



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning of SS Bin (Blender)/ IPC with BIN washing and Drying System and with CIP pump	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for Cleaning of SS Bin/ IPC (blender).

2.0 SCOPE:

This procedure is applicable to Cleaning of Bin (blender) in Production department.

3.0 RESPONSIBILITY:

Technical Associate: Cleaning and Operation

Production Officer/Executive: Checking cleaning and operation

Head Production: SOP Compliance

IPQA Person: Verification of cleaning & Line Clearance

4.0 DEFINITION(S):

SS Bin/ IPC (blender).

5.0 PROCEDURE:

5.1 Cleaning of Bin Washing Machine

5.1.1 After the completion of cleaning activity of Bin put the "TO BE CLEANED" status label on equipment.

5.1.2 Clean the Outer surface and inner surface with dry lint free cloth followed by wet lint free cloth.

5.1.3 Dry the equipment by using clean lint free cloth and followed by compressed air.

5.1.4 Mop the inner and outer surface of bin washing machine with 70% v/v IPA solution.

5.1.5 Put 'CLEANED' status label 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.

5.1.6 Record the cleaning start and completion time in equipment usage log sheet as per SOP.

5.2 Frequency for cleaning of Bin Washing Machine

5.2.1 Cleaning of Bin Washing Machine to be done at the end of every shift and record the same in equipment usage log sheet as per SOP.

5.2.2 After cleaning of Bins, if Bin is not used within 72 hrs, then clean the bin "before use", at Bin Washing Machine with the recipe of "IBC-CLEANED" followed by dry lint free duster and dully sign the "CLEANED" label again. Record the activity in equipment usage log sheet as per SOP.

5.3 Operation of Bin Washing Machine



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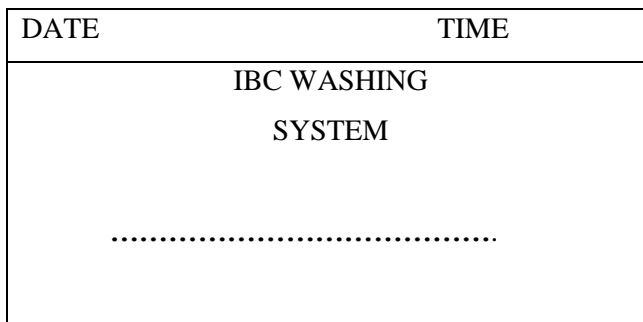
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- 5.3.1 Remove “CLEANED” status label of bin, open discharge valve, and remove the top lid gasket from the top lid with the help of Teflon screw driver and remove the gasket, then Place the unclean IPC in to the machine from “UNCLEAN DOOR” side.
- 5.3.2 Close the door and push the door for 3-4 Second to lock.
- 5.3.3 Switch ON main control supply from the unclean side, to power on the touch Panel and main control circuit of the system.
- 5.3.4 Fill the required soap solution (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) in the soap holding tank.

Note:

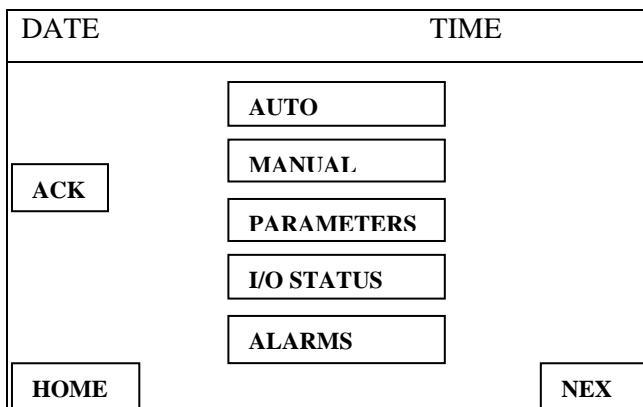
1. Before navigating the Touch Panel, ensure that all system required utilities are as per the requirement.

5.3.5 After switch on the panel the screen shows as follows-



5.3.6 From the main screen switch to the mode selection screen.

5.3.7 The screen shows as follows





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5.3.8 Here at this screen we select the Auto mode machine operation, manual mode machine operation, checking the input and output status of machine and alarm history as per requirement.

5.3.9 Enter all parameters as per required recipe in to the PARAMETER SCREEN as shows follows-

WASH RECIPE: _____				
1. Int Cold Wash -----	2. Ext cold wash -----			
3. Int Soap Wash -----	4. Ext Soap Wash -----			
5. Int Hot Rinse -----	6. Ext hot Rinse -----			
7. Ext purified wash -----	8. Int purified wash -----			
9. Air Purging -----	10. Drying -----			
NOTE: ALL TIMINGS ARE IN SEC.				
HOME	Store	Load	Delete	NEX

5.3.11 Recipe can be edited / loaded / deleted in before both auto and manual mode.

5.3.12 There are three level password protection for operation of machine are as follows-

1. Level One – Technical Associate, machine operation and cleaning. At Level one machine operates in Auto mode only.
2. Level Two – Officer & executive, operate the machine in auto and manual mode.
3. Level Three – Manager; Edit, delete and preparation of recipe.

5.3.13 Load the recipe.

5.3.14 Save the loaded recipe by pressing the ‘Save Recipe’ it shows:

Save Recipe Replace existing
Enter = Select, PREV = Cancel



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5.3.15 If you want to replace the existing recipe, then press 'Enter', and if you want to save as another one, then press the '▼'. The 'Replace existing, converted to 'Save as new', then press '<⏪'. Screen shows:

Save recipe as:

Name :

OK	CANCEL
----	--------

5.3.16 Enter name by press on PLC, then select 'Ok' by press '<⏪' and to save press '<⏪' again. Message shows 'Recipe saved'.

5.3.17 Press 'Load Recipe' it shows

1
Enter = Select, PREV = Cancel

5.3.18 Press 'Enter' message display

WARNING
Load recipe "1"?
YES NO

Press 'YES' recipe loaded.

5.3.19 Select the respective recipe, press '<⏪', screen shows warning message:

WARNING
Delete recipe "MAC"?
YES NO

Press 'YES', and '<⏪' recipe deleted.

5.3.20 To delete already exist recipe by pressing the 'Delete Recipe', screen shows:

ALL FILES
1
MAC
Enter = Select, PREV = Cancel

5.3.21 Then Press Next



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WASH RECIPE : _____

1. Int Cold Wash 200	2. Ext cold wash 150
3. Int Soap Wash 15	4. Ext Soap Wash 12
5. Int Hot Rinse 200	6. Ext hot Rinse 80
7. Ext purified wash 130	8. Int purified wash 90
9. Air Purging 20	10. Drying 900

NOTE: ALL TIMINGS ARE IN SEC.

HOME

Store

Load

Delete

NEXT

5.3.25 The saved recipe for 220 liter bin as follows-

IBC-220

WASH RECIPE : _____

1. Int Cold Wash 180	2. Ext cold wash 100
3. Int Soap Wash 15	4. Ext Soap Wash 12
5. Int Hot Rinse 150	6. Ext hot Rinse 80
7. Ext purified wash 130	8. Int purified wash 90
9. Air Purging 20	10. Drying 900

NOTE: ALL TIMINGS ARE IN SEC.

HOME

Store

Load

Delete

NEXT

5.3.26 The saved recipe for 50, 100, 125, 200 liter bin as follows-

IBC-25, 50, 100, 125, 200



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WASH RECIPE: _____				
1. Int Cold Wash 200	2. Ext cold wash 150			
3. Int Soap Wash 15	4. Ext Soap Wash 12			
5. Int Hot Rinse 200	6. Ext hot Rinse 80			
7. Ext purified wash 130	8. Int purified wash 90			
9. Air Purging 20	10. Drying 900			
NOTE: ALL TIMINGS ARE IN SEC.				
<input type="button" value="HOME"/>	<input type="button" value="Store"/>	<input type="button" value="Load"/>	<input type="button" value="Delete"/>	<input type="button" value="NEXT"/>

5.3.27 The saved recipe for Cleaned Bin are as follows-

IBC-CLEANED

WASH RECIPE: _____				
1. Int Cold Wash 0	2. Ext cold wash 0			
3. Int Soap Wash 0	4. Ext Soap Wash 0			
5. Int Hot Rinse 0	6. Ext hot Rinse 0			
7. Ext purified wash 60	8. Int purified wash 60			
9. Air Purging 20	10. Drying 900			
NOTE: ALL TIMINGS ARE IN SEC.				
<input type="button" value="HOME"/>	<input type="button" value="Store"/>	<input type="button" value="Load"/>	<input type="button" value="Delete"/>	<input type="button" value="NEXT"/>

5.4 Auto Operation of Bin Washing Machine

5.4.1 Press the AUTO from the mode selection screen.

5.4.2 The AUTO MODE SCREEN appears as shown below



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DATE	IBC WASHING SYSTEM	TIME
Wash Recipe	wwwwwwwwwwwwwwwwwwww	
AA		
DOOR CLOSE	HAND GUN	CYCLE
		CYCLE RESET
REMAINING TIME	IBC C	PARAMETERS
--0 sec	-----0	MON
		MIMIC
HOME	ACK	W/O SOAP
		HON
		ALARM

- 5.4.3 AUTO MODE SCREEN helps to operate the system in Auto Mode or in sequential manner.
- 5.4.4 Before operating this screen ensure all entered parameters and required utilities are correct and as per requirement.
- 5.4.5 Close unclean side door for continuous cycle and wait until PRESS START display on the STATUS block.
- 5.4.6 Select 'W/o SOAP' touch button if required.
- 5.4.7 Before start operation touch HON button of MMI only for 1200 Ltr. Bin and if bin is bare of 100,125,200,220,300,600 lts. ect. Then touch MON button.
- 5.4.8 To initialize the cycle press "CYCLE START" touch button.
- 5.4.9 All running status of continuous washing and drying cycle is displayed on this screen in SYSTEM STATUS block.
- 5.4.10 To reset the cycle press CYCLE RESET.
- 5.4.11 From here navigate to HOME and MIMIC screen.
- 5.4.12 Check the operating parameters by pressing the PARAMETERS. Below screen will display.



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DATE	TIME
<u>PARAMETER VIEW</u>	
Hot Water Temp	--0 °C
Hot Air Temp	--0 °C
Int Wah Pressure	--0 kg/cm sq
Ext Wash Pressure	--0 MMWC
	ACK

- 5.4.13 After completion of auto cycle machine stop automatically.
- 5.4.14 Open the clean side door and take IPC/Bin out from machine.
- 5.4.15 Put CLEANED label and keep cleaned IPC/Bin in cleaned equipment room.
- 5.4.16 Record the bin/ IPC cleaning start and completion time in equipment usage log sheet as per SOP.

5.5 Manual Operation of Bin Washing Machine

- 5.5.1 Select the MANUAL mode from the mode selection screen.
- 5.5.2 Follow the basic initial condition as auto mode.
- 5.5.3 To start any output touch the selected components in the screen as shown.

12/12/14	03:51:02
<u>PARAMETER VIEW</u>	
Hot Water Temp	--0 °C
Hot Air Temp	--0 °C
Int Wah Pressure	--0 kg/cm sq
Ext Wash Pressure	--0 MMWC
	ACK

- 5.5.4 The selected output and the flow will appear in green color when it is on.
- 5.5.5 To stop that running output touch again.
- 5.5.6 After completion of manual cycle machine stop.
- 5.5.7 Open the clean side door and take IPC/Bin out from machine.



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5.5.8 Mop the bin with IPA with lint free cloth.

5.5.9 Record the cleaning start and completion time in equipment usage log sheet as per SOP.

5.6 Cleaning procedure of SS Bin (Blender)/ IPC after every use with the CIP pump

5.6.1 After the completion of activity put the "TO BE CLEANED" status label on equipment and transfer the SS Bin/ IPC to be washed to the respective washing area.

5.6.2 Clean the SS Bin/ IPC (Outer surface, inner surface and discharge port) with sufficient quantity of purified water with the help of CIP pump to remove any particles/residue or any traces.

5.6.3 Clean the inner surface, outer surface and discharge port with nylon brush.

5.6.4 Remove the top lid gasket from the top lid with the help of Teflon screw driver and clean with wet lint free cloth followed by dry lint free cloth.

5.6.5 Clean the top lid groove with the with nylon brush.

5.6.6 Dismantle the air vent and clean it with purified water.

5.6.7 Clean the air vent with the wet lint free cloth followed by dry lint free cloth.

5.6.8 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 in the previous product is Efavirenz (API), followed by wet lint free cloth.

5.6.9 Finally rinse cleaned bin blender with purified water (bin blender 100 liter with 10-15 liter purified water, bin blender 200 liter with 10-20 liter purified water, bin blender 600 liter with 15-25 liter purified water, bin blender 1200 liter with 20-25 liter purified water, IPC 125 liter with 10-15 liter purified water and 220 liter IPC with 10-20 liter purified water).

5.6.10 Dry the equipment by using clean lint free cloth and followed by compressed air.

5.6.11 Mop the inner and outer surface of bin with 70% v/v IPA solution.

5.6.12 Check the integrity of top lid gasket and air vent filter and assemble to the SS Bin/ IPC blender at the time of use & check the inner surface of bin with the help of SS mirror & torch.

5.6.13 Close the butterfly valve, air vent and top lid after cleaning of bins. Shrink wrap or cover it with virgin poly bag.

5.6.14 Clean the PU wheel of SS Bin/ IPCs with wet lint free cloth to remove dust particles and traces followed by drying with dry lint free cloth.



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5.6.15 Put 'CLEANED' status label 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.

5.6.16 Record the bin/ IPC cleaning start and completion time in equipment usage log sheet as per SOP.

5.6.17 If the SS Bin/ IPC is idle for 72 hours or more after cleaning, then re-clean by moping with 70% v/v IPA solution before use and record the same in equipment usage log and on the clean status label as per reference SOP.

5.7 Precaution

5.7.1 At the running of machine if any alarm rise, then check the alarm and before acknowledge inform to maintenance for alarm.

5.7.2 Before start the operation check the all utility parameters like hot water temperature, hot air temperature, inlet wash pressure and external wash pressure.

Note

1. Visually check the bin/ IPC prior to use for cleanliness. If found unclean then re-clean before use as per SOP. Clean the bin after activity as per SOP. Inspect the bin for damage prior and after use. If found damaged, intimate to the engineering for rectification as per SOP.
2. Shrink wrap/ cover with Polybags: Covers the cleaned bins/ IPC (like open parts, hopper, exit chutes, sampling port, air vent, discharge ports and top lid) with poly bags or shrink wrap.

6.0 ABBREVIATION(S):

SOP: Standard operating procedure

No.: Number

SS: Stainless Steel

PU: Poly Urethane

7.0 REFERENCE(S):

SOP: Status Labeling

SOP: Policy of Cleaning of Equipment's (General)

SOP: Procedure for breakdown maintenance

8.0 ANNEXURE (S):



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Annexure- I: Cleaning Checklist of SS bin/ IPC

9.0

DISTRIBUTION:

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Reference copy (s) : Production department



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ANNEXURE I

CLEANING CHECKLIST OF SS Bin (BLENDER) / IPC

Name of the Equipment			
IPC No./SS Bin (Blender) No.		Previous product	
Batch No.		Date	

S.No.	Activity	Activity performed
1.	Cleaning of Outer surface, inner surface and discharge port.	
2.	Cleaning of top lid gasket and groove.	
3.	Check the integrity of top lid gasket and check the inner surface of IPC / SS Container visually.	
4.	Cleaning of PU wheel and trolley of IPC / SS Container.	
5.	Put 'CLEANED' status label having IPC No. / SS Container No., Previous product, Previous batch No. Done by, Checked by Production Officer, Date and finally checked by Quality Assurance (QA) as per reference SOP.	

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.