



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation and Cleaning of High Speed Linear Vial Washing Machine

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

To lay down a procedure for Operation and Cleaning of High Speed Linear Vial Washing Machine.

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of High Speed Linear Vial Washing Machine provided at Production department.

3.0 RESPONSIBILITY:

Operating Person – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

DPI	Dry Powder Injection
IPA	Iso Propyl Alcohol
ID No.	Identification Number
MCB	Miniature Circuit Board
MMI	Main Machine Interface
Ltd.	Limited
No.	Number
QA	Quality Assurance
SOP	Standard Operating Procedure
WFI	Water for Injection

6.0 PROCEDURE:

6.1 Precautions and Check Points:

- 6.1.1 Ensure and check the electric supply is “ON” with reference to indicator.
- 6.1.2 Ensure the cleanliness of the machine, & surrounding area is free from any unwanted materials or balance materials of previous products.
- 6.1.3 Ensure that all removable panels of machine are at the specified place.
- 6.1.4 After completion of vial washing activity, the filters installed in the vial washing machine shall be removed from filter housing and dry the filter by using filtered compressed air. Dried filters are placed in SS tray under LAF till next usage.
- 6.1.5 Ensure the availability of Compressed air, Purified Water and WFI in pressure limit tabulated below before proceeding the line clearance.



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S.No.	Filter	Vial Size (7.5 ml, 10 ml and 20 ml)
1.	Filtered Compressed Air Pressure	1.5 Kg/cm ² to 2.5 Kg/cm ²
2.	Recycle Water (Mixed of Purified Water & WFI)	1.5 Kg/cm ² to 2.5 Kg/cm ²
3.	Purified Water Pressure	1.5 Kg/cm ² to 2.5 Kg/cm ²
4.	Filtered WFI Pressure	1.5 Kg/cm ² to 2.5 Kg/cm ²
5.	WFI temperature	80°C to 90°C

6.1.6 Initially before start of vial washing, the recycle water tank is to be filled with Purified water.

6.1.7 Discard the in process checked vials record the data in respective BMR.

6.2 Machine Setting:

6.2.1 Check the electrical main supply of vial washing machine.

6.2.2 Start the main MCB (inside the panel).

6.2.3 Start main switch of Power Supply.

6.2.4 Check all utilities at user point as Purified Water, WFI and Compressed Air.

6.2.5 Open all Diaphragm valves of Re-cycle Water, Purified Water, and WFI & Compressed Air.

6.2.6 Fill the Purified Water Tank and WFI Tank provided in the machine.

6.2.7 Before starting washing operation, run the machine empty cycle for 10 minutes record in respective BMR.

6.2.8 Check the each nozzle for blockade by flushing with purified water.

6.2.9 If found nozzle pressure not ok follow the below steps;

6.2.9.1 Disassemble the row of blockage nozzle.

6.2.9.2 Check the physically nozzle condition if found blocked then replace it.

6.2.9.3 Rinse the silicone tubing in 70% IPA for throughout cleaning inside surface followed by rinsing with WFI and final flushing with filtered compressed air.

6.2.9.4 After complete cleaning & drying, assemble the washing machine parts at fixed location.

6.2.9.5 After assembly, repeat the procedure point no.6.2.8 and 6.2.9.

6.2.10 Start the De-Cartoning procedure in De-Cartoning Area as per SOP, Titled “**De-Cartoning of Vials, Nozzle and Cap**”.

6.2.11 Transfer the vials to High Speed Linear Vial washing machine Conveyor though De-cortoning conveyor after visual inspection of empty vials.



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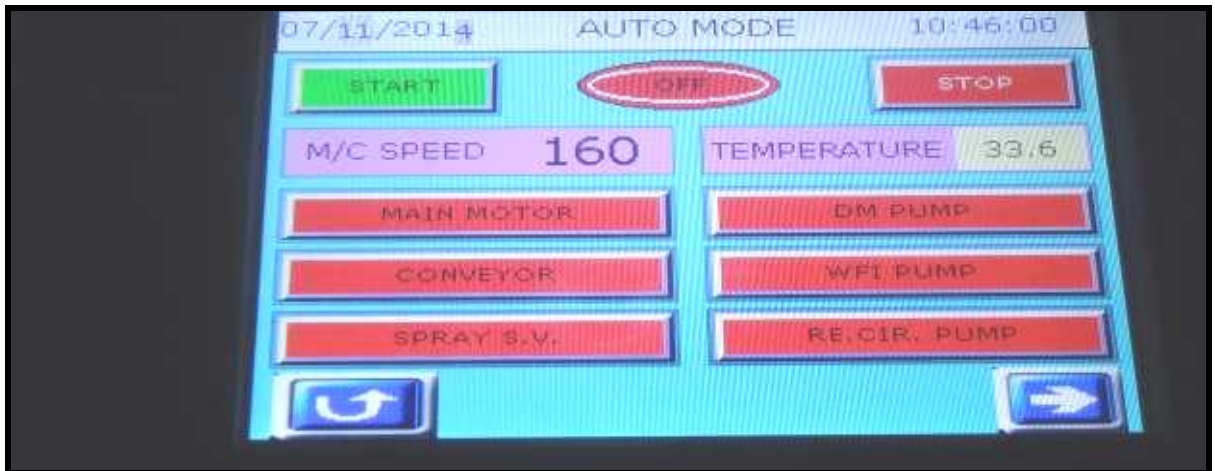
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6.3 Operation:

6.3.1 Put on the main switch control & following screen shall be display:



6.3.2 Press operation option on MMI screen & following screen shall display:



6.3.3 Now Press the ► key on the MMI screen & following screen shall display:

S.No.	Set machine speed (7.5 ml, 10 ml and 20 ml)	Observed machine speed
1.	240	120 vial/ min
2.	200	100 vial / min
3.	160	80 vial / min



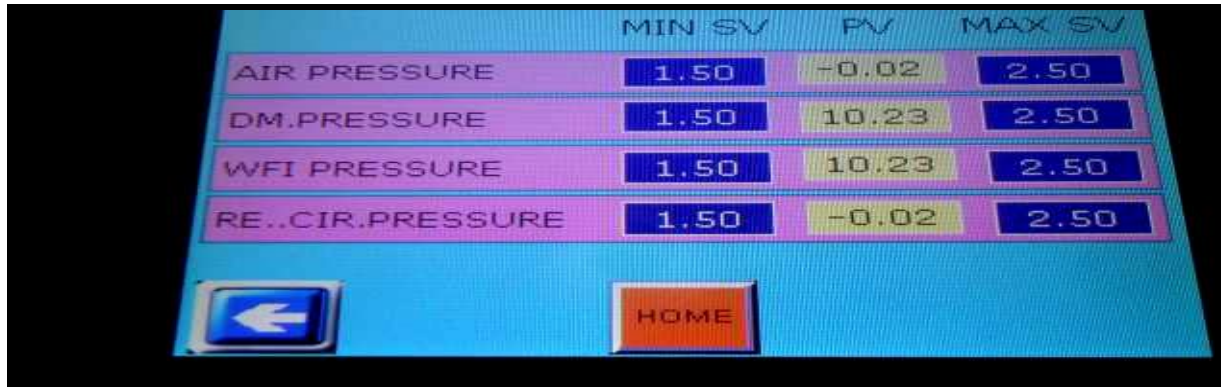
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6.3.4 Now press START key on the MMI screen to start Linear Vial Washing Machine.

6.3.5 Set the Washing machine speed by pressing Machine Speed Option on MMI screen.



6.3.6 Start main drive in slow speed and check the machine setting.

6.3.7 The vials are conveyed to In-feed Lifter through High Speed Linear Vial washing machine Conveyor.

6.3.8 The In-feed Lifter put the vials into the Cups automatically and now the vials get inverted position for washing.

6.3.9 Washing with Recycled Water, Purified Water, Water for Injection and Compressed Air alternatively as follows:

S.No.	Washing Sequence	Washing mode	
		Internal	External
1.	Vial Flushing with Filtered Compressed Air	Internal	
2.	Wash with Re-Cycled Water (Mixed of Purified Water and WFI)	Internal	External



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3.	Wash with Re-Cycled Water (Mixed of Purified Water and WFI)	Internal	
4.	Vial Flushing with Filtered Compressed Air	Internal	
5.	Wash with Purified Water	Internal	External
6.	Vial Flushing with Filtered Compressed Air	Internal	
7.	Wash with Purified Water	Internal	
8.	Vial Flushing with Filtered Compressed Air	Internal	
9.	Wash with Water for Injection	Internal	
10.	Vial Flushing with Filtered Compressed Air	Internal	

6.3.10 After washing of vials cycle, the out-feed Lifter unload the vials on dead plate of vial Sterilizing and Depyrogenating Tunnel for sterilization process and this process is continued till batch end.

6.3.11 During vial washing operation if any vial broken at in-feed of washing machine following action shall be taken:

6.3.11.1 Immediately stop the machine and remove broken Pieces of vials from washing machine chamber.

6.3.11.2 Remove the surrounding area vials which may affect due to glass pieces from broken vials.

6.3.11.3 Clean the chamber with purified water and final rinse with WFI.

6.3.12 Details of the cartridge filters used in Vial washing machine.

S.No.	Filter used for	Type of Filter	Pore Size	Filter Size	Replacement
1.	Water for Injection	Hydrophilic	5 μ	10 Inch	Physically damaged/ Filter Chock/ Integrity Fails/ 6 months \pm 7days from the date of installation
2.	Re-circulated Water	Hydrophilic	10 μ	10 Inch	
3.	Purified Water	Hydrophilic	5 μ	10 Inch	
4.	Compressed Air	Hydrophobic	0.2 μ	5 Inch	

6.4 Vial Clarity Test:

6.4.1 Stop the machine and collect 12 washed vials (one from each cup) with the help of forcep.



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- 6.4.2 Fill the half of the empty washed vials with WFI.
- 6.4.3 Cover the open mouth of WFI filled vials with clean and sterilized rubber stopper.
- 6.4.4 All covered vials transfer the IPQA office through DPB for visual inspection.
- 6.4.5 Vials should be free from any visible particulate matter.
- 6.4.6 If all the 12 vials found are free from any visible particulate matter, proceed for vial washing.
- 6.4.7 In case any of the vial contains test discrepancy for visible particulate matter then proceed one more verification (as per point 6.1) followed by one more confirmatory test if required raise the incident in case of confirmation of discrepancy for further line for action.
- 6.4.8 Discard the in process checked vials record the data in respective BMR.
- 6.4.9 **Frequency:** At start and End followed every one hour (Alternatively by production and QA) as per SOP.

6.5 Cleaning (End of Operation): Daily

- 6.5.1 Switch "OFF" the Machine.
- 6.5.2 Remove the side guard.
- 6.5.3 Clean the chamber by removing any broken glass or any particulate matter with lint free cloth.
- 6.5.4 Finally wash the chamber with Purified Water followed by WFI.
- 6.5.5 Clean the filter housing with Purified Water followed by WFI.
- 6.5.6 Mop the machine outer surface with lint free mopping pad of 70% IPA solution.
- 6.5.7 Cartridge filters for Compressed Air Re-circulated Purified Water and Water For Injection are cleaned in Unit Preparation area as per SOP, "Issuance, Usage, Replacement and Integrity Testing of Filters".
- 6.5.8 Drain the all water Tank and clean at the end of operation.
- 6.5.9 Ensure that every nozzle is washed properly and check physical status such as nozzle should not bend and correct as per designed.
- 6.5.10 Clean the Side guard with WFI and fixed it with Washing Machine chamber.
- 6.5.11 Carry out the cleaning operation every day at the end of Operation.
- 6.5.12 Record the vial washing machine filter cleaning detail and nozzle status as per **Annexure-I**, Titled "Vial Washing Machine Filter Cleaning Record".

6.6 Cleaning: Weekly



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6.6.1 Dismantle the washing machine nozzles & silicone tube for throughout cleaning.

6.6.2 Dip the nozzle in 70% IPA and clean the nozzle with the help of S.S wire.

6.6.3 Rinse the silicone tubing in 70% IPA for throughout cleaning inside surface.

6.6.4 Finally rinse with WFI and dry by using filtered compressed air.

6.6.5 After complete cleaning & drying, assemble the washing machine parts at fixed location.

6.7 Record the Operation & Cleaning details in “**Machine Utilization Record**” in SOP Titled “**Machine Utilization Record**”.

Note:-Frequency for Integrity:

Perform the filter integrity of Air filter - 15±2 Days.

6.8 Record the filter replacement in Annexure of Filter Issuance & Replacement Record of Vial Washing Machine.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Vial Washing Machine Filter Cleaning Record	
Annexure-II	Systematic Diagram of Glass Vial Washing Operation	
Annexure-III	Filter Issuance & Replacement Record of Vial Washing Machine	

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



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ANNEXURE-III SYSTEMATIC DIAGRAM OF GLASS VIAL WASHING OPERATION

Equipment:- Vial washing Machine, **Make:** – Ambika Pharma, **Model No.:-** AHLVWM-240, **Speed:-** 120 Vials Per Minute **Head Configuration:-** 12 Head

