



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning of Utensil, SS Accessories and Machine Change Parts	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for Cleaning of utensil, SS accessories and machine Change parts.

2.0 SCOPE:

2.1 This procedure is applicable to cleaning of utensil, SS accessories and machine Change parts in Production department.

3.0 RESPONSIBILITY:

3.1 Technical Associate: Cleaning and Operation

3.2 Production Officer / Executive: Checking cleaning and operation

3.3 Head Production: SOP Compliance

3.4 IPQA Person: Line Clearance

4.0 DEFINITION (S):

4.1 **Utensils:** Utensils are tools to perform some routine unskilled activity during production.

4.2 **Container:** Container are use to hold the intermediate material (API or Excipient or Both).

5.0 PROCEDURE:

5.1 Cleaning procedure of Utensil/SS accessories after every use

5.1.1 Transfer the S.S accessories to be washed to the respective washing area.

5.1.2 Clean the utensils /accessories by rubbing with nylon scrubber (If applicable) with purified water to remove any residue or any traces of powder.

5.1.3 Finally rinse the utensil / accessories with help of purified water and dry the equipment using compressed air followed by dry lint free cloth.

5.1.4 Clean the SS scales used in coating area with purified water to remove any particles/residue or any traces and dry the SS scales by using dry clean lint free cloth.

5.1.5 Clean the SS frame and its base with wet lint free cloth to remove dust particles and traces followed by drying with dry lint free cloth.

5.1.6 Ensure no water droplet presence on utensil / ss accessories before put "cleaned" label.

5.1.7 Put 'CLEANED' status label on the utensils/accessories where required, having equipment ID, Previous product, Previous batch No. Done by, Checked by Production Officer, Date and finally checked by Quality Assurance (QA) as per reference SOP.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning of Utensil, SS Accessories and Machine Change Parts	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.2 Cleaning procedure of machine change parts after use

- 5.2.1 Dismantle the change parts from respective machine.
- 5.2.2 Transfer the machine change parts to the respective washing area for cleaning affix with TO BE CLEANED status label and cover with polybag.
- 5.2.3 Wash the change parts with purified water and by rubbing with nylon scrubber followed by lint free cloth to remove residue of previous product.
- 5.2.4 Finally rinse the change parts with purified water.
- 5.2.5 Dry the change parts completely with clean dry lint free cloth (or compressed air followed by lint free duster if applicable)
- 5.2.6 Ensure no water droplet presence on change parts after cleaning.
- 5.2.7 Cover all cleaned change part with virgin poly bag and affix with cleaned label.
- 5.2.8 Transfer the cleaned change parts to respective area and assemble the machine.

5.3 Cleaning procedure of Silicon pipe after every use

- 5.3.1 Transfer the silicon pipe to be washed to the respective washing area.
- 5.3.2 Attach purified water line to the one end of silicon pipe and start purified water supply.
- 5.3.3 Allow to pass the purified water till no residue of previous product presence inside the tube.
- 5.3.4 After cleaning drain the water completely from silicon pipe and pass compressed air to ensure no water droplet presence inside the silicon tube.
- 5.3.5 Visually check the integrity of silicon tube.
- 5.3.6 Place the silicon pipe on hanger in inverted position for dryness.
- 5.3.7 Placed the silicon tube into polybag and tie the open end of poly bag or cover the open end of silicon tube with aluminum foil incase cleaned silicon pipe not wrapped with poly bag.
- 5.3.8 Attach the "CLEANED" status label with date and signature of production officer/QA officer and then kept it at designated place.

5.4 Cleaning procedure of SS Pallet, SS trolley, cage trolley for material movement

- 5.4.1 Clean the outer and inner surface of SS pallet, SS trolley and cage trolley with wet lint free cloth followed by drying with dry lint free cloth.
- 5.4.2 Clean the handle of the SS pallet and cage trolley with wet lint free followed by drying with dry lint free cloth. Ensure no droplet presence inside and out side of trolley.
- 5.4.3 Clean the PU wheel of SS pallet trolley, SS trolley, cage trolley wet lint free cloth to remove dust particles and traces followed by drying with dry lint free cloth.
- 5.4.4 Put cleaned status label on cage trolley after confirmation of physical verification by production and QA.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning of Utensil, SS Accessories and Machine Change Parts	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.5 Cleaning procedure for IPC

- 5.5.1 Transfer the IPC to washing area for cleaning.
- 5.5.2 Clean the outer surface, inner surface, top lid along with groove and discharge port of IPC with 50L to 100 L (approx) of purified water to remove any particles/ residue or any traces.
- 5.5.3 Rub the inner surface, outer surface and discharge port with help of nylon brush and clean with 30 - 50L(approx) of purified water.
- 5.5.4 Remove the top lid gasket from the top lid with the help of Teflon screw driver and mop with wet lint free cloth followed by dry lint free cloth.
- 5.5.5 Use 2% w/v Sodium Lauryl Sulphate (For 1 liter 2% Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water), for cleaning if previous product is Efavirenz (API), followed by wet lint free cloth dipped with purified water.
- 5.5.6 Finally rinse cleaned IPC with 10-15 liter of purified water.
- 5.5.7 Dry the IPC by compressed air followed by clean lint free cloth. Mop the inner and outer surface with 70% v/v IPA solution.
- 5.5.8 Check the integrity of top lid gasket and assemble to the IPC. Use s.s. mirror and torch for checking the cleanliness.
- 5.5.9 Close the butterfly valve and top lid after cleaning of IPC. Shrink wrap or cover open portion of bin with virgin poly bag.
- 5.5.10 Clean the PU wheel with lint free cloth dipped into purified water followed by dry with dry lint free cloth.
- 5.5.11 Ensure no water droplet present into IPC before put the "CLEANED" label.
- 5.5.12 Put 'CLEANED status label having IPC No., Previous product, previous batch no, Done by, Checked by Production Officer, Date and finally checked by Quality Assurance (QA) as per reference SOP.
- 5.5.13 Record the cleaning activity in Annexure I.
- 5.5.14 IPC may also clean with bin washing machine as per reference SOP.

5.6 Cleaning procedure for SS Container

- 5.6.1 Transfer the SS Container to washing area for cleaning.
- 5.6.2 Clean the SS Container; Outer surface, inner surface and top lid (Inner and Outer surface) with purified water to remove any particles/ residue or any traces.
- 5.6.3 Clean the Outer surface, inner surface and top lid (Inner and Outer surface) with nylon brush.
- 5.6.4 Clean the sharp ends of SS container with the wet lint free cloth followed by dry lint free cloth.
- 5.6.5 2% w/v Sodium Lauryl Sulphate (For 1 liter 2% Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water), to be used for cleaning if the previous product is Efavirenz (API), followed by wet lint free cloth.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning of Utensil, SS Accessories and Machine Change Parts	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.6.6 Finally rinse cleaned SS Container with purified water.
- 5.6.7 Dry the SS Container by compressed air followed by clean lint free cloth.
- 5.6.8 Clean the PU wheel and trolley of SS Container (if applicable) with wet lint free cloth to remove dust particles and traces followed by drying with dry lint free cloth.
- 5.6.9 Mop the inner and outer surface with 70% v/v IPA solution. Ensure no droplet of water present inside the container.
- 5.6.10 Put 'CLEANED status label, Checked by Production Officer with Date and finally checked by Quality Assurance (QA) as per reference SOP.
- 5.6.11 Record the cleaning activity in Annexure II.

5.7 Cleaning procedure of Racks

- 5.7.1 Clean the surface area of Racks with wet lint free cloth followed by drying with dry lint free cloth
- 5.7.2 Ensure for no droplet presence on surface of racks.

5.8 Cleaning procedure for HDPE Container

- 5.8.1 Transfer the HDPE Container to washing area for cleaning.
- 5.8.2 Clean the Outer surface, inner surface of HDPE container and lid (Inner and Outer surface), label Holder with 5 - 10 Liter of purified water to remove any particles/ residue or any traces.
- 5.8.3 Finally rinse cleaned HDPE Container with approx. 2-5 liter of purified water.
- 5.8.4 Dry the HDPE by compressed air followed by cleaned lint free cloth.
- 5.8.5 Mop the inner and outer surface with 70% v/v IPA solution.
- 5.8.6 Ensure no droplet of Water present inside the container
- 5.8.7 Put 'CLEANED status label, Checked by Production Officer with date and finally checked by Quality Assurance (QA) as per reference SOP.
- 5.8.8 Record the cleaning activity in Annexure III.

5.9 Cleaning procedure for Rejection Box

- 5.9.1 Transfer the Rejection Box to washing area for cleaning.
- 5.9.2 Clean the Outer surface, inner surface of Rejection Box and lid (Inner and Outer surface), label Holder with 40-60 Liter of purified water to remove any particles/ residue or any traces.
- 5.9.3 Finally rinse cleaned Rejection Box with approx. 15-20 liter of purified water.
- 5.9.4 Dry the Rejection Box by compressed air followed by cleaned lint free cloth.
- 5.9.5 Mop the inner and outer surface with 70% v/v IPA solution.
- 5.9.6 Ensure no droplet of Water present inside the Box.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning of Utensil, SS Accessories and Machine Change Parts	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.9.7 Put 'CLEANED' status label, Checked by Production Officer with date and finally checked by Quality Assurance (QA) as per reference SOP.

Note: -

- 1) Visually check the accessories, machine change parts, silicon pipes, SS pallets, SS Trolley, Cage trolley, IPC and SS Container prior to use for cleanliness and checked by QA person. If found unclean then re-clean before use as per SOP. Clean all accessories after activity as per SOP.
- 2) Inspect all accessories, machine change parts, silicon pipes, and SS pallets, SS Trolley, IPC, rejection Box and SS Container prior to use for any damage and after use. If found damaged, intimate to the engineering for rectification as per SOP.
- 3) Shrink wrap/ cover with Polybag, Covers all the cleaned equipments, IPC (like open pores, hopper, exit chutes, sampling port, air vent, discharge ports and top lid) with poly bags or shrink wrap cleaned equipments.
- 4) For liquid manufacturing, rinse all the cleaned equipments with purified water before use.
- 5) All unclean accessories and change parts always carried out in virgin polybag for cleaning with status label "To Be Cleaned".
- 6) Always keep clean and unclean utensil, SS accessories and machine change parts separate. While undertaking cleaning activity ensure that no cleaned utensil, SS accessories and machine change parts etc. are present in the area if present then remove before start of cleaning activity
- 7) During production activity prior to movement of IPC, rejection box and SS Container from one cubical to other wheel must be cleaned with lint free cloth to prevent cross -contamination.
- 8) At a time cleaning activity for one product should carried out in wash area.
- 9) a) Visually done the verification of SS accessories monthly for integrity/break. If found "OK" records the same in Annexure-IV.
b) If SS accessories for integrity/break found 'Not OK' record the same in Annexure-IV. Reject the SS accessories and send to scrap yard.

6.0 ABBREVIATION (S):

- 6.1 SOP : Standard operating procedure
- 6.2 No. : Number
- 6.3 SS : Stainless Steel
- 6.4 PU : Poly Urethane
- 6.5 IPA : Iso Propyl Alcohol
- 6.6 V/V : Volume / Volume
- 6.7 IPC : In Process Containers



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning of Utensil, SS Accessories and Machine Change Parts	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

6.8 HDPE : High Density Propyl Ethylene

7.0 REFERENCE (S):

- 7.1 SOP No. : Management of change parts for liquid orals
- 7.2 SOP No. : Status Labeling
- 7.3 SOP No. : Procedure for breakdown maintenance.
- 7.4 SOP No. : Policy of cleaning of equipment's (General)
- 7.5 SOP No. : Cleaning of SS Bin (Blender)/ IPC with BIN washing and Drying System and with CIP pump.

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure I	Cleaning Checklist of IPC Container.		Log Book
Annexure II	Cleaning Checklist of SS Container.		Log Book
Annexure-III	Cleaning Checklist of HDPE container		Log Book
Annexure-IV	SS Accessories verification.		Log Book

9.0 DISTRIBUTION:

- 9.1 **Master Copy** : Quality Assurance
- 9.2 **Controlled Copy (S)** : Production department(02), Quality Assurance
- 9.3 **Reference Copy (S)** : Production department(03)

10.0 REVISION HISTORY

S.No.	Version No.	Change control no.	Reason (s) for revision	Details of revision	Effective date
1.0	00	NA	New SOP	NA	



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning of Utensil, SS Accessories and Machine Change Parts	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE I Cleaning Checklist of IPC

Name of the Equipment		IPC No.	
Previous product			
Batch No.		Date	

S.No.	Activity	Activity performed
1.	Transfer the IPC to washing area for cleaning.	
2.	Clean the outer surface, inner surface, top lid along with groove and discharge port of IPC with 50L to 100 L (approx.) of purified water to remove any particles/ residue or any traces.	
3.	Rub the inner surface, outer surface and discharge port with help of nylon brush and clean with 30 -50L(approx.) of purified water.	
4.	Finally rinse cleaned IPC with 10-15 liter of purified water.	
5.	Dry the IPC by compressed air followed by clean lint free cloth.	
6.	Mop the inner and outer surface of bin with 70% v/v IPA solution.	
7.	Check the integrity of top lid gasket and assemble to the IPC. Use s.s mirror and torch for checking the cleanliness.	
8.	Close the butterfly valve and top lid after cleaning of IPC. Shrink wrap or cover open portion of bin with virgin poly bag.	
9.	Clean the PU wheel with lint free cloth dipped into purified water followed by dry with dry lint free cloth.	
10.	Ensure no water droplet present into IPC before put the "CLEANED" label.	
11.	Put 'CLEANED status label having IPC No., Previous product, previous batch no, Done by, Checked by Production Officer, Date and finally checked by Quality Assurance (QA).	

Note: Use 2% w/v Sodium Lauryl Sulphate for cleaning if previous product is Efavirenz (API), followed by wet lint free cloth dipped with purified water.

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

Note: Put '√' mark if activity is performed and put 'X' if activity is not performed.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning of Utensil, SS Accessories and Machine Change Parts	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE II

Cleaning Checklist of Container

Name of the Equipment		IPC No.	
Previous product			
Batch No.		Date	

S.No.	Activity	Activity performed
1.	Transfer the SS Container to washing area for cleaning.	
2.	Clean the SS Container; Outer surface, inner surface and top lid (Inner and Outer surface) with purified water to remove any particles/ residue or any traces.	
3.	Clean the Outer surface, inner surface and top lid (Inner and Outer surface) with nylon brush.	
4.	Clean the sharp ends of SS container with the wet lint free cloth followed by dry lint free cloth.	
5.	Rinse cleaned SS Container purified water.	
6.	Dry the SS Container by compressed air followed by clean lint free cloth.	
7.	Clean the PU wheel and trolley of SS Container (if applicable) with wet lint free cloth to remove dust particles and traces followed by drying with dry lint free cloth.	
8.	Mop the inner and outer surface of bin with 70% v/v IPA solution. Ensure no droplet of water present inside the container.	
9.	Put 'CLEANED' status label, Checked by Production Officer with Date and finally checked by Quality Assurance (QA).	

Note: Use 2% w/v Sodium Lauryl Sulphate for cleaning if previous product is Efavirenz (API), followed by wet lint free cloth dipped with purified water.

Checked By (Prod.)
Sign/date

Verified By (QA)
Sign/date

Note: Put '√' mark if activity is performed and put 'X' if activity is not performed.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning of Utensil, SS Accessories and Machine Change Parts

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

ANNEXURE IV

SS Accessories Verification

Department: _____

Section\area: _____

Month: _____

S.No.	Name of Accessories	Jan		Feb		Mar		Apr		May		Jun		Jul		Aug		Sep		Oct		Nov		Dec		Remarks Ok\not ok
		I	O	I	O	I	O	I	O	I	O	I	O	I	O	I	O	I	O	I	O	I	O	I	O	
	Sign/date																									
	Sign/date																									
	Sign/date																									
	Sign/date																									

Note: Put issued quantity in "I" column and observed quantity at the end of the month in "o" column. Put ok incase if quantity issued is equal to observed quantity, otherwise put not ok and put details in rejected accessories at 02 of 02.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning of Utensil, SS Accessories and Machine Change Parts

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

Month	Name of Rejected Accessories	Rejected Qty.	*Reason of rejection	New Accessories Issued on	Checked By	Remarks
Jan						
Feb						
Mar						
Apr						
May						
Jun						
Jul						
Aug						
Sep						
Oct						
Nov						
Dec						

*Put reason of rejection like breakage during use, breakage during cleaning, dent in the accessories etc.