



PERFORMANCE QUALIFICATION REPORT FOR CARTON PACKING MACHINE

**PERFORMANCE QUALIFICATION
REPORT
FOR
CARTON PACKING MACHINE**

EQUIPMENT ID. No.	
LOCATION	Packing Area
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



PERFORMANCE QUALIFICATION REPORT FOR CARTON PACKING MACHINE

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QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR CARTON PACKING MACHINE

1.0 REPORT 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)			



PERFORMANCE QUALIFICATION REPORT FOR CARTON PACKING MACHINE

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 the 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 scope of this report is limited for qualification of Carton Packing Machine installed in Packing Area.
- This report provides all the relevant information of the performance qualification activity, In-process observations and analytical data of testing of collected samples.



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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 execution of Performance Qualification Report.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Review Authorization and Compilation of the Performance Qualification Report.• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity.• Monitoring of Performance Qualification.• Post Approval of Performance Qualification Report after Execution.
Production	<ul style="list-style-type: none">• Review of Performance Qualification Report.• To co-ordinate and support Performance Qualification Activity.• Post Approval of Performance Qualification Report after Execution.
Engineering	<ul style="list-style-type: none">• Reviewing of qualification protocol for correctness, completeness and technical excellence• 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	Carton Packing Machine
Equipment ID.	
Manufacturer's Name	ACG-Pampac
Supplier's Name	ACG-Pampac
Model	HICART PLUS
Serial Number	
Location of Installation	Packing Area



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6.0 PRE – QUALIFICATION REQUIREMENTS:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

6.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)
1.	DQ Protocol approved		
2.	IQ Protocol approved		
3.	OQ Protocol approved		
4.	PQ Protocol approved		
5.	SOP for Operation & Cleaning of Carton Packing Machine		
6.	SOP for Preventive Maintenance Carton Packing Machine		

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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7.0 TESTS AND CHECKS:

7.1 Evaluation of Performance by Using First Batch:

7.1.1 At Maximum Speed:

Product Name			Date of test		
Batch No.			Pack Size		
Speed			Total Packed carton		
Time	Total No. of Checked Cartons	Improper Flap Folding	Printing Quality	Damage Carton	Total Rejection
$\text{Total Rejection(\%)} = \frac{\text{Total Rejection} \times 100}{\text{Total No. of Checked Cartons}}$					

RESULTS: Rejection should not be more than 2.00 %.

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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7.1.2 At Optimum Speed:

Product Name			Date of test		
Batch No.			Pack Size		
Speed			Total Packed carton		
Time	Total No. of Checked Cartons	Improper Flap Folding	Printing Quality	Damage Carton	Total Rejection
Total Rejection(%) = $\frac{\text{Total Rejection} \times 100}{\text{Total No. of Checked Cartons}}$					

RESULTS: Rejection should not be more than 2.00 %.

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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7.1.3 At Minimum Speed

Product Name			Date of test		
Batch No.			Pack Size		
Speed			Total Packed carton		
Time	Total No. of Checked Cartons	Improper Flap Folding	Printing Quality	Damage Carton	Total Rejection
Total Rejection(%) = $\frac{\text{Total Rejection} \times 100}{\text{Total No. of Checked Cartons}}$					

RESULTS: Rejection should not be more than 2.00 %.

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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7.2 Evaluation of Performance by Using Second Batch

7.2.1 At Maximum Speed:

Product Name			Date of test		
Batch No.			Pack Size		
Speed			Total Packed carton		
Time	Total No. of Checked Cartons	Improper Flap Folding	Printing Quality	Damage Carton	Total Rejection
Total Rejection(%) = $\frac{\text{Total Rejection} \times 100}{\text{Total No. of Checked Cartons}}$					

RESULTS: Rejection should not be more than 2.00 %.

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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7.2.2 At Optimum Speed:

Product Name			Date of test		
Batch No.			Pack Size		
Speed			Total Packed carton		
Time	Total No. of Checked Cartons	Improper Flap Folding	Printing Quality	Damage Carton	Total Rejection
Total Rejection(%) = $\frac{\text{Total Rejection} \times 100}{\text{Total No. of Checked Cartons}}$					

RESULTS: Rejection should not be more than 2.00 %.

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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7.2.3 At Minimum Speed

Product Name		Date of test			
Batch No.		Pack Size			
Speed		Total Packed carton			
Time	Total No. of Checked Cartons	Improper Flap Folding	Printing Quality	Damage Carton	Total Rejection
Total Rejection(%) = $\frac{\text{Total Rejection} \times 100}{\text{Total No. of Checked Cartons}}$					

RESULTS: Rejection should not be more than 2.00 %.

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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Evaluation of Performance by Using Third Batch

7.2.4 At Maximum Speed:

Product Name			Date of test		
Batch No.			Pack Size		
Speed			Total Packed carton		
Time	Total No. of Checked Cartons	Improper Flap Folding	Printing Quality	Damage Carton	Total Rejection
Total Rejection(%) = $\frac{\text{Total Rejection} \times 100}{\text{Total No. of Checked Cartons}}$					

RESULTS: Rejection should not be more than 2.00 %.

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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7.2.5 At Optimum Speed:

Product Name			Date of test		
Batch No.			Pack Size		
Speed			Total Packed carton		
Time	Total No. of Checked Cartons	Improper Flap Folding	Printing Quality	Damage Carton	Total Rejection
Total Rejection(%) = $\frac{\text{Total Rejection} \times 100}{\text{Total No. of Checked Cartons}}$					

RESULTS: Rejection should not be more than 2.00 %.

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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7.2.6 At Minimum Speed

Product Name			Date of test		
Batch No.			Pack Size		
Speed			Total Packed carton		
Time	Total No. of Checked Cartons	Improper Flap Folding	Printing Quality	Damage Carton	Total Rejection
Total Rejection(%) = $\frac{\text{Total Rejection} \times 100}{\text{Total No. of Checked Cartons}}$					

RESULTS: Rejection should not be more than 2.00 %.

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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7.3 Calculation of Rejection:

Batch No.	Speed (Carton / min.)	No. of Carton Checked	Passed Cartons	Rejected Cartons
Total Carton Taken`			Rejection %	

RESULTS: Rejection should not be more than 2.00 %.

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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8.0 CHECKLIST OF ALL TESTS & CHECKS:

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

Tests or Checks	Executed (Yes/No)	Remark	Verified by Quality Assurance
Verification of Documents			
Evaluation of Performance by Using Three batch			
Uniformity of Product for Rejection			

Inference:

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Reviewed By
Manager QA
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR CARTON PACKING MACHINE

9.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

10.0 NON COMPLIANCE:

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11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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

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PERFORMANCE QUALIFICATION REPORT FOR CARTON PACKING MACHINE

14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

Asst.	:	Assistant
RPQ	:	Performance Qualification Report
Nos.	:	Numbers.
SOP	:	Standard Operating Procedure
CPM	:	Carton Packing Machine
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PPQ	:	Performance Qualification Protocol



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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)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			