



STANDARD OPERATING PROCEDURE

Title: Operation and Cleaning of Double Cone Blender

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

To lay down a Procedure for Operation and Cleaning of Double Cone Blender.

2.0 SCOPE:

This SOP is applicable for Operation and cleaning of Double Cone Blender provided in Production area in Dry Powder Injection Section.

3.0 RESPONSIBILITY:

Officer/Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
DPI	Dry Powder Injection
LAF	Laminar Air Flow
NMT	Not More Than
QA	Quality Assurance
QC	Quality Control
RH	Relative Humidity
SOP	Standard Operating Procedure
WFI	Water for Injection

6.0 PROCEDURE:

6.1 OPERATION:

Prior to Blending Operation following parameters are to be checked:

6.1.1 Ensure that temperature of Blending Room is NMT 25°C & RH is NMT 30%.

6.1.2 Assemble Sterilized Double Cone Blender on shaft.

6.1.3 “Switch ON” the electric supply.

6.1.4 Rotate the Blender by inching button in such a direction that dispensed materials are easily transferred to the Blender.



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- 6.1.5 Check the gross weight of all the containers having sterile powder, and record the same at specified column in the BMR respectively.
- 6.1.6 Dispense the required quantity of the materials under LAF.
- 6.1.7 Open the lid of the Blender by loosening its screw.
- 6.1.8 Transfer the dispensed materials in Blender and close its lid tightly.
- 6.1.9 Start the Blender and Blend the material for validated time as per the product.
- 6.1.10 After completion of blending intimate QA department to collect the sample for analysis of the said blend and handover to QC for Filling & Sealing release.
- 6.1.11 After QA sampling unloads the blend in sterile container and keeps it aside until it is released by QA for further processing.
- 6.1.12 Weigh all the container having blended powder for its gross weight individually.
- 6.1.13 Record the weighing details at specified column in the BMR respectively.
- 6.1.14 Record the operation details as per “**Machine Utilization Record**” in SOP Titled “**Machine Utilization Record**”.

6.2 CLEANING:

- 6.2.1 Disassemble the Double Cone Blender from shaft covered it with Polybag and transfer it to washing area in Container Closure Preparation Room.
- 6.2.2 Rinse it thoroughly with Purified Water.
- 6.2.3 Wipe it externally as well as internally by using 0.1% non-ionic SLS soap solution.
- 6.2.4 Rinse it thrice externally as well as internally thoroughly with Purified Water to remove the soap.
- 6.2.5 Finally rinse it with 10 liter WFI externally and internally twice.
- 6.2.6 Intimate to QC Department to collect the sample of final Rinse Water for wash water analysis.
- 6.2.7 After getting approval from QC/QA Department, sterilize the washed Double Cone Blender at 121°C for 30 minutes in Autoclave Cum Bung Processor.
- 6.2.8 Unload the sterilized Blender to sterile side and shift it to Blending Room & keep it under LAF.
- 6.2.9 Record the cleaning and sterilization details in “**Machine Utilization Record**” in SOP titled “**Machine Utilization Record**”.
- 6.2.10 **Frequency:** During Product Change Over/After 5 Batch of Similar Products in continuation / before processing of a batch to be manufactured in case after 12 hours from the completion of last Processed Product’s batch processing.



PHARMA DEVILS

PRODUCTION DEPARTMENT

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7.0 ANNEXURES:

Not Applicable.

ENCLOSERS: 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

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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