MISCELLANEOUS STUDY FOR DISINFECTION & TRANSFER OF ARTICLES TO ASEPTIC PROCESSING AREA THROUGH DYNAMIC PASSBOXES

1.0 PRE-APPROVAL

Signing of this approval page of protocol indicates agreement with the qualification approach described in this document.

Name	Department/Designation	Signature	Date
Prepared By:			
	Microbiology		
Reviewed By:			
	Microbiology		
	Production		
	Quality assurance		
Approved By:			
	Quality assurance		

2.0 PURPOSE

The purpose of this Study is to validate the procedure for disinfection & transfer of articles to aseptic processing area through dynamic pass boxes.

3.0 SCOPE

This protocol is applicable for disinfection and transfer efficiency study of articles which are transfer from unclassified area to aseptic area through dynamic pass boxes in Pharma microhub Pvt Ltd.

4.0 REASON FOR VALIDATION

To assess the disinfection and transfer efficiency during article transfer.

5.0 ABBREVIATIONS

Abbreviations	Details
No.	Number
SCDA	Soybean Casein Digest Agar
NLT	Not less than
CFU	Colony Forming Unit
RODAC	Replicate Organism Detection and Counting
SS	Stainless Steel
LAF	Laminar Air Flow
PP Bottle	Polypropylene bottles
Pu Tube	Polyurethane Tube
DOP	Dioctyl Phthalate
PAO	Poly Alpha Olefin
NVPC	Non-viable particulate count
FEP Tubing	Fluorinated ethylene propylene tubing
Mm	Milli meter

6.0 RESPONSIBILITY

6.1 Microbiology:

- ✓ Preparation of protocol /Summary report.
- ✓ Execution of protocol.

6.2 Quality Assurance

- ✓ Review and Approval of protocol/ Summary report.

6.3 Production

- ✓ Review of protocol/ report

7.0 OVERVIEW

To assess the effectiveness of disinfectant against the articles transferring into the aseptic area for routine purpose, by recovering microorganisms from the articles.

8.0 TRAINING

All the concerned personnel who involve in validation shall be given training on the approved protocol and the training details shall be captured in Training Record and on the job training sheets shall be updated accordingly.

8.1 Instrument Used and their preventive maintenance Status:

Measure Instruments used to test in the protocol execution to be calibrated before the usage. List down the details in the below tabular column.

Sr.No.	Instrument Name	Instrument ID.No.	Preventive maintenance		Checked By Sign/Date
			Done Date	Due Date	

Remarks:

Test instruments used and their calibration status have been verified and found satisfactory.

☐ Yes ☐ No ☐ NA Attachment No:-_____

Verified by:	Reviewed by:
Sign/Date	Sign/Date

9.0 STUDY DESIGN

Materials which cannot be sterilized before they are transferred into to aseptic area, shall be sanitized Material transfer method validation will assure that articles are being transferred into the clean rooms with bio-load complying with the regulatory and in-house specification limits.

Materials which gets transferred into the clean rooms from the unclassified areas will be identified and shall be grouped into different brackets and a worst case material in that respective group shall be used during the study and shall be monitored accordingly.

Materials which are intended for transfer into the respective clean room(s) will be sanitized as per the standard procedure defined in the SOP and sanitized articles shall be monitored for bioburden at the identified locations.

Acceptance criteria shall be pre-defined and shall be in compliance with the specification limits as defined in the SOP (Environmental monitoring).

The study shall be planned and executed with an ultimate aim of ensuring no material enters into most critical area or Grade A facility with an objectionable bio load on it.

10.0 VALIDATION TESTS, ITS RATIONALE AND ACCEPTANCE CRITERIA:

The validation tests, with rationale and acceptance criteria are mentioned in the below table.

Sr.No.	Name/Title of test	Rationale/Reference for test	Acceptance criteria
01	Verification of microbial load during transfer of sanitized articles	To find out the bio load after sanitization of articles transfer into aseptic area through dynamic pass box based on the MOC of the outer surface, Size of the article & Difficult to sanitize	Unclassified area: for information only. Grade-A: 1 Grade-B: 5 Grade-C: 25

11.0 VALIDATION PROCEDURE & OBSERVATIONS

11.1 Materials / Equipment / Requirement:

11.1.1 Following materials are required to perform the validation.

Articles	MOC of outer surface	Bracket approach articles	Rationale for bracket approach
1. SCDA (90 mm Plates) (Gamma irradiated) 2. SCDA (55 mm Plates) 3. Sterile saline with swab (Gamma irradiated) 4. Laminated sheets 5. Clean room Tape (Gamma irradiated) 6. Gamma irradiated marker 7. Gamma irradiated thermal Sterile Large Gloves	Plastic cover	SCDA (90 mm Plates) (Gamma irradiated)	All articles are wrapped with the plastic cover. Hence for the bracket approach SCDA 90 mm was selected for the sampling based on the larger surface area.
1. Battery charger 2. Air Sampler Charger 3. Camera 4. Anemometer 5. Photometer 6. Machine lubricants	Hard plastic	Air Sampler Charger	All articles are made of hard plastic, hence as a worst case the sanitize surface Air Sampler Charger selected for the sampling based on the

Articles	MOC of outer surface	Bracket approach articles	Rationale for bracket approach
7. Electrical Items, switch board, tube lights etc. 8. Conductivitybuffer Solution Bottles 9. conveyor belt 10. Air sampler 11. Smoke generator 12. Container for WFI used for Air Flow Pattern 13. Sterile Pen / Sterile Marker 14. Digital hygrometer			complexity of the surface area.
1. Glass Sampling bottle	Duran / Borosilicate Glass type-I	Glass Sampling bottle	Glass sampling bottle is with glass surface, hence considered for sampling.
1. Multimeter 2. Gaskets	PVC	Multimeter	Multimeter is the larger surface for sampling and hard to sanitize, hence for the bracket approach multimeter was selected for the sampling.
1. PU tube 2. Poly bags 3. Polyethylene terephthalate bottles 4. PP bottles 5. Iso-Propyl Alcohol bottles	Polyethylene terephthalate	Polyethylene terephthalate bottles	Hard to sanitize, hence Polyethylene terephthalate bottles is considered as worst case for the sampling as a bracket approach.
1. Tester 2. Screw driver	Platinum coated, Hardened mild steel and PVC	Screw driver	All articles are made of Hardened mild steel & PVC, however the Screw driver set are hard to sanitize, hence it is considered as a worst case sampling for the bracket approach.
1. Ready to use Aluminium flip off seals 2. Ready to use Rubber Stoppers	Tyvek cover	Ready to use rubber stoppers	Ready to use Rubber Stoppers to be wrapped with the Tyvek cover and transferred to aseptic area through dynamic pass box, hence as a worst case the Ready to use rubber plugs is included considering larger surface area for the sampling.
1. NVPC particle counter	Stainless still	NVPC particle	All articles are combined

Articles	MOC of outer surface	Bracket approach articles	Rationale for bracket approach
2. NVPC battery charger 3. Fogger surface 4. SS mop sticks 5. SS stands 6. SS Bins 7. SS Petri carrier 8. Tool box 9. SS trays 10. Standard weights 11. Nuts 12. Bolts 13. Return air raiser/ Pre filters/ HEPA filters 14. Equipment used for DOP/PAO testing of HEPA Filters 15. SS Status Board 16. Magnehelic gauges 17. Data logger 18. Compressed Air sampler		counter	with the plastic and stainless steel surfaces, however the NVPC particle counter surfaces are the hard to clean surfaces and larger surface area for the sampling, hence the NVPC particle counter surface are selected for the bracket approach for sampling.
Filling Machine Parts (Star wheel/worm Teflon Parts/ Guide.	Teflon	Star wheel	Star wheel is difficult to clean, hence sampling is considered.
1. Silicone tubings 2. braided silicone tubings 3. FEP Tubings 4. Pharma pure Tube	Silicon	Pharma pure Tube	Silicone tubings is difficult to sanitize, hence sampling is considered.

11.1.2 The following articles/materials are required for execution.

- Sterile soybean casein digest agar Ready to use media (55 mm Plates (RODAC))
- 0.45µ membrane filter/sterile ready to use filtration funnels
- Sterile swab with saline / Ready to use swab
- Manifold / Setino pump
- Filtration accessories
- Sterile 0.1% peptone water
- Sterilized Forceps.
- Sterile gloves
- Disinfectants
    - 70% IPA
    - 3%Korsolex rapid

- 1% Bacillocid
- 1% Microbac forte

11.1.3 Rationale for selection of Sampling Locations.

Article Name	Sampling Location	Rationale
SCDA (90 mm Plates) (Gamma irradiated)	• Top surface • Bottom surface	• Top surface and bottom surface of the media plates comes under contact with the gloved hand surface and pass box bottom surface. Hence sampling shall be done to find the bioload after sanitization. • Sampling location is a regular surface; hence sampling shall be done by contact plate method.
Air sampler charger	Air sampler charger	• Air sampler charger surface is the hard to sanitize. Hence sampling shall be done to find the bioload after sanitization. The sample surface is an regular surface; hence sampling shall be done by contact plate method
Glass bottle	• External body surface • Bottom surface	• Glass bottle body and bottom surface is regular surface. Cap surface and body surface come in contact during handling. Hence sampling shall be done to find the bioload after sanitization. This is even surface and hence sampling shall be done by contact plate method. • Bottom surface, which is contact to the pass box surface, sampling shall be done by contact plate method.
Multimeter	• Wire plug in & switches surface	• Wire plug in & switches & wire surfaces are the hard to sanitize surfaces. Hence sampling shall be done to find the bioload after sanitization. • Sampling location is an irregular surface; hence sampling shall be done by swab method.
Polyethylene terephthalate bottle	• Polyethylene terephthalate bottles	• Polyethylene terephthalate bottles surface is the hard to sanitize surfaces. Hence sampling shall be done to find the bioload after sanitization. • Sampling location is an irregular surface; hence sampling shall be done by swab method.
Screw driver	• Screw driver holder surface.	• Screw driver holder surface and screw holder surface are the hard to sanitize surfaces. Hence sampling shall be done to find the bioload after sanitization. • Sampling location is an irregular surface; hence sampling shall be done by swab method.
Ready to use rubber stoppers	• Bottom surface	• Bottom surface of the Ready to use rubber stoppers comes in contact with the gloved hand and surface and pass box bottom surface. Hence sampling shall be done to find the bioload after

Article Name	Sampling Location	Rationale
		sanitization. • Sampling location is a regular surface; hence sampling shall be done by contact plate method.
NVPC particle counter	• NVPC counter top surface. • NVPC counter bottom surface.	• Top surface which is comes in contact with the gloved hands. Hence sampling shall be done to find the bioload after sanitization. The sample surface is an regular surface; hence sampling shall be done by contact plate method. • Bottom surface which is comes in contact with the pass box bottom surface, hence sampling shall be done to find the bioload after sanitization, the surface is regular surface, hence sampling shall be done by contact plate method.
Star wheel	Star wheel surface	• Star wheel surface is the hard to sanitize. Hence sampling shall be done to find the bio load after sanitization. The sample surface is an irregular surface; hence sampling shall be done by swab method.
Pharma pure Tube	Pharma pure Tubing surface	• Sampling location is an irregular surface; hence sampling shall be done by swab method.

11.1.4 Selection of Articles for Sampling.

11.1.4.1 Bracketing approach shall be followed for Article selection. Following factors are considered for bracketing approach.

- MOC of the outer surface
- Size of the article
- Difficult to sanitize
- Complexity of the material

11.1.5 Based on bracketing approach following articles are required to execute the transfer validation study.

1.	SCDA (90 mm Plates) (Gamma irradiated)
2.	Air Sampler Charger
3.	Glass bottle
4.	Multimeter
5.	Polyethylene terephthalate bottle
6.	Screw driver

S. No.	Name of the Article and Material
7.	Ready to use rubber stoppers
8.	NVPC particle counter
9.	Star wheel
10.	Pharma pure tube

11.2 **Articles transfer procedure from Corridor to Grade-C (Autoclave and Compounding area) dynamic pass box.**

11.2.1 Perform the surface monitoring for articles as per annexure-1 before sanitization. It is considered as Sample No-01 and record the details in Annexure-I.

11.2.2 Transfer the articles from Corridor to Grade-C (Autoclave and Compounding area) dynamic pass box with equipment ID:DPB/PD/001

11.2.3 Ensure the following things before placing the articles in dynamic pass box.

- Ensure that the Dynamic pass box is cleaned.
- Ensure that the Dynamic pass box differential pressure limit shall be within specified limit.

11.2.4 Sanitize the articles with a sterilized mop wet with 3% Bacillocid special.

11.2.5 Pass box usage shall be entered in the respective pass box usage log book.

11.2.6 Close the door, allow for contact time for 15 min as per SOP

11.2.7 Enter into Grade-C area as per SOP, after completion of the contact time of 15minutes, open the dynamic pass box

11.2.8 Unload the articles and place the unloaded articles on SS table or trolley in Grade- C area.

11.2.9 Perform the surface monitoring for the unloaded articles as per annexure-II. It is considered as a Sample No-02 and record the details in Annexure-II.

11.3 **Articles transfer procedure from Grade-C area to Grade-B (Cool Zone Area) dynamic pass box.**

11.3.1 Transfer the articles as per annexure-III near to the dynamic pass box it is present between the Autoclave area and cool zone area.

11.3.2 Operate the dynamic pass box as per SOP

11.3.3 Open the door of the Dynamic pass box from Grade-C area side.

11.3.4 Sanitize the articles with a mop wet with 3% bacillocid special and place it in the pass box.

11.3.5 Close the door, allow for contact time for 15 min.

11.3.6 Pass box usage shall be entered in the pass box usage log book.

11.3.7 Enter into Grade-B area as per SOP.

11.3.8 After completion of the contact time of 15 minutes, open the dynamic pass box

11.3.9 While Unload the articles, sanitize the articles with a sterilized mop wet with 0.2µ filtered/ sterile 70% IPA disinfectant. and place the unloaded articles on SS table or trolley in Grade- B area

11.3.10 Perform the surface monitoring for sanitized articles as per the annexure-III. It is considered as a Sample No-03 and record the details in Annexure-III.

11.4 **Articles transfer procedure from cool zone area to Filling LAF.**

11.4.1 Transfer the articles near to Filling LAF and sanitize the articles with 0.2µ filtered/ sterile 70% IPA ensure articles are visually dried.

11.4.2 Perform the surface monitoring for sanitized articles as per the annexure-IV in filling LAF. It is considered as a Sample No-04 and record the details in Annexure-IV.

11.4.3 The study shall be performed for 3 repeats with all scheduled disinfectants

Sampling and activity details:

Sample	Sampling performed as per annexure	Grade	Sanitization activity
Sample-1	Annexure-I	Unclassified	Before sanitization
Sample-2	Annexure-II	Grade-C	3% bacillocid special with contact time of 15 minutes as mentioned in SOP
Sample-3	Annexure-III	Grade-B	Disinfect the items with a sterilized mop wet with 0.2µ filtered 3% bacillocid special with 15 minutes contact time as mentioned in SOP
Sample-4	Annexure-IV	Grade-A	Disinfect the items with a sterilized mop wet with 0.2µ filtered/ sterile 70% IPA

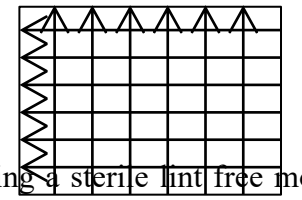
11.5 **Sampling Method:**

11.5.1 Sampling shall be performed by swab method and contact plate method as mentioned in Environmental monitoring SOP

11.6 **Swab Method**

- Monitoring of irregular surfaces by swab method:
- Lift the swab stick and squeeze the excess liquid by pressing the swab bud gently to the inner surface of the test tube before sampling.
- Take care not to touch the bud of the swab while handling.
- Holding the stem, swab the sample site first with horizontal strokes and then rotate the bud and swab in vertical strokes.
- Swab approximately an area of 25cm^2 at the sample site. Transfer the swabbed cotton bud into test tube containing 10ml solution with neutralizer tube and close the test tube.

  Note: The sampling area covered should be greater than or equal to 25 cm^2 but no larger than 30cm^2 or sampling shall done such that it covers the maximum surface of the intended location.



- Wipe the sampled area using a sterile lint free mop moistened with the disinfectant where applicable.
- Transfer the swabs to the MLT area for further analysis. Analyze the swab samples as soon as possible for microbiological analysis after sampling.
- For testing transfer adequate number of sterile 0.1% peptone water bottles and all other accessories required for membrane filtration.
- Under aseptic conditions, vortex the tube containing swab and then squeeze the swab on the inner walls of the test tube and remove swab from the test tube.
- Assemble the sterile membrane filtration set under LAF. Pre-wet the membrane with approx 50mL of sterile 0.1% peptone water. Then, filter the sample contents through the 0.45µ sterile membrane filter.
- Rinse the filter with approx. 100mL of peptone. Remove the membrane filter and place on the surface of the ready to use Soyabean casein digest agar plates supplemented with neutralizer.
- Place the membrane such that there are no air bubbles between membrane and the agar surface.
- Incubate all the plates in upright position at 20-25°C for 72 hrs followed by 30-35°C for further 48 hrs.

- At the end of the incubation period, count the number of colonies and record the observations as CFU respective annexures. (Annexure-I, Annexure-II, Annexure-III & Annexure-IV)

11.7 **Contact plate sampling method.**

- Monitoring of regular surfaces by contact plate (RODAC plate) method:
- Take the contact plate (RODAC plate), gently touch the sample area with the agar surface and roll the plate across the surface to be sampled. The contact plate will leave a growth media residue behind; therefore, immediately after sampling with the contact plate, the sampled area shall be thoroughly wiped with a non-shedding wipe soaked in sterile 70% IPA.
- After completion of contact plate sampling, immediately close the lid with care to avoid the contamination.
- After completion of sampling, wipe the sampling location with disinfectant using a sterile lint free mop.
- After completion of sampling, transfer the plates to the SS canisters. Bring the canisters back to the incubation room.
- Incubate the plates at 20-25°C for 72 hrs followed by 30-35 °C for48 hrs.
- At the end of the incubation period, count the number of colonies in each of the plate and record the observations in the respective Annexures. (Annexure-I, Annexure-II, Annexure-III & Annexure-IV)

12.0 ACCEPTANCE CRITERIA:

- Acceptance criteria for before and after sanitization shall be as mentioned in below table.

Grade	**Limit** (CFU/ 55 mm RODAC plate/ 25 cm^2 swab)
Unclassified Area (Sample-1)	For information Only
C (Sample-2)	25
B (Sample-3)	5
A (Sample-4)	1
Negative Control	No growth

13.0 Revalidation criteria:

Re-validation shall be performed any changes as bellow

- Any changes in transfer procedure.
- Change in disinfectant concentration and change in disinfectant.
- Evaluation shall be performed in case of any new article introduction. Based on evaluation conclusion requirement of transfer validation shall be assessed.

14.0 List of Annexures:

14.1 Annexure-I : Surface monitoring for articles before sanitization (Sample-01)
14.2 Annexure-II : Surface monitoring for unloaded articles (Sample-02)
14.3 Annexure-III : Surface monitoring for unloaded articles (Sample-03)
14.4 Annexure-IV : Surface monitoring for unloaded articles (Sample-04)

15.0 SUMMARY AND CONCLUSION

16.0 POST-APPROVAL

The signatures below indicate approval of this report.

Name	Department/Designation	Signature	Date
Compiled By:			
Reviewed By:			
Approved By:			

17.0 PURPOSE & SCOPE

The purpose of this summary report is to document the validation results for the procedure used to disinfect and transfer materials from unclassified areas to the aseptic processing area (Grade A/B) via dynamic pass boxes at Pharma Micro Hub Pvt Ltd.

The study evaluates the effectiveness of the current sanitization procedures and the bracketing approach used for worst-case items, ensuring that no entry of surface-borne bio-load compromises the classified environments.

18.0 SUMMARY OF STUDY DESIGN & METHODOLOGY

- Bracketing Approach: Materials were grouped by Surface Material (MOC), size, configuration complexity, and sanitization difficulty. The defined worst-case items (e.g., NVPC counter, Air Sampler Charger, Star wheel, Multimeter) were used to validate the groups.
- Transfer Sequence & Sanitization:
  - Unclassified to Grade C: Disinfected using 3% Bacillocid Special with a 15-minute contact time inside Dynamic Passbox (DPB/PD/001).
  - Grade C to Grade B: Disinfected using 3% Bacillocid Special (15-minute contact time), followed by a 0.2µ filtered 70% IPA wipe during unloading.
  - Grade B to Grade A (LAF): Final sanitization step with 0.2µ filtered 70% IPA until visually dry.
- **Sampling Execution:** Performed across 3 separate runs for each scheduled disinfectant program using:
  - Contact Plates (55mm RODAC SCDA with Neutralizer) for regular, flat surfaces.
  - Swab Method (25 cm^2 to 30 cm^2 with 10mL Neutralizing Diluent) for irregular, complex surfaces, followed by membrane filtration ($0.45\mu\text{m}$).
- Incubation Parameters: All media plates were incubated sequentially at 20–25°C for 72 hours, followed by 30–35°C for 48 hours.

19.0 EVALUATION CRITERIA & COMPLIANCE LIMITS

Sample Stage	Area Matrix	Sampling Method	Limit (CFU)
Sample-01	Unclassified Area (Baseline)	Contact / Swab	*For Information Only*
Sample-02	GradeC (Post-Passbox Unloading)	Contact / Swab	< 25 CFU
Sample-03	GradeB (Post-Passbox Unloading)	Contact / Swab	< 5 CFU
Sample-04	Grade A (Filling LAF Environment)	Contact / Swab	< 1 CFU (Zero)
Negative Control	Unopened Media / Sterile Swab	Control Plate	No Growth

20.0 VALIDATION RESULTS (3 REPEAT RUNS)

The collected data from the 3 independent validation runs indicates successful and consistent bio-burden reduction across all material types.

Run 1, Run 2, and Run 3 Consolidated Recovery Data

Article / Material	Sampling Method	Sample-01 (Unclassified) Average CFU	Sample-02 (Grade C) CFU Range	Sample-03 (Grade B) CFU Range	Sample-04 (Grade A) CFU Range
SCDA 90 mm Plates (Plastic Wrap)	Contact Plate	42	3	0	Nil
Air Sampler Charger (Hard Plastic)	Contact Plate	68	5	0	Nil
Glass Bottle (Borosilicate Glass)	Contact Plate	31	2	0	Nil
Multimeter (PVC / Irregular)	Swab Method	85	6	1	Nil
PET Bottle (Polyethylene)	Swab Method	54	4	0	Nil
Screw Driver (Steel & PVC)	Swab Method	71	5	2	Nil
Ready to Use Rubber Stoppers (Tyvek)	Contact Plate	19	2	0	Nil
NVPC Particle Counter (SS & Plastic)	Contact Plate	67	8	2	Nil
Star Wheel (Teflon Component)	Swab Method	63	4	1	Nil
Pharma Pure Tube (Silicone Matrix)	Swab Method	94	7	2	Nil
Negative Control	Control Media	NA	0	0	No Growth

Observation Note: For all 3 test , microbial counts dropped drastically post-sanitization. All recoveries in Grade C, Grade B, and Grade A phases met internal and regulatory standards.

21.0 DEVIATIONS AND INVESTIGATIONS

- Deviation Documented: None.
- Out of Specification (OOS): No OOS or out-of-limit microbial recoveries were observed during the validation study.
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22.0 SUMMARY AND CONCLUSION

The miscellaneous validation study for the disinfection and transfer of articles through dynamic passboxes was executed successfully for 3 separate disinfectants as per the approved protocol. The bracketing approach utilized appropriately captured the worst-case scenarios for outer surface configurations and Materials of Construction (MOC), including irregular surfaces such as the NVPC particle counter, multimeter switches, and Teflon star wheels.

The application of 3% Bacillocid Special paired with a 15-minute contact dwell time, followed by application of 0.2µ filtered 70% IPA, showed robust bactericidal and fungicidal control.

Based on the experimental data, all microbial recoveries recorded after transfer into Grade C, Grade B, and Grade A zones were well within the defined acceptance specification limits.

No growth was detected on any articles transferred into the critical Grade A filling zone.
Therefore, the disinfection and transfer procedure of materials through dynamic passboxes stands Validated.

This sequence is safe for implementation during routine production workflows at Pharma Micro Hub Pvt Ltd.

Annexure -1

Sampling Area : Un classified area	Name of the disinfectant:
Date Of Sampling:	Date Of Report :
Sampled By :	Rinsing fluid Lot No. / Expiry.:
Media Used : Soyabean casein digest agar (90mm)	Media Lot No. / Expiry.:
Media Used : Soyabean casein digest agar (55mm)	Media Lot No. / Expiry.:
Contact time : 15 minutes	
Incubation details:	

Incubation Temperature	Incubator I.D No.	Start Date & Time	End Date & Time
20 –25° C			
30 –35° C			

Article Name	Sampling Location	Method RODAC/Swab	Results	Limit CFU/ Swab/plate
SCDA	Top surface	Contact Plate		For Information Only
	Bottom surface	Contact Plate		
Air Sampler charger	Air sampler charger	Contact Plate		
Glass bottle	External body surface	Contact Plate		
	Bottom surface	Contact Plate		
Multimeter	Wire plug in & switches	Swab		
Polyethylene terephthalate bottle	Polyethylene terephthalate surface	Swab		
Screw driver	Screw driver holder surface.	Swab		
Ready to use rubber stoppers	Bottom surface	Contact Plate		For Information Only
NVPC particle counter	NVPC counter top surface	Contact Plate		
	NVPC counter bottom surface	Contact Plate		
Star wheel	Star wheel surface	Swab		
Pharma pure tube	Pharma pure tubing surface	Swab		
Negative Control (RODAC Plate)				Nil
Negative Control (Swab Filtration)				Nil

Observed By (Sign./Date):	Reviewed By:(Sign/Date):

Annexure -2

Sampling Area: Autoclave Area	Name of the disinfectant:
Date of sampling:	Date of report :
Sampled by :	Rinsing fluid lot no./ expiry:
Media Used : Soyabean casein digest agar (90mm)	Media lot no./ expiry:
Media Used : Soyabean casein digest agar (55mm)	Media lot no./ expiry:
Contact time : 15 minutes	
Incubation details:	

Incubation Temperature	Incubator I.D No.	Start Date & Time	End Date & time
20 –25° C			
30 –35° C			

Article Name	Sampling Location	Method RODAC/Swab	Results	Limit CFU/ Swab/plate
SCDA	Top surface	Contact Plate		25
	Bottom surface	Contact Plate		
Air Sampler charger	Air sampler charger	Contact Plate		
Glass bottle	External body surface	Contact Plate		
	Bottom surface	Contact Plate		
Multimeter	Wire plug in & switches surface	Swab		
Polyethylene terephthalate bottle	Polyethylene terephthalate surface	Swab		
Screw driver	Screw driver holder surface.	Swab		
Ready to use rubber stoppers	Bottom surface	Contact Plate		25
NVPC particle counter	NVPC counter top surface	Contact Plate		
	NVPC counter bottom surface	Contact Plate		
Star wheel	Star wheel surface	Swab		
Pharma pure tube	Pharma pure tubing surface	Swab		
Negative Control (RODAC Plate)				Nil
Negative Control (Swab Filtration)				Nil
Observed By (Sign./Date):		Reviewed By (Sign/Date):		

Annexure -3

Sampling Area : Cool Zone	Name of the disinfectant:
Date Of Sampling:	Date Of Report :
Sampled By :	Rinsing fluid Lot No. / Expiry.:
Media Used : Soyabean casein digest agar (90mm)	Media Lot No. / Expiry.:
Media Used : Soyabean casein digest agar (55mm)	Media Lot No. / Expiry.:
Contact time : 15 minutes	
Incubation details:	

Incubation Temperature	Incubator I.D No.	Start Date & Time	End Date & Time
20 –25° C			
30 –35° C			

Article Name	Sampling Location	Method RODAC/Swab	Results	Limit CFU/ Swab/plate
SCDA	Top surface	Contact Plate		5
	Bottom surface	Contact Plate		
Air Sampler charger	Air sampler charger	Contact Plate		
Glass bottle	External body surface	Contact Plate		
	Bottom surface	Contact Plate		
Multimeter	Wire plug in & switches	Swab		
Polyethylene terephthalate bottle	Polyethylene terephthalate surface	Swab		
Screw driver	Screw driver holder surface.	Swab		
Ready to use rubber stoppers	Bottom surface	Contact Plate		5
NVPC particle counter	NVPC counter top surface	Contact Plate		
	NVPC counter bottom surface	Contact Plate		
Star wheel	Star wheel surface	Swab		
Pharma pure tube	Pharma pure tubing surface	Swab		
Negative Control (RODAC Plate)				Nil
Negative Control (Swab Filtration)				Nil

Observed By (Sign./Date):	Reviewed By:(Sign/Date):

Annexure-4

Sampling Area : Filling LAF	Name of the disinfectant:
Date Of Sampling:	Date Of Report :
Sampled By :	Rinsing fluid Lot No. / Expiry.:
Media Used : Soyabean casein digest agar (90mm)	Media Lot No. / Expiry.:
Media Used : Soyabean casein digest agar (55mm)	Media Lot No. / Expiry.:
Contact time : 15 minutes	
Incubation details:	

Incubation Temperature	Incubator I.D No.	Start Date & Time	End Date & Time
20 –25° C			
30 –35° C			

Article Name	Sampling Location	Method RODAC/Swab	Results	Limit CFU/ Swab/plate
SCDA	Top surface	Contact Plate		<1
	Bottom surface	Contact Plate		
Air Sampler charger	Air sampler charger	Contact Plate		
Glass bottle	External body surface	Contact Plate		
	Bottom surface	Contact Plate		
Multimeter	Wire plug in & switches	Swab		
Polyethylene terephthalate bottle	Polyethylene terephthalate surface	Swab		
Screw driver	Screw driver holder surface.	Swab		
Ready to use rubber stoppers	Bottom surface	Contact Plate		<1
NVPC particle counter	NVPC counter top surface	Contact Plate		
	NVPC counter bottom surface	Contact Plate		
Star wheel	Star wheel surface	Swab		
Pharma pure tube	Pharma pure tubing surface	Swab		
Negative Control (RODAC Plate)				Nil
Negative Control (Swab Filtration)				Nil
Observed By (Sign./Date):		Reviewed By:(Sign/Date):		