



PERFORMANCE QUALIFICATION REPORT FOR HI-CART CODING MACHINE

**PERFORMANCE QUALIFICATION
REPORT
FOR
HI- CART CODING MACHINE**

EQUIPMENT ID. No.	
LOCATION	PACKING HALL
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	Nil



PERFORMANCE QUALIFICATION REPORT FOR HI-CART CODING MACHINE

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PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR HI-CART CODING MACHINE

1.0 REPORT PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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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 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 Hi-Cart Coding Machine installed in Packing Hall.
- 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, Pre-Approval 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.
Quality Control	<ul style="list-style-type: none">• Analytical Support (Microbiological Testing/Analysis).
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	Hi-Cart Coding Machine
Equipment	
Manufacturer's Name	
Supplier's Name	
Location of Installation	Packing Hall

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)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	DQ Protocol approved				
2.	IQ Protocol approved				
3.	OQ Protocol approved				
4.	PQ Protocol approved				
5.	SOP for Operation & Cleaning of Hi-Cart Coding Machine				
6.	SOP for Preventive Maintenance Hi-Cart Coding 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 TRIAL- 1

Date of test				Product Name	
Batch No.				Pack Size	
Speed	Low Speed (110 carton/min)			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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Date of test				Product Name	
Batch No.				Pack Size	
Speed	Optimum Speed (144 carton/ min)			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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Date of test				Product Name	
Batch No.				Pack Size	
Speed	High Speed (180 carton/ min)			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:



PERFORMANCE QUALIFICATION REPORT FOR HI-CART CODING MACHINE

TRIAL NO - 2

Date of test				Product Name	
Batch No.				Pack Size	
Speed	Low Speed (110 carton/ min)			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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PERFORMANCE QUALIFICATION REPORT FOR HI-CART CODING MACHINE

Date of test				Product Name	
Batch No.				Pack Size	
Speed	Optimum Speed (144 carton/ min)			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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PERFORMANCE QUALIFICATION REPORT FOR HI-CART CODING MACHINE

Date of test				Product Name	
Batch No.				Pack Size	
Speed	High Speed (180 carton/ min)			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:



PERFORMANCE QUALIFICATION REPORT FOR HI-CART CODING MACHINE

7.3 TRIAL No.: 3

Date of test				Product Name	
Batch No.				Pack Size	
Speed	Low Speed (110 carton/ min)			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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PERFORMANCE QUALIFICATION REPORT FOR HI-CART CODING MACHINE

Date of test				Product Name	
Batch No.				Pack Size	
Speed	Optimum Speed (144 carton/ min)			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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PERFORMANCE QUALIFICATION REPORT FOR HI-CART CODING MACHINE

Date of test				Product Name	
Batch No.				Pack Size	
Speed	High Speed (180 carton/ min)			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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7.3 Calculation of Rejection:

Trial No.	Speed (Carton / min.)	No. of Carton Checked	Passed Cartons	Rejected Cartons
01	110			
	144			
	180			
02	110			
	144			
	180			
03	110			
	144			
	180			
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
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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)	Remarks
Verification of Documents		
Speed Synchronization		
Uniformity of Product		

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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9.0 DOCUMENTS TO BE ATTACHED:

- Executed Raw Data.
- 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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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

- Asst. : Assistant
- Ltr. : Litre
- Nos. : Numbers.
- SOP : Standard Operating Procedure
- HIC : Hi-cart coding machine
- DQ : Design Qualification
- IQ : Installation Qualification
- OQ : Operational Qualification



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17.0 REPORT POST-APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			