



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
PROTOCOL
FOR
GARMENT WASHING MACHINE**

PROTOCOL No.:

**PERFORMANCE QUALIFICATION
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EQUIPMENT ID. No.	
LOCATION	Washing & Sterilization Area
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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1.0 PROTOCOL -APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			



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2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the **Garment Washing Machine (Make: LG) (Capacity- 7.0 Kg)** installed in Washing & Sterilization Area.
- This Protocol will define the methods and documentation used to qualify the Garment Washing Machine for Performance Qualification.



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4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this Protocol.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Initiation, Review, Authorization and Compilation of the Performance Qualification.• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity.• Monitoring of Performance Qualification. Activity.
Production	<ul style="list-style-type: none">• Review & Approval of Performance Qualification Protocol.• To co-ordinate and support Performance Qualification Activity.
Quality Control	<ul style="list-style-type: none">• Analytical Support (Microbiological Testing/Analysis)
Engineering	<ul style="list-style-type: none">• Review & Approval of qualification protocol for correctness, completeness and technical excellence.• Responsible for trouble shooting (if occurred during execution).• Maintenance & preventive maintenance as per schedule.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Garment Washing Machine
Equipment ID.	
Manufacturer's Name	
Supplier's Name	
Capacity	7 Kg.
Model	
S.No.	
Location of Installation	Washing & Sterilization Area

6.0 EQUIPMENT DESCRIPTION:

With 8 kg load capacity, Fully Automatic Garment Washing Machine can cater to the needs of everyone. The Garment Washing Machine is equipped with Turbo Clean technology that enables movement of the drum in the opposite direction of the pulsator, giving a perfect wash. The Punch +3 pulsator ensures that detergent rich water penetrates inside the fibers of the clothes. Its Fuzzy Logic control feature has built-in sensors that automatically sense the load capacity, detergent, water level, and decide the appropriate wash program. Along with perfect washing, you will get thoroughly rinsed clothes with this washing machine. Its waterfall circulation feature enables uniform circulation of water. The Air dry function helps in removing moisture from clothes eliminates bad odor and facilitates quick drying of clothes. Durable and sturdy, the washing machine comes with a rust resistant stainless steel tub which protects against stains and bad odor. There is an anti bacterial filter which ensures proper cleanliness as well as sanitation of the washing machine and clothes.

Main parts of Garment Washing Machine are as follow:

- 1) I-Sensor:** I-Sensor mark cleverly uses color schemes to indicate the amount of detergent using. Orange means less, green is proper and red stands for excessive detergent.
- 2) Water Inlet Control Valve:** Near the water inlet point of the washing there is water inlet control valve. When you load the clothes in washing machine, this valve gets opened automatically and it closes automatically depending on the total quantity of the water required. The water control valve is actually the solenoid valve.
- 3) Water Pump:** The water pump circulates water through the washing machine. It works in two directions, re-circulating the water during wash cycle and draining the water during the spin cycle.



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4) Tub: There are two types of tubs in the washing machine; inner and outer. The clothes are loaded in the inner tub, where the clothes are washed, rinsed and dried. The inner tub has small holes for draining the water. The external tub covers the inner tub and supports it during various cycles of clothes washing.

5) Agitator or Rotating Disc: The agitator is located inside the tub of the washing machine. It is the important part of the washing machine that actually performs the cleaning operation of the clothes. During the wash cycle the agitator rotates continuously and produces strong rotating currents within the water due to which the clothes also rotate inside the tub. The rotation of the clothes within water containing the detergent enables the removal of the dirt particles from the fabric of the clothes. Thus the agitator produces most important function of rubbing the clothes with each other as well as with water. In some washing machines, instead of the long agitator, there is a disc that contains blades on its upper side. The rotation of the disc and the blades produce strong currents within the water and the rubbing of clothes that helps in removing the dirt from clothes.

6) Motor of the Washing Machine: The motor is coupled to the agitator or the disc and produces it rotator motion. These are multispeed motors, whose speed can be changed as per the requirement. In the fully automatic washing machine the speed of the motor i.e. the agitator changes automatically as per the load on the washing machine.

7) Timer: The timer helps setting the wash time for the clothes manually. In the automatic mode the time is set automatically depending upon the number of clothes inside the washing machine.

8) Printed Circuit Board (PCB): The PCB comprises of the various electronic components and circuits, which are programmed to perform in unique ways depending on the load conditions (the condition and the amount of clothes loaded in the washing machine). They are sort of artificial intelligence devices that sense the various external conditions and take the decisions accordingly. These are also called as fuzzy logic systems. Thus the PCB will calculate the total weight of the clothes, and find out the quantity of water and detergent required, and the total time required for washing the clothes. Then they will decide the time required for washing and rinsing.

9) Drain Pipe: The drain pipe enables removing the dirty water from the washing that has been used for the washing purpose.

7.0 REASON FOR QUALIFICATION:

- New equipment in Washing & Sterilization Area.

8.0 SITE OF STUDY:

Washing & Sterilization Area.



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9.0 FREQUENCY OF QUALIFICATION:

- Once in a 2 year.
- After any major breakdown or after major modification.
- Periodically

10.0 PRE - QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- SOP for Operation & Cleaning of Garment Washing Machine.
- SOP for Preventive Maintenance of Garment Washing Machine



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11.0 TESTS AND CHECKS:

11.1 PARTICULATE MATTER TEST & PHYSICAL CHECK:

11.1.1 LOAD - I

A) OBJECTIVE:

To demonstrate that the Garment washing machine is able to wash the garments and eliminate the contamination (Particulate Matters) from the washed garments & maintaining their physical quality.

B) LOAD DETAILS:

- 05 Nos. Boiler Suit, 05 Nos. Head Gear & 5 Pair Socks (10 Nos.).

C) METHOD APPLIED:

- Press the POWER (AUTO OFF) button to turn power ON and open the water tap.
- Add the detergent through detergent charging port (0.2% SLS).
- Open the lid and add 05 Nos. Boiler Suit, 05 Nos. Head Gear & 5 Pair Socks (10 Nos.) into the washing tub and close the lid.
- Press the PROGRAM button to select the program (Quick Wash) and the start the cycle for 30 Minutes in Auto Mode.
- After completion of cycle, washed garments shall be inspected physically if there is any damage of garments like garments retained the color, no damage and holes, complete dryness and the easy movement of zips.
- Take 01 Nos. of Head Gear 01 no of Boiler suit and 01 Nos of socks Pair from the washed load and put them into individual beaker having one liter of particulate free water.
- Send 100 ml Water For TOC test.
- Take three test tubes of 200 ml and transfer approximately 100 ml of rinse water of head gear from above beaker and check for the presence of any foreign matter like black particle, fiber etc. visually.
- The above mentioned cycle shall be run 3 times to ensure the consistency of washing cycle.

D) ACCEPTANCE CRITERIA:

- The garments washed at above set parameter, retained the quality of the garments in terms of physical appearance like retained the color, no damage and tear, complete dryness and the easy movement of zips.
- The washed garments should be free from any foreign matter.
- TOC of Rinse Water NMT 500 ppb

E) RESULT RECORDING:

Record the Observations in Performance Qualification Report.



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11.1.2 LOAD - II

A) OBJECTIVE:

To demonstrate that the Garment washing machine is able to wash the garments and eliminate the contamination (Particulate Matters) from the washed garments & maintaining their physical quality.

B) LOAD DETAILS:

- 10 Nos. Booties (05 Pair).

C) METHOD APPLIED:

- Press the POWER (AUTO OFF) button to turn power ON and open the water tap.
- Add the detergent through detergent charging port (0.2% SLS).
- Press the PROGRAM button to select the program (Quick Wash) and the start the cycle for 30 Minutes in Auto Mode.
- Open the lid and add 10 Nos. Booties (5 Pair) into the washing tub and close the lid.
- After completion of cycle, washed garments shall be inspected physically if there is any damage of garments like garments retained the color, no damage and holes, complete dryness.
- Take 03 Nos. of booties from the washed load and put them into individual beaker having one liter of particulate free water.
- Send 100 ml Water For TOC test.
- Take three test tubes of 200 ml and transfer approximately 100 ml of rinse water of booties from above beaker and check for the presence of any foreign matter like black particle, fiber etc. visually.
- The above mentioned cycle shall be run 3 times to ensure the consistency of washing cycle.

D) ACCEPTANCE CRITERIA:

- The garments washed at above set parameter, retained the quality of the garments in terms of physical appearance like retained the color, no damage and tear, complete dryness.
- The washed garments should be free from any foreign matter.
- TOC of Rinse Water NMT 500 ppb.

E) RESULT RECORDING:

Record the Observations in Performance Qualification Report.



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11.1.3 LOAD - III

A) OBJECTIVE:

To demonstrate that the Garment washing machine is able to wash the garments and eliminate the contamination (Particulate Matters) from the washed garments & maintaining their physical quality.

B) LOAD DETAILS:

- 10 Nos. Lint free Duster (Mopping Pad).

C) METHOD APPLIED:

- Press the POWER (AUTO OFF) button to turn power ON and open the water tap.
- Add the detergent through detergent charging port (0.2% SLS).
- Open the lid and add 10 Nos. Lint free Duster (Mopping Pad) into the washing tub and close the lid.
- Press the PROGRAM button to select the program (Quick Wash) and the start the cycle for 30 Minutes in Auto Mode.
- After completion of cycle, washed garments shall be inspected physically if there is any damage of garments like garments retained the color, no damage and holes, complete dryness.
- Take 03 Nos. Lint free Duster from the washed load and put them into individual beaker having one liter of particulate free water.
- Send 100 ml Water For TOC test.
- Take three test tubes of 200 ml and transfer approximately 100 ml of rinse water of booties from above beaker and check for the presence of any foreign matter like black particle, fiber etc. visually.
- The above mentioned cycle shall be run 3 times to ensure the consistency of washing cycle.

D) ACCEPTANCE CRITERIA:

- The garments washed at above set parameter, retained the quality of the garments in terms of physical appearance like retained the color, no damage and tear, complete dryness.
- The washed garments should be free from any foreign matter.
- TOC of Rinse Water NMT 500 ppb

E) RESULT RECORDING:

Record the Observations in Performance Qualification Report.



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11.2 FOAMING TEST:

11.2.1 LOAD - I

A) OBJECTIVE:

To demonstrate that the Garment washing machine is able to wash properly without leaving the residue of washing agent.

B) LOAD DETAILS:

- 05 Nos. Boiler Suit, 05 Nos. Head Gear & 5 Pair Socks (10 Nos.).

C) METHOD APPLIED:

- Take 03 Nos. of Head Gear from the washed load and put them into individual beaker having one liter of particulate free water.
- Take three test tubes of 50 ml and transfer approximately 10 ml of rinse water of head gear from above beaker.
- Shake the test tube for presence of air bubble of soap solution if no foam observed then perform foaming test by adding 5 ml of chloroform and wait for approximately 2 minutes for the presence of white colored layer between Chloroform and Water (Which show the presence of Soap in the solution).
- The above mentioned cycle shall be run 3 times to ensure the consistency of washing cycle.

D) ACCEPTANCE CRITERIA:

- No White colored layer should be observed in Foaming test.

E) RESULT RECORDING:

Record the Observations in Performance Qualification Report.



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11.2.2 LOAD - II

A) OBJECTIVE:

To demonstrate that the Garment washing machine is able to wash properly without leaving the residue of washing agent.

B) LOAD DETAILS:

- 10 Nos. Booties (5 Pair).

C) METHOD APPLIED:

- Take 03 Nos. of booties from the washed load and put them into individual beaker having one liter of particulate free water.
- Take three test tubes of 50 ml and transfer approximately 10 ml of rinse water of booties from above beaker.
- Shake the test tube for presence of air bubble of soap solution if no foam observed then perform foaming test by adding 5 ml of chloroform and wait for approximately 2 minutes for the presence of white colored layer between Chloroform and Water (Which show the presence of Soap in the solution).
- The above mentioned cycle shall be run 3 times to ensure the consistency of washing cycle.

D) ACCEPTANCE CRITERIA:

- No White colored layer should be observed in Foaming test.

E) RESULT RECORDING:

Record the Observations in Performance Qualification Report.



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11.2.3 LOAD - III

A) OBJECTIVE:

To demonstrate that the Garment washing machine is able to wash the garments and eliminate the contamination (Particulate Matters) from the washed garments & maintaining their physical quality.

B) LOAD DETAILS:

- 10 Nos. Lint free Duster (Mopping Pad).

C) METHOD APPLIED:

- Take 03 Nos. Lint free Duster from the washed load and put them into individual beaker having one liter of particulate free water.
- Take three test tubes of 50 ml and transfer approximately 10 ml of rinse water of booties from above beaker.
- Shake the test tube for presence of air bubble of soap solution if no foam observed then perform foaming test by adding 5 ml of chloroform and wait for approximately 2 minutes for the presence of white colored layer between Chloroform and Water (Which show the presence of Soap in the solution).
- The above mentioned cycle shall be run 3 times to ensure the consistency of washing cycle.

D) ACCEPTANCE CRITERIA:

- No White colored layer should be observed in Foaming test.

E) RESULT RECORDING:

Record the Observations in Performance Qualification Report.



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12.0 CHECKLIST OF ALL TESTS & CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

- Verification of Documents.
- Verification of Performance by Physical Check.
- Verification of Performance by foaming test.
- Verification of Performance by Particulate Matter
- Verification of Test Report of TOC Test

13.0 REFERENCES:

The Principle References are as following:

- Validation Master Plan.
- Schedule - M – “Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.”
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2. Good Manufacturing Practices and Inspection.
- Operation and Cleaning of Garment Washing Machine.

14.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

15.0 NON COMPLIANCE:

- All the Non-compliances of procedure, specifications, sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.



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17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

18.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practices
FFS	:	Form Fill & Seal
GWM	:	Garment Washing Machine
Kg	:	Kilogram
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure
WHO	:	World Health Organization
SLS	:	Sodium Loryl Sulphate