# DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR GARMENT WASHING MACHINE

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|---|---|
| **DATE OF QUALIFICATION** | |
| **SUPERSEDE PROTOCOL No.** | **NIL** |

| PHARMA DEVILS | DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR GARMENT WASHING MACHINE | PROTOCOL No.: |
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## PROTOCOL CONTENTS

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## 1.0 PROTOCOL PRE – APPROVAL:

**PREPARED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| OFFICER/EXECUTIVE (QUALITY ASSURANCE) | | | |

**REVIEWED BY:**

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

**APPROVED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| HEAD (QUALITY ASSURANCE) | | | |

## 2.0 OBJECTIVE:

- To prepare the Design Qualification on the basis of user requirement, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

## 3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of **Garment Washing Machine (Make: LG (Capacity- 5.2 Kg)** to be installed in Microbiology department.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.

## 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:

| DEPARTMENTS | RESPONSIBILITIES |
|---|---|
| **Quality Assurance** | • Preparation, Review, Authorization and Compilation of Design Qualification Protocol cum Report.<br>• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.<br>• Co-ordination with Production and Engineering to carryout Design Qualification.<br>• Monitoring of Design Qualification Activity.<br>• Review of Design Qualification Protocol cum Report after Execution. |
| **Production** | • Review of the Design Qualification Protocol cum Report<br>• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.<br>• Review of Design Qualification Protocol cum Report after Execution. |
| **Engineering** | • Review of the Design Qualification Protocol cum Report. |

| DEPARTMENTS | RESPONSIBILITIES |
|---|---|
| | • Assist in the Preparation of the Protocol cum Report.<br>• To co-ordinate and support the Activity.<br>• To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e.<br>➢ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/ brochures.<br>➢ Details of utilities.<br>➢ Identification of components for calibration.<br>➢ Material of construction of all components.<br>➢ Brief Process Description.<br>➢ Safety Features and Alarms.<br>• Review of Design Qualification Protocol cum Report after Execution. |

## 5.0 PROJECT REQUIREMENTS:

To confirm that safe delivery of the equipment from the supplier site. To ensure that no unauthorized or unrecorded design modification shall take place.

If at any point in time, any change is desired in the mutually agreed design, change control procedure shall be followed and documented.

## 6.0 BRIEF PROCESS DESCRIPTION:

With 5.2 kg load capacity, **LG** 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 control system has in-built sensors that automatically sense the water level and temp. 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.

Main parts of Garment Washing Machine are as follow:

**1) 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.

**2) 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.

**3) 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.

**4) 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.

**5) 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.

**6) Timer:** The timer helps setting the wash time for the clothes manually. In the automatic mode the time is set automatically depending upon type of cycle to be processed.

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

## 7.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared for the manufacturer of equipment ensures complies with User Requirement Specification.

## 8.0 CRITICAL VARIABLES TO BE MET:

### 8.1 PROCESS/PRODUCT PARAMETERS:

| Critical variables | Acceptance criteria | Reference |
|---|---|---|
| **Application:** Garment Washing Machine is designed to wash the used garments. | Should be able to eliminate the dirty particles, grease, and oil from used garments. | Process Requirement |
| **Working:** Garment Washing Machine is designed to wash the used garments by 3- Step Washing (wash, rinse & spin). | Should be able to eliminate the dirty particles, grease, and oil from used garments and dry the items. | Process Requirement |

### 8.2 UTILITIY REQUIREMENTS/LOCATION SUITABILITY:

| Critical variables | Acceptance criteria | Reference |
|---|---|---|
| Utility connections should be available as per the manufacturer's specification. | | |
| **Electrical Supply** | Voltage : 220-240 V<br>Frequency : 50 Hz | GMP Requirement |
| **Purified Water** | 1 to 10 Kg/Cm² | Process Requirement |

## 8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

| S.No. | CRITICAL VARIABLES | ACCEPTANCE CRITERIA | REFERENCE |
|---|---|---|---|
| **1.** | Name | Front Loading Washing Machine | Design Requirements |
| **2.** | Color | Cream | |
| **3.** | Model | F8068NDP | Design Requirements |
| **4.** | Sr. No. | 104PNLP00352 | Design Requirements |
| **5.** | Weight | 59 kg | Design Requirements |
| **6.** | Max Watt | 1700W | Design Requirements |
| **7.** | Washing Capacity | 5.2 Kg | Design Requirements |
| **8.** | Dimension (W X D X H) | 600mm(W) X 440mm(D) X 850mm(H) | Design Requirements |
| **9.** | Temperature | Cold to 95º | Design Requirements |
| **10.** | Rated Voltage | 220-240 V, 50 Hz, 1700W | Design Requirements |
| **11.** | Permissible Water Pressure | 100 -1000 Kpa (1.0 – 10 Kgf/Cm2) | Design Requirements |
| **12.** | Program | Fuzzy / Wool / Quick Wash | Design Requirements |
| **13.** | Special programs | Cotton, Baby Care, Synthetic, Delicate, Hand wash/Wool, Quick 30, Rinse + Spin, Blanket & Cotton quick. | Design Requirements |
| **14.** | Washing Type | 3- Step Washing (Wash, Rinse & Spin). | Design Requirements |
| **15.** | Temperature Selection | Hot / Warm / Cold | Design Requirements |
| **16.** | Water inlet | Hot / Cold | Design Requirements |
| **17.** | Window (Glass Type) | Transparent (Glass) | Design Requirements |
| **18.** | Other Features | Auto Balance System, Child Lock, Medic Rinse, Pre-wash, Crease Care, Intensive, Time Delay, Spin, Temp. & Digital Display. | Process Requirements |
| **19.** | Inner Tube | Stainless Steel | Design Requirements |
| **20.** | Lip Type | Transparent | Design Requirements |
| **21.** | Control | Automatic | Design Requirements |
| **22.** | Wash Program | 9 (Main) + 4 (Others) | Process Requirements |

| S.No. | CRITICAL VARIABLES | ACCEPTANCE CRITERIA | REFERENCE |
|---|---|---|---|
| **23.** | Type | Front Load | Process Requirements |

## 8.4 MATERIAL OF CONSTRUCTION:

| S. NO. | PARTS NAME | MATERIAL OF CONSTRUCTION | REFERENCE |
|---|---|---|---|
| 1. | Powder Detergent Box | STD | Process Requirement |
| 2. | Magic Filter | STD | Process Requirement |
| 3. | Softener Inlet | STD | GMP Requirement |
| 4. | Bleach Dispenser | STD | GMP Requirement |
| 5. | Function Selector | STD | GMP Requirement |
| 6. | Inner Tube | Stainless Steel | Process Requirement |
| 7. | Tub | Stainless Steel | Process Requirement |
| 8. | Start/ Pause Button | STD | Process Requirement |
| 9. | Water Supply Hose | STD | Process Requirement |
| 10. | Power Plug | STD | Process Requirement |
| 11. | Nozzle | STD | Process Requirement |
| 12. | Castors | Polyurethane (PU) | GMP Requirement |
| 13. | Drain Hose | STD | Process Requirement |
| 14. | Base | STD | Process Requirement |
| 15. | Adjustable Legs | STD | Process Requirement |

**8.5 SAFETY:**

| CRITICAL VARIABLES | ACCEPTANCE CRITERIA | REFERENCE |
|---|---|---|
| Water Heater Safety | • Under certain conditions hydrogen gas may be produced in water heater that has not been used for two or more. Hydrogen gas can be explosive under these circumstances. If the hot water has not been used for two or more, prevent the possibility of damage or injury by turning on all hot water faucets and allowing them to run for several minutes. Do this before using any electrical appliance which is connected to the HOT water system. This simple procedure will allow any built-up hydrogen gas to escape. Since the gas is flammable, do not smoke or use an open flame or appliance during this process. | Safety Requirement |
| When not in use | • Wipe off dirt or dust on the controls of the power plug.<br>• At the time of cleaning the washing machine, do not apply water directly to any part of the washing machine. | Safety Requirement |
| Electrical wiring and Earthing. | • Electrical wiring should be as per approved drawings. Double external earthing to control machine panel and motors should be provided. | Safety Requirement |
| Start On/Off switch: To Stop the process immediately. | • Should be provided for equipment and operator safety. | Safety Requirement |
| Noise Level | • Below 80 db | Safety Requirement |

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| CRITICAL VARIABLES | ACCEPTANCE CRITERIA | REFERENCE |
|---|---|---|
| Laundry Area | • Keep the area underneath and around the appliances free of combustible materials such as lint, paper, rags, chemicals etc. Operating with such materials around the machine may trigger explosion or fire.<br>• Do not touch the power plug with a wet hand, it will cause electric shock.<br>• Do not put the hand, foot or anything under the washing machine while the machine is in operation, there is a rotating mechanism under the machine, can cause injury. | Safety Requirement |
| When using the washer | • Make sure that drainage is working properly.<br>• If during spinning, opening the lid does not stop the tub within about 15 seconds, immediately discontinue operating the machine.<br>• Never reach into the machine while it is running. Wait until the machine has completely stopped before opening the lid.<br>• Do not use water hotter than 60˚C.<br>• Ensure no water logging near or below washer to prevent rusting.<br>• Do not use a plug socket and wiring equipment for more than their rated capacity. | Safety Requirement |
| MCB | • MCB is provided so that when there is an overload in current or any short circuit then the MCB trips. | Safety Requirement |
| Safety Guards | • Guards for all moving parts should be provided for safety. | Safety Requirement |

## 8.6 VENDOR SELECTION:

| Critical variables | Acceptance criteria | Reference |
|---|---|---|
| Selection of Vendor for supplying the Garment Washing Machine. | Selection of Vendor is done on the basis of review of vendor.<br>Criteria for review should include vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feedback from market (customers already using the equipment). | Process Requirement |

**Reference:** (1) Specifications and Requirements as specified in P.O. and URS.

**Checked By**
**(Engineering)**
**Sign/Date:** ……

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

**Inference:**

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

## 9.0 DOCUMENTS TO BE ATTACHED:

- Purchase Order Copy.
- Any other relevant documents.

## 10.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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## 11.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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## 12.0 RECOMMENDATION:

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## 13.0 ABBREVIATIONS:

| | | |
|---|---|---|
| AC | : | Alternating Current |
| cGEP | : | Current Good Engineering Practice |
| cGMP | : | Current Good Manufacturing Practice |
| db | : | Decibel |
| GA | : | General Arrangement |
| GWM | : | Garment Washing Machine |
| HP | : | Horse Power |
| Hr | : | Hour |
| Hz | : | Hertz |
| Kg | : | Kilogram |
| MOC | : | Material of Construction |
| NMT | : | Not More Than |
| P & ID | : | Piping and Instrumentation Diagram |
| PCB | : | Printed Circuit Board |
| PO | : | Purchase Order |
| SS | : | Stainless Steel |
| STD | : | Standard |
| URS | : | User requirement specification |
| V | : | Voltage |
| W | : | Watt |

## 14.0 REVIEWED BY:

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| HEAD (ENGINEERING) | | | |

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| HEAD (PRODUCTION) | | | |

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| HEAD (QUALITY ASSURANCE) | | | |