PERFORMANCE QUALIFICATION REPORT FOR BAR CODE TRACK & TRACE SYSTEM LOCATION: PACKING AREA

DATE OF QUALIFICATION	
SUPERSEDE REPORT NUMBER	**NIL**

PERFORMANCE QUALIFICATION REPORT FOR BAR CODE TRACK & TRACE

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PERFORMANCE QUALIFICATION REPORT FOR BAR CODE TRACK & TRACE

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)			

PERFORMANCE QUALIFICATION REPORT FOR BAR CODE TRACK & TRACE

2.0 OBJECTIVE:

- To demonstrate that the equipment will operate reproducibly and consistently within its operating range.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the equipment.

3.0 SCOPE :

- The Report covers all aspects of Performance Qualification for the Bar Code Track & Trace System being used.
- This Protocol will define the methods and documentation used to qualify the Bar Code Track & Trace System for PQ.

PERFORMANCE QUALIFICATION REPORT
FOR
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4.0 RESPONSIBILITY:

The Validation/ Qualification Team, comprising of a representative from each of the following

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.
Production	• Review of Report. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Review of Report. • To Provide Analytical Support.
Engineering	• Review of Report. • To co-ordinate and support Performance Qualification Activity.

Departments, shall be responsible for the overall compliance of this Report:

PERFORMANCE QUALIFICATION REPORT FOR BAR CODE TRACK & TRACE

5.0 EQUIPMENT DETAILS:

Equipment Name	**Bar Code Track & Trace System**
Equipment ID No.	
Capacity	**150 carton/Min**
Manufacturer's Name	**Cyklop Packaging system**
Supplier Name	**Cyklop Packaging system**
Location of Installation	**Packing Area**

PERFORMANCE QUALIFICATION REPORT FOR BAR CODE TRACK & TRACE

6.0 TRAINING RECORDS:

SUPERVISORY STAFF						
S.No.	**Name of Trainee**	**Designation**	**Department**	**Training on protocol is given(Yes/No)**	**Signature of Trainee**	**Verified by (Sign/Date) (QA)**
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						

Name of Trainer_____

Inference: _____

_____

_____

Reviewed By
(Sign/Date): _____
(Manager QA)

PERFORMANCE QUALIFICATION REPORT FOR BAR CODE TRACK & TRACE

7.0 PRE QUALIFICATION REQUIREMENTS:

7.1 SYSTEM PRE-REQUISITES:

- Verify the DQ/IQ/OQ of the Bar Code Track & Trace System has been executed and approved.
- Verify the Operating and Cleaning SOP of the Bar Code Track & Trace System has been prepared.

S.No.	Document Name	Document / SOP No.	Completed (Yes / No)	Checked By (Production) (Sign/Date)	Verified By (QA) (Sign/Date)
1.	DQ Protocol				
2.	IQ Protocol				
3.	OQ Protocol				
4.	Operating Procedure SOP				
5.	Cleaning Procedure SOP				

Verified By): _____
(Quality Assurance)
(Sign/Date)

Inference: _____

_____

_____

Reviewed By
(Sign/Date): _____
(Manager QA)

PERFORMANCE QUALIFICATION REPORT FOR BAR CODE TRACK & TRACE

7.2 CALIBRATION STATUS OF TEST INSTRUMENTS:

- Verify the Calibration Status of Instruments used in Performance Qualification.

S. No.	Instrument Name	Calibration Status	Calibration Done Date	Calibration Due Date	Verified By (QA) (Sign/Date)

7.3 PROPOSED PRODUCT BATCH INFORMATION:

S. No.	Product Name	Batch No.	Batch Size	Mfg. Date	Expiry Date

Verified By): _____
(Quality Assurance)
(Sign/Date)

Inference: _____

_____

_____

Reviewed By
(Sign/Date): _____
(Manager QA)

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8.0 TEST & CHECK

24-HOUR BOX PRINTING STUDY.

S.No.	PROCEDURE	OBSERVED RESULTS	ACCEPTANCE CRITERIA	OBSERVATION
1	Start the machine	Start Time:	The batch coding of the boxes is doing properly with 2D Barcode	
2	After 24-hour run is completed, verify printing Ability and the functionality of the printer under the min/max points	End Time:	The batch coding of the boxes is doing properly with 2D Barcode	

Verified By): _____
(Quality Assurance)
(Sign/Date)

Inference:_____

_____

_____

Reviewed By
(Sign/Date):_____
(Manager QA)

PERFORMANCE QUALIFICATION REPORT FOR BAR CODE TRACK & TRACE

10.0 DOCUMENTS TO BE ATTACHED:

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

12.0 NON COMPLIANCE:

13.0 CHANGE CONTROL, IF ANY:

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

15.0 CONCLUSION:

16.0 RECOMMENDATION:

PERFORMANCE QUALIFICATION REPORT FOR BAR CODE TRACK & TRACE

17.0 EXECUTED REPORT 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)			

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18.0 ABBREVIATION:

No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	current Good Manufacturing Practices
EU	:	European Union
QA	:	Quality Assurance
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
ID	:	Identification
RPM	:	Rotation per Minutes
SOP	:	Standard Operating Procedure