloves are used for manual interventions during routine operations by operator. Monitoring of the glove port gloves determines the contamination due to the activity performed. |
| B3SA77 | On finger dab surface of glove port glove (Near conveyor-3) | A | Contact plate using 90mm plate |
| B3SA78 | On finger dab surface of glove port glove (Left side near to the Lyo-1 loading) | A | Contact plate using 90mm plate | To monitor the Surface cleanliness of Glove port, which are used for the handling of varies aseptic manipulation for removing of fallen vials and clearing the jams on the conveyer and for performing the loading and unloading activates near the lyophilizer area (ALUS-I). |
| B3SA79 | On finger dab surface of glove port glove (Right side near to the Lyo-1 loading) | A | Contact plate using 90mm plate |
| B3SA80 | On finger dab surface of glove port glove (Left side near to the Lyo-1 Unloading) | A | Contact plate using 90mm plate |
| B3SA81 | On finger dab surface of glove port glove (Right side near to the Lyo-1 Unloading) | A | Contact plate using 90mm plate |
| B3SA82 | On finger dab surface of glove port glove (Left side near to the Lyo-2 loading) | A | Contact plate using 90mm plate | Glove port gloves are used for the handling of varies aseptic manipulation for removing of fallen vials and clearing the jams on the conveyer and for performing the loading and unloading activates near the lyophilizer area (ALUS-I). These locations are selected for monitoring to determine the contamination due to activities performed and demonstrate the cleaning and disinfection practices. |
| B3SA83 | On finger dab surface of glove port glove (Right side near to the Lyo-2 loading) | A | Contact plate using 90mm plate |
| B3SA84 | On finger dab surface of glove port glove (Left side near to the Lyo-2 Unloading) | A | Contact plate using 90mm plate |
| B3SA85 | On finger dab surface of glove port glove (Right side near to the Lyo-2 Unloading) | A | Contact plate using 90mm plate |
| B3SA86 | On finger dab surface of glove port glove (Left side of the out feed turn table) | A | Contact plate using 90mm plate | The glove port gloves are used for manual interventions during routine operations by operator. Monitoring of the glove port gloves determines the contamination due to the activity performed. |
| B3SA87 | On finger dab surface of glove port glove (Right side of the out feed turn table) | A | Contact plate using 90mm plate |
| B3SA88 | Mobile LAF’s | On the bottom surface of Mobile LAF (Inside) (PF-MBL-4001) | A | Contact plate using RODAC | The mobile LAF’s are used for transfer of sterilized accessories. These locations are selected for monitoring to determine the cleaning and disinfection practices and to demonstrate the practices of personnel. |
| B3SA89 | On the bottom surface of Mobile LAF (Inside) (PF-MBL-4002) | A | Contact plate using RODAC |
| B3SA90 | On the bottom surface of Mobile LAF (Inside) (PF-MBL-4003) | A | Contact plate using RODAC |
| B3SA91 | On the bottom surface of Mobile LAF (Inside) (PF-MBL-4004) | A | Contact plate using RODAC |
| B3SA92 | On the bottom surface of Mobile LAF (Inside) (PF-MBL-4005) | A | Contact plate using RODAC |

**NOTE:** As all the surface monitoring locations in aseptic area are selected for the routine monitoring, the proposed location IDs for above locations are mentioned in the tables given below along with the frequency of sampling.

**List of surface monitoring locations to be monitored at the end of every batch:**

Following locations are selected for surface monitoring and these locations shall be monitored at the end of every batch based on the critical activities performed at the respective locations.

| **Location code** | **Room Name** | **Location Description** | **No activity** | **Batch activity** | **Type of sample** | **Proposed sample location name** |
| --- | --- | --- | --- | --- | --- | --- |
| B3SA1 | Vial Filling Room | On Surface of In-feed turn table | YES | YES | RODAC | L4RA1 |
| B3SA2 | Vial Filling Room | On Surface of conveyor near to the filling nozzle | YES | YES | RODAC | L4RA2 |
| B3SA3 | Vial Filling Room | On Surface of Filling nozzles | NO | YES | SWAB | L4SA1 |
| B3SA4 | Vial Filling Room | On Surface of filling nozzle barrier (Above the filling nozzle) | YES | YES | RODAC | L4RA3 |
| B3SA5 | Vial Filling Room | On Surface of Rubber stopper bowl | NO | YES | RODAC | L4RA4 |
| B3SA6 | Vial Filling Room | On Surface of Rubber stopper chute | NO | YES | SWAB | L4SA2 |
| B3SA7 | Vial Filling Room | On Surface of Forceps near to the Tare weight | NO | YES | SWAB | L4SA3 |
| B3SA8 | Vial Filling Room | On Surface of Forceps near to the Gross weight | NO | YES | SWAB | L4SA4 |
| B3SA9 | Vial Filling Room | On Surface of Forceps near to the Rubber stopper bowl | NO | YES | SWAB | L4SA5 |
| B3SA10 | Vial Filling Room | On finger dab surface of glove port glove(In front of In-feed turn table) | NO | YES | 90MM | L4CA1 |
| B3SA11 | Vial Filling Room | On finger dab surface of glove port glove(In front of In-feed Star wheel) | NO | YES | 90MM | L4CA2 |
| B3SA12 | Vial Filling Room | On finger dab surface of glove port glove( Left side of filling Nozzles) | NO | YES | 90MM | L4CA3 |
| B3SA13 | Vial Filling Room | On finger dab surface of glove port glove ( Right side filling Nozzles) | NO | YES | 90MM | L4CA4 |
| B3SA14 | Vial Filling Room | On finger dab surface of glove port glove( Left side Rubber stopper bowl) | NO | YES | 90MM | L4CA5 |
| B3SA15 | Vial Filling Room | On finger dab surface of glove port glove(Right side Rubber stopper hopper) | NO | YES | 90MM | L4CA6 |
| B3SA16 | Vial Filling Room | On finger dab surface of glove port glove( Left side near to the rubber stoppers loading tray) | NO | YES | 90MM | L4CA7 |
| B3SA17 | Vial Filling Room | On finger dab surface of glove port glove( Right side near to the rubber stoppers loading tray) | NO | YES | 90MM | L4CA8 |
| B3SA18 | Vial Filling Room | On finger dab surface of glove port glove( Opposite to the rubber stopper bowl) | NO | YES | 90MM | L4CA9 |
| B3SA19 | Vial Filling Room | On finger dab surface of glove port glove( Near to the out feed conveyor or stoppering station) | NO | YES | 90MM | L4CA10 |
| B3SA20 | Vial Filling Room | On finger dab surface of glove port glove(Left side near to the NT-1 Swing conveyor) | NO | YES | 90MM | L4CA11 |
| B3SA21 | Vial Filling Room | On finger dab surface of glove port glove( Right side near to the NT-1 Swing conveyor) | NO | YES | 90MM | L4CA12 |
| B3SA22 | Vial Filling Room | On finger dab surface of glove port glove( Left side near to the NT-2 conveyor) | NO | YES | 90MM | L4CA13 |
| B3SA23 | Vial Filling Room | On finger dab surface of glove port glove(Right side near to the NT-2 conveyor) | NO | YES | 90MM | L4CA14 |
| B3SA24 | Vial Filling Room | On finger dab surface of glove port glove( Near to the NT-3 conveyor) | NO | YES | 90MM | L4CA15 |
| B3SA25 | Vial Filling Room | On finger dab surface of glove port glove -1 ( Left side door left glove port of NT-5 conveyor) | NO | YES | 90MM | L4CA16 |
| B3SA26 | Vial Filling Room | On finger dab surface of glove port glove -2 (Left side door right glove port of NT-5 conveyor) | NO | YES | 90MM | L4CA17 |
| B3SA27 | Vial Filling Room | On finger dab surface of glove port glove -1 ( Right side door left glove port of NT-5 conveyor) | NO | YES | 90MM | L4CA18 |
| B3SA28 | Vial Filling Room | On finger dab surface of glove port glove -2 (Right side door right glove port of NT-5 conveyor) | NO | YES | 90MM | L4CA19 |
| B3SA29 | Vial Filling Room | On surface of Buffer tank top lid (Non operation side) | YES | YES | RODAC | L4RA5 |
| B3SA30 | Vial Filling Room | On finger dab surface of glove port glove(near in-feed turn table) (Non operation side) | NO | YES | 90MM | L4CA20 |
| B3SA31 | Vial Filling Room | On finger dab surface of Right side glove port glove(Opposite to the in-feed star wheel) (Non operation side) | NO | YES | 90MM | L4CA21 |
| B3SA32 | Vial Filling Room | On finger dab surface of Left side glove port glove (Opposite to the in-feed star wheel) (Non operation side) | NO | YES | 90MM | L4CA22 |
| B3SA33 | Vial Filling Room | On finger dab surface of Right side glove port glove (Back side of the filling pumps) (Non operation side) | NO | YES | 90MM | L4CA23 |
| B3SA34 | Vial Filling Room | On finger dab surface of Left side glove port glove(Back side of the filling pumps) (Non operation side) | NO | YES | 90MM | L4CA24 |
| B3SA35 | Vial Filling Room | On finger dab surface of Right side glove port glove(Near to the Buffer tank) (Non operation side) | NO | YES | 90MM | L4CA25 |
| B3SA36 | Vial Filling Room | On finger dab surface of Left side glove port glove(Near to the Buffer tank) (Non operation side) | NO | YES | 90MM | L4CA26 |
| B3SA37 | Vial Filling Room | On finger dab surface of glove port glove(Opposite to the rejection conveyor) (Non operation side) | NO | YES | 90MM | L4CA27 |
| B3SA38 | Vial Filling Room | On finger dab surface of Right side glove port glove (Opposite to the NT-1 Swing conveyor) (Non operation side) | NO | YES | 90MM | L4CA28 |
| B3SA39 | Vial Filling Room | On finger dab surface of Left side glove port glove (Opposite to the NT-1 Swing conveyor) (Non operation side) | NO | YES | 90MM | L4CA29 |
| B3SA40 | Vial Filling Room | On finger dab surface of glove port glove (Near to the NT-2 disk wheel) (Non operation side) | NO | YES | 90MM | L4CA30 |
| B3SA41 | Vial Filling Room | On finger dab surface of Right side glove port glove (Opposite to the NT-3 conveyor Disk) (Non operation side) | NO | YES | 90MM | L4CA31 |
| B3SA42 | Vial Filling Room | On finger dab surface of Left side glove port glove (Opposite to the NT-3 conveyor Disk) (Non operation side) | NO | YES | 90MM | L4CA32 |
| B3SA43 | Vial Sealing Room-II | On surface of sealing bowl | NO | YES | RODAC | L4RA6 |
| B3SA44 | Vial Sealing Room-II | On surface of seals hopper (Inside) | NO | YES | RODAC | L4RA7 |
| B3SA45 | Vial Sealing Room-II | On surface of seals loading tray | NO | YES | RODAC | L4RA8 |
| B3SA46 | Vial Sealing Room-II | On finger dab surface of glove port glove(Opposite to the NT-4 conveyor) | NO | YES | 90MM | L4CA33 |
| B3SA47 | Vial Sealing Room-II | On finger dab surface of Left side glove port glove (Opposite to the seals in-feed conveyor) | NO | YES | 90MM | L4CA34 |
| B3SA48 | Vial Sealing Room-II | On finger dab surface of Right side glove port glove(Opposite to the seals in-feed conveyor) | NO | YES | 90MM | L4CA35 |
| B3SA49 | Vial Sealing Room-II | On finger dab surface of Left side glove port glove (Seals loading side) | NO | YES | 90MM | L4CA36 |
| B3SA50 | Vial Sealing Room-II | On finger dab surface of Right side glove port glove(Seals loading side) | NO | YES | 90MM | L4CA37 |
| B3SA51 | Vial Sealing Room-II | On finger dab surface of glove port glove(Near to the seals bowl) | NO | YES | 90MM | L4CA38 |
| B3SA52 | Vial Sealing Room-II | On finger dab surface of Left side glove port glove(Out feed star wheel) | NO | YES | 90MM | L4CA39 |
| B3SA53 | Vial Sealing Room-II | On finger dab surface of Right side glove port glove (Out feed star wheel) | NO | YES | 90MM | L4CA40 |
| B3SA54 | Vial Sealing Room-II | On finger dab surface of glove port glove (Opposite to the seal station) (Non-operating side) | NO | YES | 90MM | L4CA41 |
| B3SA55 | Vial Sealing Room-II | On finger dab surface of glove port glove (Opposite to infeed warm wheel) (Non-operating side) | NO | YES | 90MM | L4CA42 |
| B3SA56 | Vial Sealing Room-II | On finger dab surface of glove port glove (Opposite to the NT-4 conveyor) (Non-operating side) | NO | YES | 90MM | L4CA43 |
| B3SA57 | Vial Sealing Room-I | On surface of sealing bowl | NO | YES | RODAC | L4RA9 |
| B3SA58 | Vial Sealing Room-I | On surface of seals hopper (Inside) | NO | YES | RODAC | L4RA10 |
| B3SA59 | Vial Sealing Room-I | On surface of seals loading tray | NO | YES | RODAC | L4RA11 |
| B3SA60 | Vial Sealing Room-I | On finger dab surface of glove port glove (Near to the seal bowl) | NO | YES | 90MM | L4CA44 |
| B3SA61 | Vial Sealing Room-I | On finger dab surface of Left side glove port glove(Near Rejection conveyor) | NO | YES | 90MM | L4CA45 |
| B3SA62 | Vial Sealing Room-I | On finger dab surface of Right side glove port glove (Near Rejection conveyor) | NO | YES | 90MM | L4CA46 |
| B3SA63 | Vial Sealing Room-I | On finger dab surface of Left side glove port glove(Near sealing station) | NO | YES | 90MM | L4CA47 |
| B3SA64 | Vial Sealing Room-I | On finger dab surface of Right side glove port glove (Near sealing station) | NO | YES | 90MM | L4CA48 |
| B3SA65 | Vial Sealing Room-I | On finger dab surface of Left side glove port glove (Seals loading side) | NO | YES | 90MM | L4CA49 |
| B3SA66 | Vial Sealing Room-I | On finger dab surface of Right side glove port glove (Seals loading side) | NO | YES | 90MM | L4CA50 |
| B3SA67 | Vial Sealing Room-I | On finger dab surface of Left side glove port glove (Near to the infeed conveyor) | NO | YES | 90MM | L4CA51 |
| B3SA68 | Vial Sealing Room-I | On finger dab surface of Right side glove port glove (Near to the infeed conveyor) | NO | YES | 90MM | L4CA52 |
| B3SA69 | Vial Sealing Room-I | On surface of infeed conveyor | YES | YES | RODAC | L4RA12 |
| B3SA70 | Lyo Loading & Unloading Room | On surface of Lyo-1 bridge plate | YES | YES | RODAC | L4RA13 |
| B3SA71 | Lyo loading and unloading room | On surface of Lyo- loading star wheel | NO | YES | SWAB | L4SA6 |
| B3SA72 | Lyo Loading & Unloading Room | On surface of Lyo-2 bridge plate | YES | YES | RODAC | L4RA14 |
| B3SA73 | Lyo loading and unloading room | On surface of Lyo-2 loading star wheel | NO | YES | SWAB | L4SA7 |
| B3SA74 | Lyo Loading & Unloading Room | On finger dab surface of glove port glove (Left side of the Lyo infeed conveyor) | NO | YES | 90MM | L4CA53 |
| B3SA75 | Lyo Loading & Unloading Room | On finger dab surface of glove port glove (Right side of the Lyo infeed conveyor) | NO | YES | 90MM | L4CA54 |
| B3SA76 | Lyo Loading & Unloading Room | On finger dab surface of glove port glove (Near conveyor-2) | NO | YES | 90MM | L4CA55 |
| B3SA77 | Lyo Loading & Unloading Room | On finger dab surface of glove port glove (Near conveyor-3) | NO | YES | 90MM | L4CA56 |
| B3SA78 | Lyo Loading & Unloading Room | On finger dab surface of glove port glove (Left side near to the Lyo-1 loading) | NO | YES | 90MM | L4CA57 |
| B3SA79 | Lyo Loading & Unloading Room | On finger dab surface of glove port glove (Right side near to the Lyo-1 loading) | NO | YES | 90MM | L4CA58 |
| B3SA80 | Lyo Loading & Unloading Room | On finger dab surface of glove port glove (Left side near to the Lyo-1 Unloading) | NO | YES | 90MM | L4CA59 |
| B3SA81 | Lyo Loading & Unloading Room | On finger dab surface of glove port glove (Right side near to the Lyo-1 Unloading) | NO | YES | 90MM | L4CA60 |
| B3SA82 | Lyo Loading & Unloading Room | On finger dab surface of glove port glove (Left side near to the Lyo-2 loading) | NO | YES | 90MM | L4CA61 |
| B3SA83 | Lyo Loading & Unloading Room | On finger dab surface of glove port glove (Right side near to the Lyo-2 loading) | NO | YES | 90MM | L4CA62 |
| B3SA84 | Lyo Loading & Unloading Room | On finger dab surface of glove port glove (Left side near to the Lyo-2 Unloading) | NO | YES | 90MM | L4CA63 |
| B3SA85 | Lyo Loading & Unloading Room | On finger dab surface of glove port glove (Right side near to the Lyo-2 Unloading) | NO | YES | 90MM | L4CA64 |
| B3SA86 | Lyo Loading & Unloading Room | On finger dab surface of glove port glove (Left side of the out feed turn table) | NO | YES | 90MM | L4CA65 |
| B3SA87 | Lyo Loading & Unloading Room | On finger dab surface of glove port glove (Right side of the out feed turn table) | NO | YES | 90MM | L4CA66 |
| B3SA88 | Mobile LAF | On the bottom surface of Mobile LAF (Inside) (PF-MBL-4001) | Yes | Yes | RODAC | L4RA15 |
| B3SA89 | Mobile LAF | On the bottom surface of Mobile LAF (Inside) (PF-MBL-4002) | Yes | Yes | RODAC | L4RA16 |
| B3SA90 | Mobile LAF | On the bottom surface of Mobile LAF (Inside) (PF-MBL-4003) | Yes | Yes | RODAC | L4RA17 |
| B3SA91 | Mobile LAF | On the bottom surface of Mobile LAF (Inside) (PF-MBL-4004) | Yes | Yes | RODAC | L4RA18 |
| B3SA92 | Mobile LAF | On the bottom surface of Mobile LAF (Inside) (PF-MBL-4005) | Yes | Yes | RODAC | L4RA19 |
| B3SB2 | Change room-III | On the surface of door handle of garment cubicle (PF-GCU-4001) | YES | YES | SWAB | L4SB8 |
| B3SB10 | Cool Zone | On the surface of Wall (Near entry door) | YES | YES | RODAC | L4RB8 |
| B3SB11 | Cool Zone | On outer surface of cool zone unloading LAF Flaps (PF-LAF-4004) | YES | YES | RODAC | L4RB9 |
| B3SB12 | Cool Zone | On bottom surface of dynamic pass box (Inside) | YES | YES | RODAC | L4RB10 |
| B3SB13 | Cool Zone | On surface of cool zone parts storage area LAF Flaps (Outside) (PF-LAF-4003) | YES | YES | RODAC | L4RB11 |
| B3SB21 | Filtration Room | On outer surface of ceiling suspended LAF flaps (ID No.: PF-LAF-4007) | YES | YES | RODAC | L4RB13 |
| B3SB22 | Filtration Room | surface of wall (Inside filtration ceiling suspended LAF) | YES | YES | RODAC | L4RB14 |
| B3SB23 | Filtration Room | On surface of filtration vessel on top of lid (500 Ltrs. FV2) (ID No.: PF-FVL-4002) | YES | YES | RODAC | L4RB15 |
| B3SB24 | Filtration Room | On surface of filtration vessel on top of lid (200 Ltrs. FV1) (ID No.: PF-FVL-4001) | YES | YES | RODAC | L4RB16 |
| B3SB25 | Filtration Room | On surface of filtration vessel IPC (500 Ltrs. FV2) | YES | YES | RODAC | L4RB17 |
| B3SB26 | Filtration Room | On surface of filtration vessel IPC (200 Ltrs. FV1) | YES | YES | RODAC | L4RB18 |
| B3SB36 | Filling Room | On the surface of Wall (Near entry door) | YES | YES | RODAC | L4RB26 |
| B3SB37 | Filling Room | On surface of Balance touch screen | YES | YES | RODAC | L4RB27 |
| B3SB38 | Filling Room | On surface of online NVPC HMI | YES | YES | RODAC | L4RB28 |
| B3SB39 | Filling Room | On surface of Filling machine HMI | YES | YES | RODAC | L4RB29 |
| B3SB40 | Filling Room | On surface of door knobs of filling cabinet (in front of filling nozzles) | YES | YES | SWAB | L4SB11 |
| B3SB41 | Filling Room | On surface of door knobs in front of filling nozzles (under extended LAF) | YES | YES | SWAB | L4SB12 |
| B3SB42 | Filling Room | On surface of clean room telephone | YES | YES | RODAC | L4RB30 |
| B3SB43 | Filling Room | On surface of SS trolley handle | YES | YES | SWAB | L4SB13 |
| B3SB44 | vial Sealing Room-2 | On Surface of door handles in-front of seals loading (Under extended LAF) | YES | YES | SWAB | L4SB14 |

**Following locations were selected for surface monitoring with a frequency of once in a month:**

Below mentioned locations are selected for surface monitoring. However, these locations shall be monitored once in a month (preferably at the end of batch) and if there is no batch activity for the entire month, then monitoring of these locations shall be performed on non-production day. As all these locations are selected to ensure the cleanliness of the various sampling surfaces, the representative surfaces are selected for monitoring at the end of every batch and these locations are considered for surface monitoring at lesser frequency.

1. **Door handles of mobile LAFs, dynamic pass boxes and garment cubicle:** Monitoring by volumetric air sampling locations are proposed for routine monitoring in mobile LAFs which effectively demonstrates the air quality of the mobile LAFs. There were no recoveries and excursions observed in these locations during PQ and routine monitoring period. Hence, it is proposed to monitor the bottom surfaces of mobile LAFs with lesser frequency.
2. **Cross over benches, wall surfaces, push plates, door handles of entry doors and equipment door handles**: The settle plate and Monitoring by volumetric air sampling locations are proposed for routine monitoring in mobile LAFs, garment cubicle and dynamic pass boxes and locations inside the each and every room which effectively demonstrates the air quality. Considering the observed recoveries and excursions in these locations during PQ and routine monitoring period, it is proposed to monitor these locations with lesser frequency.
3. **HMI’s:** The surface sampling of the HMI’s are selected for routine monitoring as it provides a representation to determine the cleaning and disinfection practices. Hence, HMI’s near filling machine and filling room are selected for monitoring at the end of every batch where the filled vials (unstoppered) are available in this room. Considering the criticality of locations, HMIs in filling room demonstrates the cleanliness of the equipments. However, it is proposed to monitor the other HMIs with lesser frequency.

| **Location code** | **Room Name** | **Location Description** | **No activity** | **Batch activity** | **Type of sample** | **Proposed sample location name** |
| --- | --- | --- | --- | --- | --- | --- |
| B3SB1 | Change room-III | On surface of cross over bench | Yes | Yes | RODAC | L4RB1 |
| B3SB3 | Change room-III | On the surface of Wall | Yes | Yes | RODAC | L4RB2 |
| B3SB4 | Buffer Room | On the surface of push plate of door towards sterile corridor | Yes | Yes | RODAC | L4RB3 |
| B3SB5 | Buffer Room | On the surface of SS table under ceiling suspended LAF | Yes | Yes | RODAC | L4RB4 |
| B3SB6 | APA corridor | On the surface of push plate of door towards cool zone | Yes | Yes | RODAC | L4RB5 |
| B3SB7 | APA corridor | On the surface of door handles of garment cubicle (PF-GCU-4001) | Yes | Yes | SWAB | L4SB1 |
| B3SB8 | APA corridor | On surface of Garment cubicle lower shelf (PF-GCU-4001) | Yes | Yes | RODAC | L4RB6 |
| B3SB9 | APA corridor | On the surface of push plate of door towards filling room | Yes | Yes | RODAC | L4RB7 |
| B3SB14 | Mobile LAF | On the surface of Mobile LAF Door handles (PF-MBL-4001) | Yes | Yes | SWAB | L4SB2 |
| B3SB15 | Mobile LAF | On the surface of Mobile LAF Door handles (PF-MBL-4002) | Yes | Yes | SWAB | L4SB3 |
| B3SB16 | Mobile LAF | On the surface of Mobile LAF Door handles (PF-MBL-4003) | Yes | Yes | SWAB | L4SB4 |
| B3SB17 | Mobile LAF | On the surface of Mobile LAF Door handles (PF-MBL-4004) | Yes | Yes | SWAB | L4SB5 |
| B3SB18 | Mobile LAF | On the surface of Mobile LAF Door handles (PF-MBL-4005) | Yes | Yes | SWAB | L4SB6 |
| B3SB19 | Air Lock | On surface of door handles of dynamic pass box | Yes | Yes | SWAB | L4SB7 |
| B3SB20 | Air Lock | On bottom surface of dynamic pass box (Inside) | Yes | Yes | RODAC | L4RB12 |
| B3SB27 | Vial Sealing Room-1 | On the surface of handle of door towards sterile corridor . | Yes | Yes | SWAB | L4SB9 |
| B3SB28 | Vial Sealing Room-1 | On the surface of vial capping machine HMI | Yes | Yes | RODAC | L4RB19 |
| B3SB29 | Vial Sealing Room-1 | On Surface of door handles in-front of seals loading (Under extended LAF) | Yes | Yes | SWAB | L4SB10 |
| B3SB30 | Lyoloading and unloading room | On the surface of Wall (Near entry door) | Yes | Yes | RODAC | L4RB20 |
| B3SB31 | Lyoloading and unloading room | On the surface of ALUS-1 HMI | Yes | Yes | RODAC | L4RB21 |
| B3SB32 | Lyoloading and unloading room | On the surface of Lyo-1 HMI | Yes | Yes | RODAC | L4RB22 |
| B3SB33 | Lyoloading and unloading room | On the surface of ALUS-2 HMI | Yes | Yes | RODAC | L4RB23 |
| B3SB34 | Lyoloading and unloading room | On the surface of Lyo-2 HMI | Yes | Yes | RODAC | L4RB24 |
| B3SB35 | Lyoloading and unloading room | On surface of online NVPC HMI | Yes | Yes | RODAC | L4RB25 |
| B3SB45 | vial Sealing Room-2 | On the surface of vial capping machine HMI | Yes | Yes | RODAC | L4RB31 |
| B3SB46 | APA Change Room-IV | On the surface of push plate of door towards sterile corridor | Yes | Yes | RODAC | L4RB32 |
| B3SB47 | APA Change Room-IV | On surface of wall near door towards change room-V | Yes | Yes | RODAC | L4RB33 |
| B3SC29 | Change room-II | On the surface of cross over bench | Yes | Yes | RODAC | L4RC1 |
| B3SC30 | Change room-II | On the surface of push plate of door towards change room-III | Yes | Yes | RODAC | L4RC2 |
| B3SC31 | APA Change Room-V | On the surface of return air raiser grill (EN- AHU-0008/RG/04) | Yes | Yes | RODAC | L4RC3 |
| B3SD1 | Change room-I | On surface of cross over bench towards change room-II | Yes | Yes | RODAC | L4RD1 |

**Sequence of sampling for surface monitoring in Grade-A Aseptic area:**

Based on the criticality of the activities, it is proposed to perform surface monitoring in the sequential manner. Given below is the sequence of sampling in grade-A area:

* Glove port gloves near infeed turn table
* Infeed Turn table
* Forceps- infeed
* Glove port gloves near filling
* Filling Nozzles
* nozzle barrier, conveyors
* Forceps near filling pump
* Buffer tank
* Glove port Gloves near stoppering station.
* rubber stopper bowl
* rubber stopper chute
* Conveyor surfaces
* Glove ports near sealing station.

**Rationale for the sequence of sampling:** Sampling of locations on the machine requires the opening of the door which exposes the glove port gloves to the adjacent environment and there is a probability that the glove port gloves may get in contact with the gown of the sampling personnel. Hence, the glove port gloves (classified as Grade-A) are sampled first in the particular zone. Subsequently the critical surfaces like filling nozzles are considered for monitoring which are considered as critical as the product gets filled through these nozzles. Further, other surfaces like stopper bowl, stopper chute, turn tables, forceps and other filling machine surfaces are considered for surface monitoring.