



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Movement of Used Blender from Blending Area to Equipment Washing Area

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
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1.0 OBJECTIVE:

To lay down a Procedure for Movement of Used Blender from Blending Area to Equipment Washing Area.

2.0 SCOPE:

This SOP is applicable for Movement of Used Blender from Blending Area to Equipment Washing Area of Dry Powder Injectable Section.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

DPI	Dry Powder Injection
%	Percentage
IPA	Isopropyl Alcohol
Ltd.	Limited
LAF	Laminar Airflow Unit
No.	Number
QA	Quality Assurance
SOP	Standard Operating Procedure
WFI	Water for Injection

6.0 PROCEDURE:

- 6.1 After unloading of all blended sterile material in blending room under LAF recap of blender properly.
- 6.2 Wipe up entire outer surface of empty used blender and trolley with 70% IPA.
- 6.3 After mopping of used empty blender & trolley with 70% IPA, blender shall load on trolley and affix **"To Be Cleaned"** label and move towards cooling zone.
- 6.4 Open the sterile side door of Autoclave cum Bung processor.
- 6.5 Unload the blender in Autoclave cum Bung processor.
- 6.6 After loading of used blender in Autoclave cum Bung processor, close the sterile side door properly.
- 6.7 Communicate the message to the operator who is working in non sterile area of Autoclave cum Bung processor to unload used Blender for washing.
- 6.8 Non sterile area operator should open the non sterile area side door and ensure the status label affixed on blender.
- 6.9 Unload the blender to be clean on trolley of non sterile area.



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6.10 Move the trolley towards equipment washing area for washing purpose.

6.11 CLEANING OF AUTOCLAVE CUM BUNG PROCESSOR AFTER TRANSFER OF USED BLENDER:

6.11.1 Wipe up outside body of Autoclave cum Bung processor with wet sponge.

6.11.2 Wipe off all the inner surface of Autoclave cum Bung processor with wet sponge.

6.11.3 Wash thoroughly with Purified Water followed by final rinse with WFI.

6.12 CLEANING OF MANUFACTURING BLENDER AND TROLLEY:

6.12.1 Rub the blender by nylon brush using 0.1% SLS Solution.

6.12.2 Then wash with purified water and remove the any visible material with the help of nylon brush particularly the corners.

6.12.3 Wash thoroughly with Water for Injection (WFI).

6.12.4 Dry the blender with compressed air.

6.12.5 Wash the trolleys with Purified water finally rinse it with WFI.

6.12.6 Record the Blender Movement for Washing & Autoclave Cleaning details as per **Annexure-I**, Titled “**Cleaning of Used Blender, Movement & Autoclave Cum Bung Processor**”.

6.12.7 CLEANING FREQUENCY: After every transfer of used blender through Autoclave cum Bung processor.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Cleaning of Used Blender, Movement & Autoclave Cum Bung Processor	

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



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10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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

