DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR GARMENT WASHING MACHINE

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

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

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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)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

2.0 OBJECTIVE:

- To prepare the Design Qualification on the basis of URS, 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- 7.0 Kg)** to be installed in Washing Sterilization Area.
- 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. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity. • Review of Design Qualification Protocol cum Report after Execution.
Production	• Review of the Design Qualification Protocol cum Report • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Design Qualification Protocol cum Report after Execution.
Quality Control	• Review of Design Qualification Protocol cum Report after Execution.
Engineering	• Review of the Design Qualification Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e. ➢ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/ brochures. ➢ Details of utilities. ➢ Identification of components for calibration. ➢ Material of construction of all components. ➢ Brief Process Description. ➢ Safety Features and Alarms. • 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 un-authorized 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 7 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 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.

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 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 (Rubbing, rubbing & shaking, shaking and disentangling).	Should be able to eliminate the dirty particles, grease, and oil from used garments.	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 V Input : 460 W Phase : 3 Phase Frequency : 50 Hz	GMP Requirement
Purified Water	0.3 to 10 Kg/Cm²	Process Requirement

8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S. No.	Critical Variables	Acceptance Criteria
1.	Name	Front Loading Washing Machine
2.	Model	FH296HDL24.AL SPEPL(IN)
3.	Sr.No.	…….
4.	Capacity (Direct Drive)	6.0 Kg
5.	Dimension (W X D X H)	600 X 440 X 850
6.	Rated Voltage	220 V, 50 Hz 2100W
7.	Color	White
8.	Pulsator	Punch + 3
9.	Program	Fuzzy / Wool / Quick Wash
10.	Special programs	Smart Rinse / Tub Clean / Aqua Reserve / Favorite
11.	Washing Type	3- Step Washing (Rubbing, rubbing & shaking, shaking and disentangling).
12.	Temperature Selection	Hot / Warm / Cold
13.	Hot/ Cold Water inlet	Hot / Cold
14.	Water level Selection	10
15.	Window (Glass Type)	Transparent (Glass)
16.	Other Features	Auto Balance System, Child Lock, Digital Display, Memory Backup, Turbo Soak, Fuzzy logic control, Air Dry, Health + Filter, Turbo drum, I-Sensor, Waterfall Circulation.
17.	Delay Start (Hrs.)	Yes (3 ~ 48 Hrs.)
18.	Inner Tube	Stainless Steel
19.	Lip Type	Transparent
20.	Control	Fully Automatic
21.	Wash Program	12
22.	Type	Front Load
23.	RPM	1400

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. • 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. • Do not touch the power plug with a wet hand, it will cause electric shock. • 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. • If during spinning, opening the lid does not stop the tub within about 15 seconds, immediately discontinue operating the machine. • Never reach into the machine while it is running. Wait until the machine has completely stopped before opening the lid. • Do not use water hotter than 60˚C. • Ensure no water logging near or below washer to prevent rusting. • Do not use a plug socket and wiring equipment for more than their rated capacity.	Safety Requirement

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
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. 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.

Verified By
(Quality Assurance)
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
FFS	:	Form Fill Seal
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 (QUALITY CONTROL)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			