PERFORMANCE QUALIFICATION REPORT FOR CARTON CODING MACHINE

EQUIPMENT ID. No.	
LOCATION	**Sugar Melting Room**
DATE OF QUALIFICATION	
SUPERSEDES REPORT No.	**NIL**

REPORT CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CARTON CODING MACHINE	PROTOCOL No.:

1.0 REPORT PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

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 qualification protocol is limited to qualification of Carton Coding Machine Installed in Sugar Melting Room.
- 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, 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 Activity. • 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 (Microbial Testing/ chemical Analysis).
Engineering	• Reviewing of qualification report 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.

5.0 EQUIPMENT DETAILS:

Equipment Name	SS CARTON CODING MACHINE
ID. Number	
Capacity	1000 Ltr.
Gross Capacity	1200 Ltr.
Manufacturer's Name	Bright Pharma Engineering Pvt. Ltd.
Sr. No.	
Supplier's Name	Bright Pharma Engineering Pvt. Ltd.
Location of Installation	Sugar Melting Area

6.0 PRE – QUALIFICATION REQUIREMENTS:

6.1 Training Record of Validation Team:

All the persons involved in the execution of qualification activity must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working.

6.2 Verification of Documents:

Verify that the DQ/IQ/OQ of Carton Coding Machine has been executed and approved.

Verify that SOP for Operating, Cleaning and Preventive Maintenance of the Carton Coding Machine has been prepared.

S. No.	Document Name	Completed (Yes/No)	Checked By Engineering Sign/Date	Verified By (QA) Sign/Date
1.	Executed and approved DQ Protocol Cum Report			
2.	Executed and approved IQ Protocol Cum Report			
3.	Executed and approved OQ Protocol Cum Report			
4.	Approved PQ Protocol			
5.	SOP for Operating, Cleaning of the Carton Coding Machine			
6.	SOP for Preventive Maintenance of the Carton Coding Machine			

7.0 TESTS AND CHECKS :

7.1 Equipment Volumetric Capacity (In Liters) Test:

Name of equipment		**Capacity of vessel**	
Make		**Equipment id no.**	

Date of test	Trial no.	Acceptance criteria	Observation
		1000 liter ± 0.3%	
		200 liter ± 0.3%	
		1000 liter ± 0.3%	
		200 liter ± 0.3%	
		1000 liter ± 0.3%	
		200 liter ± 0.3%	

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Production
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Quality Assurance
Sign/Date……

Inference:

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Reviewed By
Manager QA
Sign/Date:……

7.2 Equipment Volumetric Capacity (In Liters) Test by chemical assay method at Minimum Speed of stirrer:

Trial No.:01

Name of equipment		**Capacity of vessel**	
Make		**Equipment Id no.**	
Stirrer Speed		**Area**	**Syrup Mfg. room**

Date	Volume of tank	Weight of Nacl	Result	Acceptance criteria
			Assay	
	200 Ltr.			**0.882% to 0.912%**
	400 Ltr.			
	600 Ltr.			
	800 Ltr.			
	1000 Ltr.			

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PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CARTON CODING MACHINE	PROTOCOL No.:

Trial No.:02

Name of equipment		**Capacity of vessel**	
Make		**Equipment Id no.**	
Stirrer Speed		**Area**	**Syrup Mfg. room**

Date	Volume of tank	Weight of Nacl	Result	Acceptance criteria
			Assay	
	200 Ltr.			**0.882% to 0.912%**
	400 Ltr.			
	600 Ltr.			
	800 Ltr.			
	1000 Ltr.			

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PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CARTON CODING MACHINE	PROTOCOL No.:

Trial No.:03

Name of equipment		**Capacity of vessel**	
Make		**Equipment Id no.**	
Stirrer Speed		**Area**	**Syrup Mfg. room**

Date	Volume of tank	Weight of Nacl	Result	Acceptance criteria
			Assay	
	200 Ltr.			**0.882% to 0.912%**
	400 Ltr.			
	600 Ltr.			
	800 Ltr.			
	1000 Ltr.			

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7.3 Equipment Volumetric Capacity (In Liters) Test by chemical assay method at Maximum Speed of stirrer:

Trial No.:01

Name of equipment		**Capacity of vessel**	
Make		**Equipment Id no.**	
Stirrer Speed		**Area**	**Syrup Mfg. room**

Date	Volume of tank	Weight of Nacl	Result	Acceptance criteria
			Assay	
	200 Ltr.			**0.882% to 0.912%**
	400 Ltr.			
	600 Ltr.			
	800 Ltr.			
	1000 Ltr.			

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PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CARTON CODING MACHINE	PROTOCOL No.:

Trial No.:02

Name of equipment		**Capacity of vessel**	
Make		**Equipment Id no.**	
Stirrer Speed		**Area**	**Syrup Mfg. room**

Date	Volume of tank	Weight of Nacl	Result	Acceptance criteria
			Assay	
	200 Ltr.			**0.882% to 0.912%**
	400 Ltr.			
	600 Ltr.			
	800 Ltr.			
	1000 Ltr.			

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PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CARTON CODING MACHINE	PROTOCOL No.:

Trial No.:03

Name of equipment		**Capacity of vessel**	
Make		**Equipment Id no.**	
Stirrer Speed		**Area**	**Syrup Mfg. room**

Date	Volume of tank	Weight of Nacl	Result	Acceptance criteria
			Assay	
	200 Ltr.			**0.882% to 0.912%**
	400 Ltr.			
	600 Ltr.			
	800 Ltr.			
	1000 Ltr.			

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7.4 Test For Verification Of Uniformity Of Mixing at Minimum Speed of stirrer:

Trial No.:01

Date of test		**Capacity of vessel**	
Name of equipment		**Equipment Id no.**	
Weight of sodium chloride		**Speed**	

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
After 05	Top	Description	Lump free solution	
	Bottom	Description	Lump free solution	
After 10	Top	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	% RSD of Assay		≤ 2%	
After 30	Top	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	5-7	

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CARTON CODING MACHINE	PROTOCOL No.:

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	% RSD of Assay		≤ 2%	

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PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CARTON CODING MACHINE	PROTOCOL No.:

Trial No.:02

Date of test		**Capacity of vessel**	
Name of equipment		**Equipment Id no.**	
Weight of sodium chloride		**Speed**	

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
After 05	Top	Description	Lump free solution	
	Bottom	Description	Lump free solution	
After 10	Top	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	% RSD of Assay		≤ 2%	
After 30	Top	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	5-7	

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CARTON CODING MACHINE	PROTOCOL No.:

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	% RSD of Assay		≤ 2%	

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PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CARTON CODING MACHINE	PROTOCOL No.:

Trial No.:03

Date of test		**Capacity of vessel**	
Name of equipment		**Equipment Id no.**	
Weight of sodium chloride		**Speed**	

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
After 05	Top	Description	Lump free solution	
	Bottom	Description	Lump free solution	
After 10	Top	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	% RSD of Assay		≤ 2%	
After 30	Top	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within	

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CARTON CODING MACHINE	PROTOCOL No.:

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
			0.882% W/V – 0.912%W/V	
	% RSD of Assay		≤ 2%	

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Manager QA
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7.5 Test For Verification Of Uniformity Of Mixing at Maximum Speed of stirrer:

Trial No.:01

Date of test		**Capacity of vessel**	
Name of equipment		**Equipment Id no.**	
Weight of sodium chloride		**Speed**	

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
After 05	Top	Description	Lump free solution	
	Bottom	Description	Lump free solution	
After 10	Top	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	% RSD of Assay		≤ 2%	
After 30	Top	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	5-7	

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CARTON CODING MACHINE	PROTOCOL No.:

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	% RSD of Assay		≤ 2%	

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PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CARTON CODING MACHINE	PROTOCOL No.:

Trial No.:02

Date of test		**Capacity of vessel**	
Name of equipment		**Equipment Id no.**	
Weight of sodium chloride		**Speed**	

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
After 05	Top	Description	Lump free solution	
	Bottom	Description	Lump free solution	
After 10	Top	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	% RSD of Assay		≤ 2%	
After 30	Top	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	5-7	

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CARTON CODING MACHINE	PROTOCOL No.:

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	% RSD of Assay		≤ 2%	

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Manager QA
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PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CARTON CODING MACHINE	PROTOCOL No.:

Trial No.:03

Date of test		**Capacity of vessel**	
Name of equipment		**Equipment Id no.**	
Weight of sodium chloride		**Speed**	

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
After 05	Top	Description	Lump free solution	
	Bottom	Description	Lump free solution	
After 10	Top	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	% RSD of Assay		≤ 2%	
After 30	Top	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	5-7	
		Assay	Assay of active content should be within	

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CARTON CODING MACHINE	PROTOCOL No.:

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
			0.882% W/V – 0.912%W/V	
	% RSD of Assay		≤ 2%	

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Sign/Date……

Inference:

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Manager QA
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8.0 CHECKLIST OF ALL TESTS AND CHECKS:

Tests or checks	Executed [Yes/No]	Remark
Equipment Volumetric Capacity (In Litres) Test		
Verification of Volume of Solution by assay of sodium chloride		
Test For Verification Of Uniformity Of Mixing		

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Manager QA
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9.0 DOCUMENTS ATTACHED:

- Test Report from QC lab
- Any other Relevant Documents.
- Training Record

10.0 NON COMPLIANCE:

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11.0 DEVIATION FROM PRE-DEFINED 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:

%	:	Percentage
cGMP	:	Current Good Manufacturing Practices
CQA	:	Corporate Quality Assurance
DQ	:	Design Qualification
ID.	:	Identification
IQ	:	Installation Qualification
LTD.	:	Limited
MBM	:	Carton Coding Machine
Nacl	:	Sodium Chloride
No.	:	Number
OQ	:	Operational Qualification
PPQ	:	Performance Qualification Protocol
PVT	:	Private
RPQ	:	Report performance qualification
RSD	:	Relative standard deviation
SOP	:	Standard Operating Procedure

17.0 REPORT POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE			