

PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE		
Department: Microbiology	SOP No.:	
Title: Cleaning and Operation Procedure for Bag Mixer	Effective Date:	
Supersedes: Nil	Review Date:	
Issue Date:	Page No.:	

1.0 PURPOSE:

To lay down the procedure for Cleaning and operation procedure of Bag mixer.

2.0 SCOPE:

This Standard Operating Procedure is applicable at Microbiology Department of

3.0 REFERENCES:

3.1 Instruction manual

4.0 **RESPONSIBILITY:**

- 4.1 Officer or Executive of Microbiology department shall be responsible for preparation of new or revision of existing SOPs.
- 4.2 Head of the department / designee of respective areas & QA shall be responsible for reviewing the SOPs.
- 4.3 Plant Head and Head-Quality shall be responsible for approval of SOP.
- 4.4 QA shall be responsible for distribution and control of SOPs to various departments.

5.0 ABBREVIATIONS:

- 5.1 CC : Change Control
- 5.2 IPA : Isopropyl alcohol
- 5.3 NA : Not Applicable
- 5.4 No. : Number
- 5.5 QA : Quality Assurance
- 5.6 QC : Quality Control
- 5.7 SOP : Standard Operating Procedure

6.0 DEFINITION:

6.1 **Standard Operating Procedure (SOP):** A written authorized procedure, which gives instructions for performing operations

7.0 PROCEDURE:

7.1 Cleaning Procedure:

7.1.1 Before start cleaning, ensure that the power switch is OFF



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- 7.1.2 Clean the internal as well as external surfaces using 70 % IPA.
- 7.1.3 Record the cleaning in the cleaning log as per Annexure-2.
- 7.1.4 Frequency of cleaning: Once in a month or as and when required.
- **7.2** Operation Procedure:
- 7.2.1 Connect the power cord to power point and switch on the power point.
- 7.2.2 Adjust the timer as per analysis requirement for which blending is to be carried out.
- 7.2.3 Open the door of the bag-mixer and put the stomacher bag containing sample such a way that half portion of bag including mouth will remain out of the bag-mixer.
- 7.2.4 Close the door of the bag-mixer, and paddles will move automatically till set time.
- 7.2.5 Open the door of the bag-mixer and remove the stomacher bag and close the door again.
- 7.2.6 Switch OFF the main Switch.

7.3 Maintenance:

7.3.1 In case of malfunctioning of equipment, "DO NOT USE" label shall be affixed on equipment and service engineer or location engineer shall be informed for rectification. After the rectification maintain the record as per Annexure-1.

8.0 **DISTRIBUTION:**

- 8.1 Quality Assurance
- 8.2 Quality Control

9.0 ANNEXURES:

- 9.1 Annexure- 1 : Equipment History Card
- 9.2 Annexure- 2 : Cleaning Log of Bag-mixer

10.0 REVISION HISTORY:

Version Number	Revision Details	Effective Date	Ref. Change Control Number