



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	1 of 20	

1.0 OBJECTIVE:

To lay down a Procedure for Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Area, Manufacturing Area and Unit preparation area.

2.0 SCOPE:

This SOP is applicable for Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Area, Manufacturing area and Unit preparation Area in production department.

3.0 RESPONSIBILITY:

Operating Person: Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

HEPA	High Efficiency Particulate Air
LAF	Laminar Air Flow
Ltd.	Limited
No.	Number
Pvt.	Private
QA	Quality Assurance
RH	Relative Humidity
SS	Stainless Steel
SOP	Standard Operating procedure
UV	Ultra Violet
v/v	Volume by Volume
WFI	Water for Injection

6.0 PROCEDURE:

6.1 Precaution:

- 6.1.1 Perform the area cleaning and sanitization when there is no production activity/ whenever required.
- 6.1.2 For open equipment ensure that they are covered before cleaning and sanitization activity.
- 6.1.3 Handle the disinfectants carefully to avoid contact with skin and eyes.
- 6.1.4 Use only validated and approved filtered disinfectants. Do not use expired disinfectant solutions.
- 6.1.5 Take care to avoid disinfectant contamination with product.
- 6.1.6 Use the disinfectants in rotation on daily basis as per SOP to avoid the development of microbial resistance.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	2 of 20	

6.1.7 Cleaning should start from most critical area and end at less critical area.

6.1.8 Use separate lint free mop and fresh solution for cleaning of different areas to avoid contamination of mop and solution.

6.1.9 Perform cleaning and sanitization of dead plate (Depyrogenation Tunnel) from aseptic area. Record the cleaning details in respective logbook.

6.1.10 During cleaning and sanitization, door interlocking shall be in emergency mode.

6.1.11 Refer nomenclature described in SOP for ID of mop handle and mopping head.

6.1.12 ID of mop handle shall be embossed on each mop handle and ID of mopping head shall be marked on each mopping head at the time of issuance of mopping head.

6.1.13 Cleaning shall always be done in unidirectional manner (from top to bottom/ inside to outside /from more critical to less critical area)

6.1.14 After every two strokes of mopping, squeeze the mop in the empty bucket. Ensure approx. 10% overlapping between two mop strokes.

6.1.15 Discard the mopping head, if found dirty or damaged physically.

6.2 Schedule of Disinfectants:

6.2.1 Disinfectants shall be rotated on daily basis. Disinfectant shall be prepared and used as per the schedule mentioned in SOP.

6.3 General Cleaning Procedure to be followed in Sterile Area:

6.3.1 Collect the solid waste (if any) from aseptic area and pack it in double poly bag, label it, and send it for destruction to scrap yard.

6.3.2 Cleaning shall be performed using Three bucket system three bucket system includes:

6.3.2.1 First bucket containing water for injection.

6.3.2.2 Second bucket containing water for injection.

6.3.2.3 Third bucket empty.

6.3.2.4 Dip lint free mop in WFI Solution.

6.3.2.5 Clean the desired area.

6.3.2.6 Squeeze the used mop in empty bucket.

6.3.2.7 Dip the mop in SS bucket containing WFI and squeeze in empty bucket.

6.3.2.8 Clean the floor and coving with WFI by using lint free mop.

6.3.2.9 Clean the equipment, as per respective cleaning procedure.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	3 of 20	

6.3.2.10 Clean utility lines, HEPA filter grills, electrical fixtures, return air grill (outside), view panels, doors, corners, with a lint free mop dipped in WFI.

6.3.3 Sanitization shall be performed using three bucket system which includes.

6.3.3.1 First Bucket containing filtered scheduled disinfectant.

6.3.3.2 Second bucket containing water for injection.

6.3.3.3 Third bucket empty.

6.3.4 Dip lint free mop in filtered scheduled disinfectant solution.

6.3.5 Sanitize the desired area.

6.3.6 Squeeze the used mop in empty bucket.

6.3.7 Dip the mop in SS bucket containing WFI and squeeze in empty bucket.

6.3.8 Dip the mop in bucket containing sterile scheduled disinfectant and squeeze in empty bucket.

6.3.9 Sanitize the wall, floor and coving with schedule disinfectant solution by using lint free mop.

6.3.10 Sanitize the equipment, as per respective cleaning procedure.

6.3.11 Sanitize utility lines, HEPA filter grills, electrical fixtures, return air grill (outside), view panels, doors, corners, with a lint free mop dipped in scheduled disinfectant solution.

6.3.12 Clean and Sanitize the Drain Points as per SOP.

6.3.13 Mop SS cross over bench, SS tables & stools and LAF tops with lint free mop dipped in scheduled disinfectant solution.

6.3.14 After completion of the cleaning and sanitization activity Person involved in cleaning and sanitization activity shall exit from the aseptic area as per SOP and re-enter area (if required).

6.3.15 Record the cleaning and sanitization activities in cleaning and sanitization record.

6.3.16 Garment cubical shall be cleaned once in a day. In case of filling area garment cubical, open the sterile garment cubical, remove all the garments and keep in SS sterile container and close the lid. Clean the inner surface of garment cubical followed by outer surface with lint free mop dipped in scheduled disinfectant. Switch 'ON' the garment cubical for approximately 10 minutes for UV exposure. Transfer the garment from SS sterile container to garment cubical.

Frequency: Once in a day or whenever required.

6.3.17 Frequency of Cleaning of Accessories:

6.3.17.1 Ceiling, HEPA filters grills, tube light and electrical fixtures, return air grill shall be cleaned weekly once.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	4 of 20	

6.3.17.2 SS table, crossover bench, doors, view glass, walls, floors, SS pallets, sop stands, petri plate stands, SS trolley, SS bucket, used garment collection bin, mirror, status board, utility lines should be cleaned daily once.

6.3.17.3 Equipment's like LAF, tanks outer surface, tunnel in sequence are clean from upper to lower surface by scheduled approved filtered disinfectant.

6.3.17.4 In case of holidays / non-working days, AHU's will run as normal operation and cleaning and sanitization activity shall be performed on next working day.

6.4 Specific Cleaning and Sanitization Procedure for Sterile Area, Vial Washing, Ampoule Washing, Manufacturing Area and Unit Preparation Area, Hold Room:

6.4.1 For Sterile Area:

6.4.1.1 Sterile area cleaning and sanitization shall be performed as per below sequence:

	Ceiling & Walls
	Outer Surface of Equipments
	Accessories
	View Glass and Doors
	Floor

6.4.1.2 Daily Cleaning and Sanitization:

6.4.1.2.1 In daily cleaning, the cleaning of the area should be first with filtered WFI only to clean-up the spillage in the area. Disinfectant solution should be applied after cleaning the area.

6.4.1.2.2 Enter the sterile area as per SOP.

6.4.1.2.3 Take freshly prepared disinfectant solution scheduled for the day in one SS bucket, Filtered WFI in second bucket & third bucket empty.

6.4.1.2.4 Wipe the view glass & door with a lint free mop dipped in scheduled disinfectant solution.

6.4.1.2.5 Clean the external surface of all the equipments.

6.4.1.2.6 Floor shall be cleaned in the last stage of cleaning.

6.4.1.2.7 After every two strokes of moping, squeeze the mop in the empty bucket. Ensure approx. 10% overlapping between two mop strokes.

6.4.1.2.8 Clean the mop in filtered WFI kept in the second bucket.

6.4.1.2.9 Dip the mop in the disinfectant solution and continue the mopping.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	5 of 20	

6.4.1.2.10 After cleaning of one area, discard the used disinfectant & WFI and use fresh solution for another area.

6.4.1.2.11 Repeat the above procedure for cleaning of entire sterile area.

6.4.1.2.12 After completion of cleaning and sanitization activity, person performing cleaning/ sanitization shall replace the sterile area garment with fresh sterile area garment.

Frequency: At the end of the operation / at the end of the shift (in case of no production activity)/whenever required.

6.4.1.3 Weekly Cleaning and Sanitization :

6.4.1.3.1 In addition to daily cleaning and sanitization activity, clean the ceiling, with disinfectant solution as per schedule, pressure/temperature/RH measuring device, electrical fittings and telephone).

6.4.1.3.2 For fixtures having electrical fitting do not spray the schedule disinfectant, just wipe with dry lint free mop.

6.4.1.3.3 In case of tube light fixtures if foreign material or dust found then switch off the tube light, open the tube light fixtures from service floor and clean it using dry clean lint free mops.

FREQUENCY: Once in a week, at the end of the operation / at the end of the shift (in case of no production activity)/whenever required.

6.4.2 For Vial Washing, Ampoule Washing, Manufacturing area and unit preparation area, Hold room:

6.4.2.1 Vial washing, ampoule washing , manufacturing area and unit preparation area, hold room cleaning shall be performed as per below sequence:

	Ceiling & walls
	Outer surface of equipments
	Accessories
	View glass and doors
	Floor

6.4.2.2 Daily Cleaning and Sanitization:

6.4.2.2.1 Enter into the area as per respective SOP.

6.4.2.2.2 Ensure that the batch activity is not in progress in respective areas.

6.4.2.2.3 Wipe the view glass & door with a lint free mop dipped in scheduled disinfectant solution.

6.4.2.2.4 Floor shall be cleaned in the last stage of cleaning.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	6 of 20	

6.4.2.2.5 After every two strokes of moping, squeeze the mop in the bucket.

6.4.2.2.6 Dip the mop in the disinfectant solution and continue the mopping.

6.4.2.2.7 Repeat the above procedure for cleaning of entire areas.

6.4.2.2.8 After completion of cleaning and sanitization activity, person performing cleaning/sanitization shall replace the garment with fresh garment.

Frequency: At the end of the operation / at the end of the shift (in case of no production activity)/whenever required.

6.4.2.3 Weekly Cleaning and Sanitization:

6.4.2.3.1 In addition to daily cleaning activity, clean the ceiling, with disinfectant solution as per schedule, pressure/temperature/RH measuring device, electrical fittings and telephone).

6.4.2.3.2 For fixtures having electrical fitting do not spray the schedule disinfectant, just wipe with dry lint free mop.

6.4.2.3.3 In case of tube light fixtures if foreign material or dust found then switch off the tube light, open the tube light fixtures from service floor and clean it using dry clean lint free mops.

Frequency: Once in a week, at the end of the operation / at the end of the shift (in case of no production activity)/whenever required.

6.5 Transfer of Tools for Maintenance Purpose:

6.5.1 Tools & equipment required to carry the maintenance activity shall be carried in the sterile area, manufacturing area, vial washing and unit preparation area as:

6.5.1.1 A set of sterilized tools required for routine assembly shall be kept in the sterile area.

6.5.1.2 Tools from outside (if required), shall be transferred in the sterile area by sanitizing with scheduled disinfectant followed by dry mopping using lint free mop & 10 minutes UV exposure in pass box.

6.5.1.3 A set of tools required for routine assembly shall be kept in the vial washing and unit preparation area.

6.5.1.4 Tools from outside (if required), shall be transferred in respective area by sanitizing with scheduled disinfectant followed by dry mopping using lint free mop & 10 minutes UV exposure in pass box.

6.6 Cleaning/Sanitization Sequence of Grade C & D Area in Aseptic, Manufacturing, Vial/Ampoule Washing, Unit Preparation and Ampoule Hold Area:

6.6.1 Cleaning/Sanitization sequence of grade C & D area in aseptic area.

6.6.1.1 Fill the disinfectant solution in the bucket system.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	7 of 20	

6.6.1.2 One person shall perform the cleaning/sanitization of entry change room of aseptic area in below sequence.

↓	Aseptic area Corridor (Grade B)
	Entry change room III (Grade B)

6.6.1.3 Second person shall perform the cleaning/sanitization of return change room of aseptic area in below sequence.

↓	Return change room I (Grade C)
	Return change room II (Grade D)

6.6.1.4 Other person enters inside entry change room I from D area corridor, collect mop for cleaning and sanitization from return change room II (through double side open almira, located between entry change room I and return change room II). The person is then enters inside entry change room II for primary gowning and perform cleaning in sequence mentioned below:

↓	Entry change room II (Grade C)
	Entry change room I (Grade D)

6.6.2 Cleaning/Sanitization sequence of grade C & D area in manufacturing, vial/ampoule washing, unit preparation area and ampoule hold area.

6.6.2.1 Fill the disinfectant solution in the bucket system.

6.6.2.2 One person shall perform the cleaning/sanitization of entry change room of manufacturing, vial/ampoule washing and unit preparation area in below sequence.

↓	Entry change room II (Grade C)
	Entry change room I (Grade D)

6.6.2.3 Second person shall perform the cleaning/sanitization of return change room manufacturing, vial/ampoule washing, unit preparation and ampoule hold area in below sequence.

↓	Return change room I (Grade C)
	Return change room II (Grade D)



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	8 of 20

6.7 After cleaning & sanitization leave the area at least for 10 minutes to achieve the maximum effectiveness of used disinfectant solution.

6.8 After completion of cleaning & sanitization activity perform the fogging of area as per SOP.

6.9 Specific Cleaning and Sanitation Procedure for Hard to Clean Areas:

6.9.1 Specific cleaning and sanitization procedure for hard to clean areas to avoid accumulated waste, dust, debris and other similar material shall be done as shown in **Annexure VII**.

6.9.2 Frequency: At the end of the activity / at the end of the shift (in case of production activity) / whenever required.

6.10 Recording of Cleaning and Sanitization Activity:

6.10.1 Record the cleaning and sanitization details in “**Cleaning & Sanitization Record (Sterile Area)**” as per format shown in **Annexure-I**.

6.10.2 Record the cleaning and sanitization details in “**Cleaning & Sanitization Record (Unit Preparation Area)**” as per format shown in **Annexure-II**.

6.10.3 Record the cleaning and sanitization details in “**Cleaning & Sanitization Record (Vial Washing Area)**” as per format shown in **Annexure-III**.

6.10.4 Record the cleaning and sanitization details in “**Cleaning & Sanitization Record (Manufacturing Area)**” as per format shown in **Annexure-IV**.

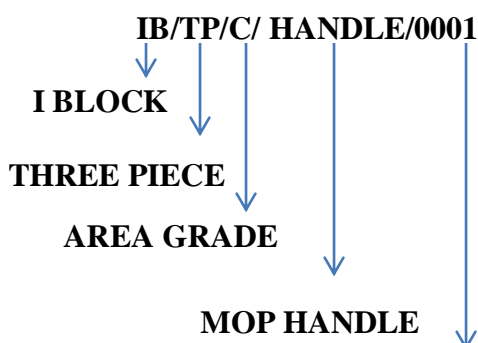
6.10.5 Record the cleaning and sanitization details in “**Cleaning & Sanitization Record (Ampoule Washing Area)**” as per format shown in **Annexure-V**.

6.10.6 Record the cleaning and sanitization details in “**Cleaning & Sanitization Record (Ampoule Hold Room)**” as per format shown in **Annexure-VI**.

6.10.7 Record the details of mopping head usage in “**Mopping head Usage Record**” as per format shown in **Annexure-VIII**.

6.10.8 Record the cleaning and sanitization details of grade D area in “**Cleaning & Sanitization Record (Grade D Area)**” as per format shown in **Annexure-IX**.

6.11 Nomenclature of Mop Handle ID and Mop Head ID.





PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	9 of 20	

SERIAL No.

6.11.1 Refer below abbreviations for nomenclature of Mop Handle ID and Mop Head ID:

IB	I Block
QB	Q Block
AMP	Ampoule
DPI	Dry Powder Inj.
TP	Three Piece
B/C/D	Area Grade
HANDLE	Mop Handle
HEAD	Mop Head

For example - IB/AMP/B/HEAD/0001 refers to mopping head no. 0001 of B grade area of ampoule section I block.

6.11.2 Record the issuance and destruction of mopping head in annexure- VIII "Mopping Head Usage Record"

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Cleaning & Sanitization Record (Sterile Area)	
Annexure-II	Cleaning & Sanitization Record (Unit Preparation Area)	
Annexure-III	Cleaning & Sanitization Record (Vial Washing Area)	
Annexure-IV	Cleaning & Sanitization Record (Manufacturing Area)	
Annexure-V	Cleaning & Sanitization Record (Ampoule Washing Area)	
Annexure-VI	Cleaning & Sanitization Record (Ampoule Hold Room)	
Annexure-VII	Pictorial Representation of Cleaning and Sanitation for hard to clean areas.	
Annexure-VIII	Mopping Head Usage Record	
Annexure- IX	Cleaning & Sanitization Record (Grade D Area)	

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	10 of 20	

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	11 of 20

ANNEXURE – I CLEANING & SANITIZATION RECORD (STERILE AREA)

Department : Production		Block:		Area :			
Date:			Date:				
Cleaning Schedule		Disinfectants Used		Cleaning Schedule		Disinfectants Used	
Cleaning Time (From & To) ⇒ Cleaning Details ↓		Cleaning Activity		Cleaning Time (From & To) ⇒ Cleaning Details ↓		Cleaning Activity	
Ceiling Cleaning (Weekly)				Ceiling Cleaning (Weekly)			
Wall Cleaning (Daily)				Wall Cleaning (Daily)			
Window & Glass Cleaning				Window & Glass Cleaning			
Door & Glass Cleaning				Door & Glass Cleaning			
Pallets & Furniture Cleaning				Pallets & Furniture Cleaning			
Equipment Cleaning (External Surface)				Equipment Cleaning (External Surface)			
LAF/RLAF (External Surface) except HEPA Filter				LAF/RLAF (External Surface) except HEPA Filter			
Other Surrounding Area				Other Surrounding Area			
Floor Cleaning & Mopping				Floor Cleaning & Mopping			
Other Items ,Dead plate & Accessories/Filling conveyor				Other Items, Dead plate & Accessories/ Filling conveyor			
Done By (Sign & Date)				Done By (Sign & Date)			
Checked By (Sign & Date)				Checked By (Sign & Date)			
Remarks				Remarks			



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	12 of 20

ANNEXURE II

CLEANING & SANITIZATION RECORD (UNIT PREPARATION AREA)

Department : Production		Block:		Line & Section:	
Area :					
Date:			Date:		
Cleaning Schedule	Disinfectants Used		Cleaning Schedule	Disinfectants Used	
Cleaning Time (From & To) ⇒ Cleaning Details ↓	Cleaning Activity		Cleaning Time (From & To) ⇒ Cleaning Details ↓	Cleaning Activity	
Ceiling Cleaning (Weekly)			Ceiling Cleaning (Weekly)		
Wall Cleaning (Daily)			Wall Cleaning (Daily)		
Window & Glass Cleaning			Window & Glass Cleaning		
Door & Glass Cleaning			Door & Glass Cleaning		
Pallets & Furniture Cleaning			Pallets & Furniture Cleaning		
Equipment Cleaning (External Surface)			Equipment Cleaning (External Surface)		
LAF (External Surface) except HEPA Filter			LAF (External Surface) except HEPA Filter		
Other Surrounding Area			Other Surrounding Area		
Floor Cleaning & Mopping			Floor Cleaning & Mopping		
Other Items & Accessories			Other Items & Accessories		
Done By (Sign & Date)			Done By (Sign & Date)		
Checked By (Sign & Date)			Checked By (Sign & Date)		
Remarks			Remarks		



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	13 of 20

ANNEXURE - III

CLEANING & SANITIZATION RECORD (VIAL WASHING AREA)

Department : Production		Block:		Line & Section:	
Area :					
Date:			Date:		
Cleaning Schedule		Disinfectants Used		Cleaning Schedule	
Cleaning Time (From & To) ⇒ Cleaning Details ↓		Cleaning Activity		Cleaning Time (From & To) ⇒ Cleaning Details ↓	
Ceiling Cleaning (Weekly)				Ceiling Cleaning (Weekly)	
Wall Cleaning (Daily)				Wall Cleaning (Daily)	
Window & Glass Cleaning				Window & Glass Cleaning	
Door & Glass Cleaning				Door & Glass Cleaning	
Pallets & Furniture Cleaning				Pallets & Furniture Cleaning	
Equipment Cleaning (External Surface)				Equipment Cleaning (External Surface)	
LAF (External Surface) except HEPA Filter				LAF (External Surface) except HEPA Filter	
Other Surrounding Area				Other Surrounding Area	
Floor Cleaning & Mopping				Floor Cleaning & Mopping	
Other Items & Accessories				Other Items & Accessories	
Done By (Sign & Date)				Done By (Sign & Date)	
Checked By (Sign & Date)				Checked By (Sign & Date)	
Remarks				Remarks	



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	14 of 20

ANNEXURE – IV

CLEANING & SANITIZATION RECORD (MANUFACTURING AREA)

Department : Production		Block:		Line & Section:	
Area :					
Date:			Date:		
Cleaning Schedule		Disinfectants Used		Cleaning Schedule	
Disinfectants Used		Cleaning Schedule		Disinfectants Used	
Cleaning Time (From & To) ⇒		Cleaning Activity		Cleaning Time (From & To) ⇒	
Cleaning Details ↓		Cleaning Activity		Cleaning Details ↓	
Ceiling Cleaning (Weekly)			Ceiling Cleaning (Weekly)		
Wall Cleaning (Daily)			Wall Cleaning (Daily)		
Window & Glass Cleaning			Window & Glass Cleaning		
Door & Glass Cleaning			Door & Glass Cleaning		
Pallets & Furniture Cleaning			Pallets & Furniture Cleaning		
Equipment Cleaning (External Surface)			Equipment Cleaning (External Surface)		
LAF (External Surface) except HEPA Filter			LAF (External Surface) except HEPA Filter		
Other Surrounding Area			Other Surrounding Area		
Floor Cleaning & Mopping			Floor Cleaning & Mopping		
Other Items & Accessories			Other Items & Accessories		
Done By (Sign & Date)			Done By (Sign & Date)		
Checked By (Sign & Date)			Checked By (Sign & Date)		
Remarks			Remarks		



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	15 of 20

ANNEXURE – V

CLEANING & SANITIZATION RECORD (AMPOULE WASHING AREA)

Department : Production		Block:		Line & Section:	
Area :					
Date:			Date:		
Cleaning Schedule	Disinfectants Used		Cleaning Schedule	Disinfectants Used	
Cleaning Time (From & To) ⇒ Cleaning Details ↓	Cleaning Activity		Cleaning Time (From & To) ⇒ Cleaning Details ↓	Cleaning Activity	
Ceiling Cleaning (Weekly)			Ceiling Cleaning (Weekly)		
Wall Cleaning (Daily)			Wall Cleaning (Daily)		
Window & Glass Cleaning			Window & Glass Cleaning		
Door & Glass Cleaning			Door & Glass Cleaning		
Pallets & Furniture Cleaning			Pallets & Furniture Cleaning		
Equipment Cleaning (External Surface)			Equipment Cleaning (External Surface)		
LAF (External Surface) except HEPA Filter			LAF (External Surface) except HEPA Filter		
Other Surrounding Area			Other Surrounding Area		
Floor Cleaning & Mopping			Floor Cleaning & Mopping		
Other Items & Accessories			Other Items & Accessories		
Done By (Sign & Date)			Done By (Sign & Date)		
Checked By (Sign & Date)			Checked By (Sign & Date)		
Remarks			Remarks		



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	16 of 20

ANNEXURE – VI

CLEANING & SANITIZATION RECORD (AMPOULE HOLD ROOM)

Department : Production		Block:		Line & Section:	
Area :					
Date:			Date:		
Cleaning Schedule	Disinfectants Used		Cleaning Schedule	Disinfectants Used	
Cleaning Time (From & To)⇒ Cleaning Details ↓	Cleaning Activity		Cleaning Time (From & To) ⇒ Cleaning Details ↓	Cleaning Activity	
Ceiling Cleaning (Weekly)			Ceiling Cleaning (Weekly)		
Wall Cleaning (Daily)			Wall Cleaning (Daily)		
Window & Glass Cleaning			Window & Glass Cleaning		
Door & Glass Cleaning			Door & Glass Cleaning		
Pallets & Furniture Cleaning			Pallets & Furniture Cleaning		
Equipment Cleaning (External Surface)			Equipment Cleaning (External Surface)		
LAF (External Surface) except HEPA Filter			LAF (External Surface) except HEPA Filter		
Other Surrounding Area			Other Surrounding Area		
Floor Cleaning & Mopping			Floor Cleaning & Mopping		
Other Items & Accessories			Other Items & Accessories		
Done By (Sign & Date)			Done By (Sign & Date)		
Checked By (Sign & Date)			Checked By (Sign & Date)		
Remarks			Remarks		



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	17 of 20	

ANNEXURE - VII

PICTORIAL REPRESENTATION OF CLEANING AND SANITATION FOR HARD TO CLEAN AREAS



1. Outer surface of pipe Line



2. Lower side cleaning of Conveyor



3. Inner Surface of Door Cleaning



4. Upper Surface of DGSC Cleaning





PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	18 of 20	

5. Lower Surface of DGSC Cleaning



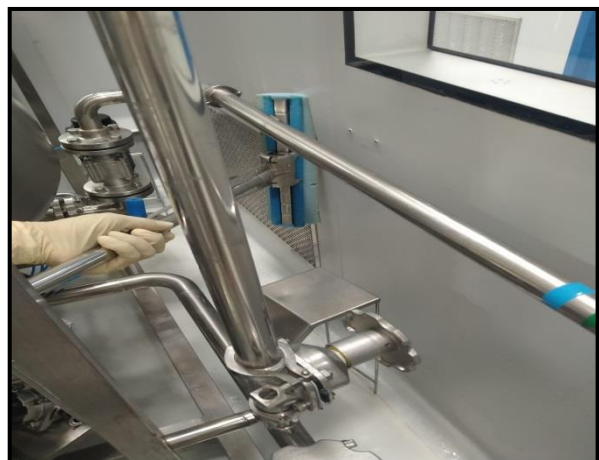
6. Lower side cleaning of vessel



7. PVC Curtains Cleaning



8. Back Surface of panel wall cleaning



9. Wall's Corner/Covings Cleaning

10. Back side of Vessels Cleaning



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	20 of 20

ANNEXURE – IX

CLEANING & SANITIZATION RECORD (GRADE D AREA)

Department : Production		Block:		Line & Section:	
Area :					
Date:			Date:		
Cleaning Schedule	Disinfectants Used		Cleaning Schedule	Disinfectants Used	
Cleaning Time (From & To)⇒ Cleaning Details ↓	Cleaning Activity		Cleaning Time (From & To) ⇒ Cleaning Details ↓	Cleaning Activity	
Ceiling Cleaning (Weekly)			Ceiling Cleaning (Weekly)		
Wall Cleaning (Daily)			Wall Cleaning (Daily)		
Window & Glass Cleaning			Window & Glass Cleaning		
Door & Glass Cleaning			Door & Glass Cleaning		
Pallets & Furniture Cleaning			Pallets & Furniture Cleaning		
Equipment Cleaning (External Surface)			Equipment Cleaning (External Surface)		
Other Surrounding Area			Other Surrounding Area		
Floor Cleaning & Mopping			Floor Cleaning & Mopping		
Other Items & Accessories			Other Items & Accessories		
Done By (Sign & Date)			Done By (Sign & Date)		
Checked By (Sign & Date)			Checked By (Sign & Date)		
Remarks			Remarks		