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

DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION PROTOCOL FOR BAR CODE TRACK & TRACE SYSTEM

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PERFORMANCE QUALIFICATION PROTOCOL FOR BAR CODE TRACK & TRACE SYSTEM

1.0 PROTOCOL 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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2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing as per the parameter defined in operational qualification and that it gives result as per the predetermined acceptance criteria.
- To demonstrate that the system 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 system.
- The document also provides the observed and obtained values indicating compliance to the PQ Protocol.

3.0 SCOPE:

- The Protocol 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.

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4.0 RESPONSIBILITY:

The Validation / Qualification Team, comprising of a representative from each of the following Departments, shall be responsible for the overall compliance of this Protocol:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Approval and Compilation of the Performance Qualification Protocol. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity • Monitoring of Performance Qualification.
Production	• Review the Performance Qualification Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Review the Performance qualification Protocol • Analytical Support (Microbiological Testing / Analysis)
Engineering	• Review the Performance Requalification Protocol. • To Co-ordinate and support Performance Requalification Activity.

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

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6.0 SYSTEM DESCRIPTION:

- The Bar Code Track & Trace System consists of SS Steel wall and other part.
- The unique shape of Bar code & track machine contains PLC, VFD, Motor, Conveyor, Camera & Gear box which insure the smooth and easy printing of the BAR code on carton.
- The Operations of the Bar Code Track & Trace System is qualified by performing the prescribed tests and comparing the results against the given Acceptance Criteria. Exceptions are documented in the space provided and resolved prior to closing the OQ.
- Upon completion of the above tests, the team will review the test results and indicate their Acceptance by signing the Authorization Page.

7.0 REASON FOR QUALIFICATION:

After completion of the Operation Qualification of the equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

Packing area.

9.0 FREQUENCY OF QUALIFICATION:

- Once in every two years.
- After any major breakdown or after major modification.
- After Change of Location

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10.0 PRE-QUALIFICATION REQUIREMENTS:

10.1 Training Detail:

- The validation team shall be authorized by Manager-QA or his/her designee.
- All the personnel involved in the Bar Code Track & Trace System Qualification should be appropriately trained both in their job related activities and on the Qualification protocol by Manager-QA or his/her designee.

10.2 SYSTEM PRE-REQUISITES:

S.No.	DESCRIPTION OF PRE-REQUISITE	COMPLETED (YES / NO)	CHECKED BY (PRODUCTION) (SIGN/DATE)	VERIFIED BY (QA) (SIGN/DATE)
1. 2. 3.	Verify that the DQ/IQ/OQ of the Bar Code Track & Trace System has been executed and approved. DQ Protocol Document No.: IQ Protocol Document No.: OQ Protocol Document No:			
4.	Verify that the final Operating and Cleaning SOPs has been prepared and available.			

10.3 TEST MATERIAL/EQUIPMENT

- Materials as BMR
- Calibrated Stop Watch for measuring Mixing time.
- Calibrated Tachometer for measuring RPM.

11.0 TESTS AND CHECKS:

11.1 MIXING EFFICIENCY:

11.2 METHOD:

BAR CODE TRACK & TRACE SYSTEM

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12.0 REFERENCES:

The Principle Reference are the following:

- Validation Master Plan.
- Schedule – M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2. Good Manufacturing Practices and Inspection.

The following references are used to give additional guidance:

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition / March 2001.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission's working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational

13.0 DOCUMENTS ATTACHED:

- Calibration Certificates.
- QC Raw Data

14.0 NON COMPLIANCE:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA shall study the impact of deviation. If deviation is acceptable and it does not have an impact on operation as well as on performance of the machine, prepare final conclusion.

15.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

All deviations, non conformances and out of specification results obtained shall be investigated in accordance with corresponding SOP's and documented in the requalification report.

16.0 CHANGE CONTROL, IF ANY:

Details of change controls initiated during the re-qualification activity, shall be documented in the requalification report

17.0 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
mm	:	Millimeter
RPM	:	Revolution per Minute