PERFORMANCE QUALIFICATION REPORT FOR AUTOCARTONATOR

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

REPORT CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AUTOCARTONATOR	PROTOCOL No.:

1.0 REPORT PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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 Autocartonator 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.

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	• 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	• Review of Performance Qualification Report. • To co-ordinate and support Performance Qualification Activity. • Post Approval of Performance Qualification Report after Execution.
Quality Control	• Analytical Support (Microbiological Testing/Analysis).
Engineering	• 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.

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AUTOCARTONATOR	PROTOCOL No.:

5.0 EQUIPMENT DETAILS:

Equipment Name	Autocartonator
Equipment	
Manufacturer's Name	Wimco ltd.
Supplier's Name	Wimco ltd.
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 Autocartonator**				
6.	**SOP for Preventive Maintenance Autocartonator**				

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AUTOCARTONATOR	PROTOCOL No.:

7.0 TESTS AND CHECKS:

7.1 TRIAL NO.:

Date of test		**Product Name**	
Batch No.		**Pack Size**	
Speed	**Low Speed (40 tubes/ min)**		

Tube No.	Printing matter	Stereo Impression	Damage Carton	Scratches
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

RESULTS: The test results Complies / Not Complies as per Specification.

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AUTOCARTONATOR	PROTOCOL No.:

7.2 TRIAL No.:

Date of test		**Product Name**	
Batch No.		**Pack Size**	
Speed	**Optimum Speed (70 tubes/ min)**		

Tube No.	Printing matter	Stereo Impression	Damage Carton	Scratches
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

RESULTS: The test results Complies / Not Complies as per Specification.

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AUTOCARTONATOR	PROTOCOL No.:

7.3 Trial No.:

Date of test		**Product Name**	
Batch No.		**Pack Size**	
Speed	**High Speed (100 tubes/ min)**		

Tube No.	Printing matter	Stereo Impression	Damage Carton	Scratches
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

RESULTS: The test results Complies / Not Complies as per Specification.

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

7.4 Calculation of Rejection:

Trial No.	Speed (Tubes/min.)	No. of Tubes Checked	Passed Tubes	Rejected Tubes
1	40			
	70			
	100			
2	40			
	70			
	100			
3	40			
	70			
	100			
Total Tubes Taken`			**Rejection %**	
Rejection NMT 2.0 %				

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

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: ……

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
cGMP	:	Current Good Manufacturing Practices
CQA	:	Corporate Quality Assurance
PQ	:	Performance Qualification
Vol.	:	Volume
i.e.	:	That is
SS	:	Stainless steel
Ltr.	:	Litre
Nos.	:	Numbers.
SOP	:	Standard Operating Procedure
SS	:	Stain less Steel
OFS	:	Autocartonator
WHO	:	World Health Organization

17.0 REPORT POST-APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			