



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
GARMENT WASHING MACHINE**

**PROTOCOL No.:**

**OPERATIONAL QUALIFICATION  
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FOR  
GARMENT WASHING MACHINE**

-6

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>Washing &amp; Sterilization Area</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDE PROTOCOL No.</b>	<b>NIL</b>



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**1.0 PROTOCOL PRE – APPROVAL:**

**PREPARED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OPERATING MANAGER (QUALITY ASSURANCE)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			



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**2.0 OBJECTIVE:**

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Garment Washing Machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

**3.0 SCOPE:**

- The scope of this Operational Qualification Protocol cum Report is limited to qualification of **Garment Washing Machine (Make: ..... ) (Capacity- 7.0 Kg)** installed in Washing & Sterilizations Area.
- This Operational Qualification Protocol cum Report will define the methods and documentation used to perform OQ activity of Garment Washing Machine.
- Successful completion of this Operational Qualification Protocol cum Report will verify that Garment Washing Machine meet all acceptance criteria and ready 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 cum Report:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, Approval and compilation of the operational Qualification Protocol cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Operational Qualification.</li><li>• Monitoring of Operation Process.</li><li>• Post Approval of Operational Qualification Protocol cum Report after Execution.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review of Operational Qualification Protocol cum Report.</li><li>• To Co-ordinate and support for execution of Operational Qualification study as per Protocol.</li><li>• Post Approval of Operational Qualification Protocol cum Report after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of Operational Qualification Protocol cum Report.</li><li>• To co-ordinate and support Operational Qualification Activity.</li><li>• Post Approval of Operational Qualification Protocol cum Report after Execution.</li></ul>



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**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Garment Washing Machine
<b>Equipment ID.</b>	
<b>Manufacturer's Name</b>	
<b>Supplier's Name</b>	
<b>Capacity</b>	7 Kg.
<b>Model</b>	
<b>Sr. No.</b>	
<b>Location of Installation</b>	Washing & Sterilization Area

**6.0 EQUIPEMENT DESCRIPTION:**

With 7 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.
- 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.



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**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 its 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 PRE - QUALIFICATION REQUIREMENTS:**

### **7.1 Verification of Documents:**

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- SOP for Operation & Cleaning of Garment Washing Machine.
- SOP for Preventive Maintenance of Garment Washing Machine



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**7.1.1 Procedure:**

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the OQ Protocol cum Report.

**7.1.2 Acceptance Criteria:**

All the documents should be available, complete and approved by respective authorities.





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**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 Verification of documents:**

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	DOCUMENT NAME	DOCUMENT / SOP No.	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING) SIGN/DATE	VERIFIED BY (QA) SIGN/DATE
1.	DQ Protocol cum Report				
2.	IQ Protocol cum Report				
3.	SOP for Operation & Cleaning of Garment Washing Machine.				
4.	SOP for Preventive Maintenance of Garment Washing Machine				

**Inference:**

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**Reviewed By  
(Manager QA)  
Sign/Date: .....**



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**8.2 Operational and Functional Checks:**

Operate the Garment Washing Machine as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

<b>COMPONENT</b>	<b>FUNCTION</b>	<b>OBSERVATIONS</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
<b>Start/ Pause Button</b>	Use to start or stop the washing machine.		
<b>Power (Auto Off) Button</b>	<ul style="list-style-type: none"><li>• Use to turn the power ON or OFF.</li><li>• Push again and power goes ON or OFF.</li></ul>		
<b>Different type of Washing Program</b>	Normal Wash, Strong Wash, Smart Rinse, Extra Rinse, Gentle Wash, Eco Wash, Favorite Wash, Silent Wash, Aqua Reserve Wash, Quick Wash, Soak Wash.		
<b>Water Level Button</b>	Use to select the proper amount of water in relation to the weight.		
<b>Inlet Water Temperature</b>	Use to select Water Temperature.		
<b>Time Left Button</b>	During Operation to indicate the remaining time.		
<b>Alarm Indication</b>	To show the error messages.		
<b>Program Button</b>	Use for selecting wash program.		
<b>Wash, Rinse, Spin Button</b>	Use when wash, rinse, spin time need to be adjusted.		
<b>Air Dry</b>	For air drying.		
<b>Child Lock Function</b>	Lock or Unlock the control buttons to prevent setting being changed.		



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<b>COMPONENT</b>	<b>FUNCTION</b>	<b>OBSERVATIONS</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
<b>Adjustable Legs</b>	Use to level the washing machine for correct balance and spin operation.		
<b>Water Supply Hose</b>	Ensure for any leakage of water.		
<b>Castor Wheels</b>	Use for easy translocation (At rear bottom edge).		
<b>Drain Hose</b>	Keep the drain hose flipped down while washing is in progress.		

**Checked By  
(Production)**

**Sign/Date:** .....

**Verified By**

**(Quality Assurance)**

**Sign/Date:** .....

**Inference:**

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**Reviewed By**

**(Manager QA)**

**Sign/Date:** .....



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**8.3 Power Failure Verification:**

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
<b>Main Power Shut Down</b>	Equipment stops in a safe and secure condition.		
<b>Main Power Restored</b>	Equipment can be restarted with no problems or adverse conditions.		

**Checked By  
(Production)  
Sign/Date: .....**

**Verified By  
(Quality Assurance)  
Sign/Date: .....**

**Inference:**

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.....

.....

**Reviewed By  
(Manager QA)  
Sign/Date: .....**





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**13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):**

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**14.0 CONCLUSION:**

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**15.0 RECOMMENDATION:**

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**16.0 ABBREVIATIONS:**

cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
GWM	:	Garment Washing Machine
ID.	:	Identification
IQ	:	Installation Qualification
MOC	:	Material of Construction
No.	:	Number
OQ	:	Operational Qualification
SOP	:	Standard Operating Procedure
WHO	:	World Health Organization



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**17.0 PROTOCOL POST -APPROVAL:**

**PREPARED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OPERATING MANAGER (QUALITY ASSURANCE)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			

**AUTHORIZED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			