



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Bin Blender (Capacity 50, 100, 200, 300, 600, 1200 Liters)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

1.1 To lay down a procedure for cleaning and Operation of bin blender (Capacity 50/100/200/300/600/1200 liters).

2.0 SCOPE:

2.1 The procedure is applicable to the cleaning and Operation of bin blender (Capacity 50/100/200/300/600/1200 liters) in production department.

3.0 RESPONSIBILITY:

- 3.1 Technical Associate : Cleaning and Operation of Bin Blender
- 3.2 Officer and Executive : Supervision of cleaning and operation of Bin Blender
- 3.3 Head Production : SOP compliance
- 3.4 IPQA Person : Line Clearance

4.0 DEFINITION(S):

4.1 NA

5.0 PROCEDURE:

5.1 CLENGING

This is a cleaning procedure applicable for cleaning after completion of every batch or after maintenance of contact parts.

- 5.1.1 Affix dully filled "UNDER CLEANING" status label on equipment with date and signature of the Production Officer as per SOP.
- 5.1.2 Ensure that power supply is turned "OFF".
- 5.1.3 Dedust the equipment with lint free dry cloth.
- 5.1.4 Wipe the equipment with 70 % v/v IPA.
- 5.1.5 Record all the observations in the Equipment usage log sheet as per SOP.
- 5.1.6 The cleaned equipment is idle for 72 hours, after this period Wipe all the parts of equipment with 70% v/v IPA solution before use and should be a counter sign on previous "CLEANED" label by production & QA officer with date as per SOP.
- 5.1.7 Record the 70 % v/v IPA cleaning time of equipment in equipment usage logbook as per SOP.
- 5.1.8 Return air riser filter should be cleaned at the time of cleaning of product cleaning /descending potency /color.



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5.2 Frequency:

5.2.1 Cleaning is applicable after completion of every batch of same product or different product.

5.3 MACHINE OPERATION:

5.3.1 Ensure 'CLEANED' label duly filled and signed is affixed on the equipment. Ensure cleanliness of equipment and area. Remove the 'CLEANED' label and affix it in the respective BMR. Affix 'UNDER PROCESS' label duly filled and signed on the equipment and records all the observations in the Equipment Usage Log Sheet as per SOP.

5.3.2 Turn 'ON' the control 'ON/OFF' key. Opening screen shall appear within one minute with date and time displaying on the top LHS and RHS corners respectively.

5.3.3 Touch 'Login' on screen. Keypad will appear on screen. To open the digit keypad touch '0-9'. Load the correct password and then touch 'Enter' for confirmation.

Note: Three access levels have been provided in the machine.

Level 3 meant for recipe edit.

Level 2 and 1 are for machine operation in auto and manual mode.

5.4 Recipe Edition:

5.4.1 Access level 3. Touch 'Recipe Edit' on the screen. 'Recipe Edit – 1' screen will appear with following process parameters 'Product Name, Batch No., Operator Name, Mfg. Date, Exp. Date, Batch size'.

5.4.2 Load the Product Name, Batch No., Mfg. Date, Exp. Date, Batch size as per respective BMR.

5.4.3 Touch 'Recipe Edit' on the screen. 'Recipe Edit – 2' screen will appear with following process parameters 'Bunker Capacity, Pre-Lubrication Time, Blender RPM, Print Interval'.

5.4.4 Load the Bunker Capacity, Pre-Lubrication Time and Print Interval as per respective BMR.

NOTE: Blender RPM is fixed.

5.4.5 Touch 'Next' on screen. Loaded process parameters shall be display on the screen.

5.4.6 Touch 'Recipe Save' on the screen to save the recipe. Keypad will appear on screen. Give suitable name to the recipe and then touch 'Enter'. Previous screen will appear. To delete any of the already exist recipe touch 'Recipe Delete' on the screen. Stored recipe list will appear on screen. Select the recipe. Warning message 'Delete Recipe' will appear on screen. Touch 'Yes' to delete.

5.4.7 Touch 'Exit' on the screen. Opening screen will appear.

5.4.8 To select already loaded recipe, touch Load recipe on the screen. Stored recipe list will appear on screen. Touch the recipe as per respective BMR the touch 'Escape'. Selected stored recipe will be loaded.

5.5 Auto Mode Operation:



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- 5.5.1 Touch 'Auto mode' on the opening screen with Operation details as 'Pre-Lubrication Cycle'. Auto mode main screen will appear with instruction 'Unlock the Safety Railing and Open the Door'.
- 5.5.2 Touch 'OFF' to turn 'ON' auto mode operational.
- 5.5.3 Unlock the safety railing and touch 'OK'. Instruction 'Insert the Bunker' will display on the screen.
- 5.5.4 Insert the bunker and lock it firmly. Touch 'OK'. Instruction 'Close the Door and Lock the Safety Railing' will display on the screen.
- 5.5.5 Close the safety railing such that it will press the railing limit switch. Touch 'OK'. Instruction 'Lift the Bunker' will display on the screen.
- 5.5.6 Touch 'OK'. Blender bin will start lifting upward and stop automatically at the middle limit switch. Instruction 'Unlock the Safety Railing and Remove the Trolley' will display on the screen.
- 5.5.7 Unlock the safety railing and remove the trolley. Touch 'OK' on the screen. Instruction 'Lock the Safety Railing' will display on the screen.
- 5.5.8 Lock the safety railing. Touch 'OK'. Instruction 'Start the Cycle' will display on the screen. Touch 'OK'. Next screen will display the set and actual blending RPM and Time.
- 5.5.9 Touch 'Start' on the screen. Cycle will start as per set parameters and stops automatically after set blending time. Next screen will show operation details as 'Pre-Lubrication Cycle Finished' and instruction 'Unlock the Safety Railing and Insert the Trolley'.
- 5.5.10 Unlock the railing and adjust the trolley below the lifted blender bin. Touch 'OK'. Instruction 'Adjust the Trolley and Lower the Bunker' will display on the screen.
- 5.5.11 Touch and hold 'Down' on screen. Blender bin will start lifting down. Touch 'Up' key to lift up the blender bin, if required.
- 5.5.12 Screen will display operation details 'Lubrication Cycle' and instruction 'Unlock the Safety Railing and Open the Door'.
- 5.5.13 Unlock the safety railing and touch 'OK'. Instruction 'Add the Lubricant' will display on the screen.
- 5.5.14 Open the lid of blender bin and add the lubricant with SS scoop and firmly close the lid. 'OK'. Instruction 'Insert the Bunker' will display on the screen.
- 5.5.15 Insert the bunker and lock it firmly. Touch 'OK'. Instruction 'Close the Door and Lock the Safety Railing' will display on the screen.
- 5.5.16 Close the safety railing such that it will press the railing limit switch. Touch 'OK'. Instruction 'Lift the Bunker' will display on the screen.
- 5.5.17 Unlock the safety railing and remove the trolley. Touch 'OK' on the screen. Instruction 'Lock the Safety



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Railing' will display on the screen.

- 5.5.18 Lock the safety railing. Touch 'OK'. Instruction 'Start the Cycle' will display on the screen. Touch 'OK'. Next screen will display the set and actual blending RPM and Time.
- 5.5.19 Touch 'Start' on the screen. Cycle will start as per set parameters and stops automatically after set blending time. Next screen will show operation details as 'Pre-Lubrication Cycle Finished' and instruction 'Unlock the Safety Railing and Insert the Trolley'.
- 5.5.20 Unlock the railing and adjust the trolley below the lifted blender bin. Touch 'OK'. Instruction 'Adjust the Trolley and Lower the Bunker' will display on the screen.
- 5.5.21 Touch and hold 'Down' on screen. Blender bin will start lifting down. Touch 'Up' key to lift up the blender bin, if required.
- 5.5.22 Screen will display operation details 'Lubrication Cycle' and instruction 'Unlock the Safety Railing and Open the Door' will display on the screen.
- 5.5.23 Unlock the safety railing. Touch 'OK'. Instruction 'Remove the Bunker' will display on the screen.
- 5.5.24 Remove the blender bin. Touch 'OK'. Instruction 'Close the Safety Railing and Lock the Door' will display on the screen.
- 5.5.25 Close the safety railing. Touch 'OK'. Opening screen will appear.

5.6 Manual Mode Operation and Unloading:

- 5.6.1 Touch 'Manual Mode' on the opening screen. Manual mode main screen will appear.
- 5.6.2 Touch 'OFF' to turn 'ON' manual mode operational.
- 5.6.3 Load the Blending time and RPM as per respective BMR.
- 5.6.4 Open the safety railing and insert the bunker and close the safety railing.
- 5.6.5 Touch and hold the 'Cage Up'. Blender bin start lifting upward. When the blender bin will reach the middle limit switch release the cage up key.
- 5.6.6 Open the safety railing and remove the trolley and again close the safety railing.
- 5.6.7 Touch 'Start' key to start the operation.
- 5.6.8 Actual time and RPM will display on screen.
- 5.6.9 Operation will stop after set time.
- 5.6.10 Touch and hold 'Bypass'. Blender bin will start lifting up and stop at the upper limit switch.
- 5.6.11 Open the safety railing and place IPC below the outlet chute of the blending bin. Open the butterfly valve and unload the bin.
- 5.6.12 On completion of operation open the safety railing and insert the trolley and again close the safety



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railing.

- 5.6.13 Touch 'Cage Down' on the screen. Blender bin will start lifting down. Touch 'Cage Up', if required.
- 5.6.14 Open the safety railing and remove the blender bin. Close the safety railing.
- 5.6.15 Touch 'Main' on screen. Opening screen will appear.
- 5.6.16 Touch 'Log Out'. 'You Are Logged Out'. Turn 'OFF' the control key.
- 5.6.17 Take the blender bin to the 'Granules Store' area, if not unloaded.
- 5.6.18 Affix 'UNDER CLEANING' label duly filled and signed on the bin blender.
- 5.6.19 Affix 'UNDER CLEANING' labels duly filled and signed on blender bin, if unloaded.
- 5.6.20 Record all the observations in equipment Usage Log Sheet as per SOP.

6.0 ABBREVIATION (S):

- 6.1 IPA : Iso Propyl alcohol
- 6.2 SOP : Standard Operating Procedure.
- 6.3 No. : Number
- 6.4 v/v : Volume/Volume
- 6.5 BMR : Batch Manufacturing Record
- 6.6 IPC : In process container
- 6.7 QA : Quality Assurance
- 6.8 SOP : Standard Operating Procedure.

7.0 REFERENCE (S):

- 7.1 SOP: Making entries in equipment usage and cleaning log sheet.
- 7.2 SOP: Cleaning of production area
- 7.3 SOP: Status Labeling

8.0 ANNEXURE (S):

- 8.1 NIL

9.0 DISTRIBUTION (S):

- 9.1 **Master Copy:** Quality Assurance
- 9.2 **Controlled "Copy (S):** Production department (02), Quality Assurance (01)



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9.3 **Reference Copy (S):** Production department (01)

10.0 REVISION HISTORY:

S.No	Version No.	Change Control No.	Reason (s) for Revision	Details of revision	Effective Date
1.	00	NA	New SOP	NA	NA