

PROTOCOL No.:

EQUIPMENT ID. No.	
LOCATION	Washing & Sterilization Area
DATE OF QUALIFICATION	
SUPERSEDES REPORT No.	NIL



PROTOCOL No.:

PROTOCOL CONTENTS

S.No.	TITLE	PAGE No.
1.0	REPORT PRE-APPROVAL	3
2.0	OBJECTIVE	4
3.0	SCOPE	4
4.0	RESPONSIBILITY	5
5.0	EQUIPMENT DETAILS	6
6.0	PRE-QUALIFICATION REQUIREMENTS	6
7.0	TESTS & CHECKS	7-16
8.0	CHECKLIST OF ALL TESTS & CHECKS	17
9.0	DOCUMENTS ATTACHED	18
10.0	NON COMPLIANCE	18
11.0	DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY	18
12.0	CHANGE CONTROL, IF ANY	18
13.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY)	19
14.0	CONCLUSION	19
15.0	RECOMMENDATION	19
16.0	ABBREVIATIONS	20
17.0	REPORT POST APPROVAL	21



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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 predefined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The Report covers all aspects of Performance Qualification for the **Garment Washing Machine** (Make: LG (Capacity- 7.0 Kg) installed in Washing & Sterilization.
- The Report provides all the relevant information of Performance Qualification Activity for Garment
 Washing Machine and all the observation of in-process checks and analytical results of analyzed
 samples.



PROTOCOL No.:

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 Performance Qualification Report.

DEPARTMENTS	RESPONSIBILITIES
	Preparation, Review, Authorization and Compilation of the
	Performance Qualification Report.
Quality Assurance	Co-ordination with Quality Control, Production and Engineering to
	carryout Performance Qualification Activity.
	Monitoring of Performance Qualification Activity.
	Post Approval of Performance Qualification Report after Execution.
	Review & Pre Approval of Performance Qualification Report.
Production	To co-ordinate and support Performance Qualification Activity.
	Post Approval of Performance Qualification Report after Execution.
Quality Control	Analytical Support (Testing/Analysis)
	Review & Pre Approval of Performance Qualification Report
	for correctness, completeness and technical excellence.
Engineering	Responsible for trouble shooting (if occurred during execution).
	Maintenance & preventive maintenance as per schedule.
	Post Approval of Performance Qualification Report after Execution.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Garment Washing Machine
Equipment ID.	
Manufacturer's Name	LG Electronics Inc.
Supplier's Name	LG
Capacity	7 Kg.
Model	
Sr.No.	
Location of Installation	Washing & Sterilization Area , FFS Line 'I' Block

6.0 PRE - QUALIFICATION REQUIREMENTS:

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

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- Approved Performance Qualification Protocol



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7.0	TESTS	AND	CHECKS :	•

7.1 Verification of Docu	ments:
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Record the observations for documents in the below mentioned table.						
S.No.	DOCUMENT NAME	DOCUMENT /SOP No.	COMPLETED (YES/NO)	CHECKED BY (PRODUCTION) SIGN/DATE	VERIFIED BY(QA) SIGN/DATE	
1.	Executed and approved					
	Design Qualification					
	document					
2.	Executed and approved					
	Installation					
	Qualification document					
3.	Executed and approved					
	Operational					
	Qualification document					
4.	PQ Protocol approved					
5.	SOP for Operation &					
	Cleaning of Garment					
	Washing Machine.					
6.	SOP for Preventive					
	Maintenance of					
	Garment Washing					
	Machine					
Infere	ence:					
•••••				Reviewed By Manager OA)		

 Reviewed By
(Manager QA) Sign & Date:
Sign & Date:



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Sign & Date:.....

7.2	PARTICULATE MATTER	& PHYSICAL CHECK	K, TOC	& FOAMING TEST	(LOAD - I):
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7.2.1 Cycle - 01:

Date of Test	Washing Program	
Cycle Start Time	Cycle End Time	
Washing Time	Load / Cycle	

PHYSICAL CHECK RECORD OF WASHED GARMENTS						
Head Gear (In Nos.)	Observation	Boiler Suit (in Nos.)	Observation	Socks (In	Observation	Acceptance Criteria
1		1		1		physical
2		2		2		appearance like no retained the
3		3		3		color, no
4		4		4		damage and
5		5		5		tear, complete dryness.

PARTICULATE MATTER TEST				
Rinse Sample observation	Acceptance Criteria			
	Garments should be free from any foreign matter			
FOAMING TEST RESULT	•			
Rinse Sample observation	Acceptance Criteria			
	No White colored layer observed			
TOC TEST RESULT				
Rinse Sample observation	Acceptance Criteria			
	NMT 500 ppb			

Спескей Бу	verified By
(Production)	(Quality Assurance)
Sign/Date:	Sign/Date:
Inference:	
	Reviewed By
	(Manager OA)



PROTO	COL No.:
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7.2.2	Cycle -	02:
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Date of Test	Washing Program	
Cycle Start Time	Cycle End Time	
Washing Time	Load / Cycle	

PHYSICAL	PHYSICAL CHECK RECORD OF WASHED GARMENTS					
Head Gear (In Nos.)	Observation	Boiler Suit (in Nos.)	Observation	Socks (In	Observation	Acceptance Criteria
1		1		1		physical
2		2		2		appearance like no retained the
3		3		3		color, no
4		4		4		damage and
5		5		5		tear, complete dryness.

Rinse Sample observation Acceptance Criteria Garments should be free from any foreign matter
EQUIMING TEST DESILIT
FOAMING TEST RESULT
Rinse Sample observation Acceptance Criteria
No White colored layer observed
TOC TEST RESULT
Rinse Sample observation Acceptance Criteria
NMT 500 ppb

Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date:
Inference:	
	Reviewed By (Manager QA) Sign & Date:



PROTO	COL No.:
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7.2.3 Cycle - 03:

Date of Test	Washing Program	
Cycle Start Time	Cycle End Time	
Washing Time	Load / Cycle	

PHYSICAL CHECK RECORD OF WASHED GARMENTS						
Head Gear (In Nos.)	Observation	Boiler Suit (in Nos.)	Observation	Socks (In	Observation	Acceptance Criteria
1		1		1		physical
2		2		2		appearance like no retained the
3		3		3		color, no
4		4		4		damage and
5		5		5		tear, complete dryness.

PARTICULATE MATTER TEST				
Rinse Sample observation	Acceptance Criteria			
	Garments should be free from any foreign matter			
FOAMING TEST RESULT				
Rinse Sample observation	Acceptance Criteria			
	No White colored layer observed			
TOC TEST RESULT				
Rinse Sample observation	Acceptance Criteria			
	NMT 500 ppb			
Charled By	Varified Ry			

Checked by			
(Production)	(Quality Assurance)		
Sign/Date:	Sign/Date:		
Inference:			
	Reviewed By		
	(Manager QA)		
	Sign & Date:		



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7.3	PARTICULATE MATTER	& PHYSICAL	CHECK FOAMING TEST	& TOC (LOAD -	II):
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7.3.1 Cycle - 01:

PARTICULATE MATTER TEST

Rinse Sample observation

Date of Test	Washing Program	
Cycle Start Time	Cycle End Time	
Washing Time	Load / Cycle	

PHYSICAL CHECK RECORD OF BOOTIES								
Booties (in Pair)	Observation	Booties (in Pair)	Observation	Acceptance Criteria				
1		6		physical				
2		7		appearance like no retained the color,				
3		8		no damage and				
4		9		tear, complete				
5		10		dryness.				

Acceptance Criteria

	*
	Garments should be free from any foreign matter
FOAMING TEST RESULT	
Rinse Sample observation	Acceptance Criteria
	No White colored layer observed
TOC TEST RESULT	
Rinse Sample observation	Acceptance Criteria
	NMT 500 ppb
Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date:
Inference:	
	Reviewed By (Manager QA) Sign & Date:



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7.3.2 Cycle - 02	02:
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Date of Test	Washing Program	
Cycle Start Time	Cycle End Time	
Washing Time	Load / Cycle	

PHYSICAL CHEO	PHYSICAL CHECK RECORD OF BOOTIES										
Booties (in Pair)	Observation	Booties (in Pair)	Observation	Acceptance Criteria							
1		6		physical appearance like							
2		7		no retained the color, no damage and tear,							
3		8		complete dryness.							
4		9									
5		10									

PARTICULATE MATTER TEST	
Rinse Sample observation	Acceptance Criteria
	Garments should be free from any foreign matter
FOAMING TEST RESULT	
Rinse Sample observation	Acceptance Criteria
	No White colored layer observed
TOC TEST RESULT	•
Rinse Sample observation	Acceptance Criteria
	NMT 500 ppb
Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date:
Inference:	
	Reviewed By (Manager QA) Sign & Date:



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Acceptance

appearance like no

physical

7.3.3 Cycle - 03:

Booties (in Pair)

1

2

PHYSICAL CHECK RECORD OF BOOTIES

Observation

Date of Test	Washing Program	
Cycle Start Time	Cycle End Time	
Washing Time	Load / Cycle	

Booties (in Pair)

6

7

Observation

Reviewed By (Manager QA)

Sign & Date:.....

3		8		retained the color, no damage and
4		9		tear, complete
5		10		dryness.
PARTICULATE MA	ATTER TEST			
Rinse Sample observ	ation	A	Acceptance Crite	ria
		C	Garments should b	be free from any foreign matter
FOAMING TEST R	ESULT			
Rinse Sample observ	ation	. A	Acceptance Crite	ria
		1	No White colored	layer observed
TOC TEST RESULT	Γ			
Rinse Sample observ	ation	A	Acceptance Crite	ria
		N	NMT 500 ppb	
Checked By (Production) Sign/Date:			(Qu	rified By nality Assurance) n/Date:
S			3	
Inference:				



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7.4	PARTICULATE MATTER	& PHYSICAL	CHECK, TOC &	FOAMING TEST	(LOAD - III):
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7.4.1	Cycle -	01:
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Date of Test	Washing Program	
Cycle Start Time	Cycle End Time	
Washing Time	Load / Cycle	

ĺ	PHYSICAL CHECK RECORD OF LINT FREE DUSTER (MOPPING PAD)				
	Pad No.	Observation	Pad No.	Observation	Acceptance Criteria
	1		6		physical appearance like
	2		7		no retained the color, no

1	U	physical appearance like
2	7	no retained the color, no
3	8	damage and tear,
4	9	complete dryness.
5	10	

PARTICULATE MATTER TEST	
Rinse Sample observation	Acceptance Criteria
	Garments should be free from any foreign matter
FOAMING TEST RESULT	
Rinse Sample observation	Acceptance Criteria
	No White colored layer observed
TOC TEST RESULT	
Rinse Sample observation	Acceptance Criteria
	NMT 500 ppb
Checked By	Verified By
(D J4!)	(O

(Production)	(Quality Assurance)
Sign/Date:	Sign/Date:
Inference:	

Reviewed By (Manager QA) Sign & Date:.....



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7.4.2	Cycle -	02:
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PARTICULATE MATTER TEST

Date of Test	Washing Program	
Cycle Start Time	Cycle End Time	
Washing Time	Load / Cycle	

Pad No.	Observation	Pad No.	Observation	Acceptance Criteria
1		6		physical appearance like
2		7		no retained the color, no
3		8		damage and tear,
4		9		complete dryness.
5		10		

Rinse Sample observation	Acceptance Criteria
	Garments should be free from any foreign matter
FOAMING TEST RESULT	
Rinse Sample observation	Acceptance Criteria
	No White colored layer observed
TOC TEST RESULT	·
Rinse Sample observation	Acceptance Criteria
	NMT 500 ppb
Checked By	Verified By
(Production)	(Quality Assurance)
Sign/Date:	Sign/Date:
Inference:	
	Reviewed By
	(Manager QA)
	Sign & Date:



PROTOCOL N	o.
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7.4.3	Cycle -	03:

PARTICULATE MATTER TEST

Date of Test	Washing Program	
Cycle Start Time	Cycle End Time	
Washing Time	Load / Cycle	

PHYSICA	AL CHECK	RECORD (JF LINT F	REE DUSTER	(MOPPING PAD)

Pad No.	Observation	Pad No.	Observation	Acceptance Criteria
1		6		physical appearance
2		7		like no retained the
3		8		color, no damage and
5		9 10		tear, complete dryness.
		10		,

Rinse Sample observation	Acceptance Criteria
	Garments should be free from any foreign matter
FOAMING TEST RESULT	
Rinse Sample observation	Acceptance Criteria
	No White colored layer observed
TOC TEST RESULT	
Rinse Sample observation	Acceptance Criteria
	NMT 500 ppb
Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date:
Inference:	
	Reviewed By (Manager QA) Sign & Date:



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8.0 **CHECKLIST OF ALL TESTS & CHECKS:**

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es/No)	Remarks
	Assurance)
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9.0	DOCUMENTS	ATTACHED:

7.0	
	Any other Relevant Documents.
10.0	NON COMPLIANCE:
11.0	DEVIATION FROM DRE DEFINED SPECIFICATION IF ANY.
11.0	DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:
12.0	CHANCE CONTROL IE ANY.
12.0	CHANGE CONTROL, IF ANY:



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13.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):
14.0	CONCLUSION:
15.0	RECOMMENDATION:



PROTOCOL No.:

16.0 ABBREVIATIONS:

cGMP : Current Good Manufacturing Practices

DQ : Design Qualification

FFS : Form Fill & Seal

GWM : Garment Washing Machine

IQ : Installation Qualification

Kg : Kilogram

OQ : Operational Qualification

SOP : Standard Operating Procedure

TOC : Total Organic Carbon



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17.0 REPORT POST- 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)			