



STANDARD OPERATING PROCEDURE

Title: Operation and Cleaning of Vertical Rotary Ampoule 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 Vertical Rotary Ampoule Washing Machine.

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Vertical Rotary Ampoule Washing Machine (Make: **TruKing Technology Ltd.**) in Production area at Ampoule Section.

3.0 RESPONSIBILITY:

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

B. No.	Batch Number
B. Size	Batch Size
ID No.	Identification Number
Ltd.	Limited
MPa	Mega Pascal
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 that proper electrical supply is provided to the machine.

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 proper working of the Ultrasonic transducer.

6.1.4 Ensure that removable Guard are at the specified place.

6.1.5 Check the pressure range of Recycle Water, Purified Water, WFI and Compressed Air as follow:

Filtered Air Pressure	:	0.2 Mpa to 0.6 Mpa
Recycle Water Pressure	:	0.2 Mpa to 0.5 Mpa
Purified Water Pressure	:	0.2 Mpa to 0.65 Mpa
Filtered WFI Pressure	:	0.2 Mpa to 0.5 Mpa



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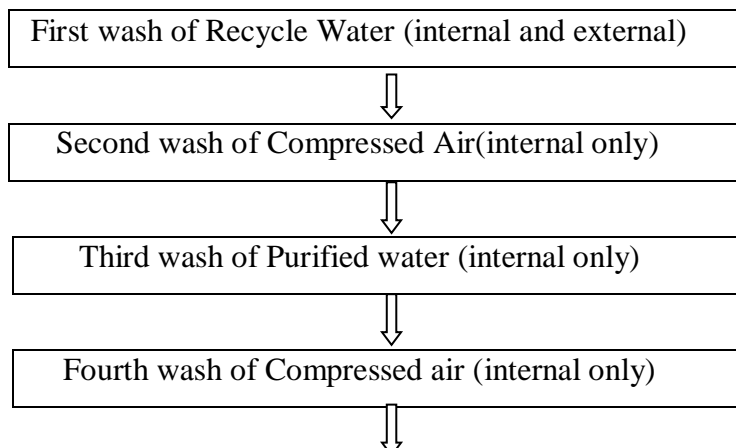
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6.2 MACHINE SETTING & OPERATION:

- 6.2.1 Before start the washing machine set the required change parts and adjusts the height as per ampoule to be washed.
- 6.2.2 Switch On Power Supply.
- 6.2.3 Check all utilities as purified water, WFI & compressed air.
- 6.2.4 Start the machine in auto system.
- 6.2.5 Open all Diaphragm valves of Re-cycle Water, Purified Water, and WFI & Compressed Air.
- 6.2.6 Fill the Recycle Water Tank with WFI provided in the machine.
- 6.2.7 Before starting washing operation, run the machine empty cycle for 10 minutes.
- 6.2.8 Start the De-Cartoning procedure in De-Cartoning Area as per SOP, Titled “**De-Cartoning of Ampoules**”.
- 6.2.9 Transfer the ampoules to Ampoule washing machine though conveyor after visual inspection of empty ampoules.

6.3 OPERATION:

- 6.3.1 Press main menu on screen and enter the password.
- 6.3.2 Press the parameter setting and set the required details as Date, B. No., Time, B. Size and Log out.
- 6.3.3 Go to production in main menu screen.
- 6.3.4 Start main drive in slow speed and check the machine’s worm setting and out feed turret setting.
- 6.3.5 Then adjust the ampoule grippers by gripped block.
- 6.3.6 After reaching to griper ampoule get inverted position and washing cycle follows as :

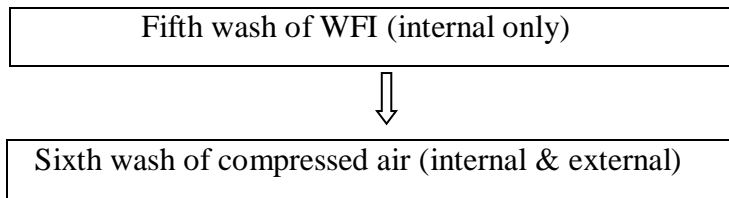




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6.3.7 After completion of all above processes grippers reverse the ampoules position and ampoules reaches to Out-feed Turret and then in to the Tunnel for sterilization process and this process is continued till batch end.

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

6.3.8.1 Immediately stop the machine and remove broken Pieces of ampoules from washing machine chamber.

6.3.8.2 Remove the surrounding area ampoules which may affect due to glass pieces from broken ampoules.

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

6.3.9 Details of the cartridge filters used in Ampoule washing machine.

S.No.	Filter location	Filter Type	Pore Size	Filter Size	Replacement
1.	Re-circulated water line	Hydrophilic	3.0 μ	10 Inch	Physically damaged/ Filter Chock/ 6 months from \pm 7days the date of installation
2.	Compressed Air line	Hydrophobic	0.2 μ	10 Inch	Physically damaged/ Filter Chock/ Integrity Fails/6 months \pm 7days from the date of installation
3.	Purified Water line	Hydrophilic	0.2 μ	10 Inch	Physically damaged/ Filter Chock/ Integrity Fails/6 months \pm 7days from the date of installation
4.	Water for Injection line	Hydrophilic	0.2 μ	10 Inch	Physically damaged/ / Filter Chock/ Integrity Fails/6 months \pm 7days from the date of installation

6.4 AMPOULE CLARITY TEST:

6.4.1 Stop the machine and take 20 washed ampoules with the help of forceps.

6.4.2 Fill half of the empty washed ampoules with WFI.



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6.4.3 Cover the open mouth of WFI filled ampoules with aluminium foil.

6.4.4 Visually check the clarity of Ampoules.

6.4.5 It should be free from any visible particulate matter.

6.4.6 Record the data in respective BMR.

6.4.7 Frequency:

6.4.7.1 At the time of start of the batch.

6.4.7.2 Every one hour. (Alternatively by production and QA).

6.5 NOZZLE BLOCKAGE TEST:

6.5.1 Physically check the each nozzle of ampoule washing machine with low pressure and slow speed of washing machine.

6.5.2 If any nozzle found blocked, Change the blocked nozzle with new one.

6.5.3 Record the data in respective BMR.

6.5.4 Frequency:

6.5.4.1 At the time of start of the batch.

6.5.4.2 Every one hour (Alternatively by production and QA).

6.6 CLEANING (END OF OPERATION): DAILY:

6.6.1 Switch off the Machine.

6.6.2 Remove the upper guard.

6.6.3 Clean the chamber by removing any broken glass or any particulate matter with lint free cloth.

6.6.4 Finally wash the machine with Purified Water followed by WFI.

6.6.5 Mop the machine from outside with the sponge or lint free cloth soaked with WFI.

6.6.6 Clean the Cartridge filters assembly for Re-circulated Water, Purified Water and Water for Injection with Purified Water followed by WFI.

6.6.7 Cartridge filters for Compressed Air, Re-circulated Purified Water and Water for Injection to be cleaned in Unit Preparation area as per **SOP, "Cleaning and Sterilization of Filters"**.

6.6.8 Fit the cleaned filters in their respective housing.

6.6.9 Drain the all water Tank and clean at the end of operation.

6.6.10 Ensure that every nozzle is washed properly and check physical status such as nozzle should not bend and correct as per designed.



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6.6.11 Clean the upper guard with WFI and attach it with Washing Machine at specified place.

6.6.12 Carry out the cleaning operation every day before startup of a shift and at the end of the shift.

6.6.13 Record the ampoule washing machine filter cleaning detail as per **Annexure-I**, Titled “**Ampoule Washing Machine Filter Cleaning Record**”.

6.7 CLEANING: WEEKLY

6.7.1 Dismantle the washing machine nozzles & tube for throughout cleaning.

6.7.2 Dip the nozzle in 70% IPA and washed the nozzle with the help of S.S wire.

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

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

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

6.8 Record the Operation & Cleaning details of Ampoule washing machine in Format “**Machine Utilization Record**”.

Note:- Frequency for Integrity:

Perform the filter integrity of Purified Water, WFI and Air filter - 15±2 Days.

6.9 Record the filter replacement in **Annexure-III**, “**Filter Issuance & Replacement Record of Ampoule Washing Machine**”.

7.0 ANNEXURES:

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

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



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ANNEXURE-II

SYSTEMATIC DIAGRAM OF GLASS AMPOULE WASHING OPERATION

Equipment:- Ampoule Washing Machine, **Make:-** Truking Technology, **Model No.:-** , **Speed:-** 450 Ampoule/minute, **Head Configuration:-** 12 Head

