OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BAR CODE TRACK & TRACE SYSTEM

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BAR CODE TRACK & TRACE SYSTEM LOCATION: PACKING AREA

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EQUIPMENT ID No.	
LOCATION	
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

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PROTOCOL CONTENTS

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BAR CODE TRACK & TRACE SYSTEM

1.0 PROTOCOL 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 verify that the equipment operates in accordance with the design and user requirements as defined by set of Acceptance Criteria's and complies with relevant cGMP Requirements.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To verify the operational features of Bar Code Track & Trace System machine to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user friendly point of view of the Machine, Cleaning Procedure, and Start up & Shut down Procedure and Safety Features.
- The purpose of operational qualification is to establish that the equipment functions as intended and designed for the particular process. It also ensures that any flaws that may have been over looked during installation qualification. The OQ will also confirm that all interlocks and safety devices function in the manner desired.

3.0 SCOPE:

- The Protocol covers all aspects of Operation Qualification for Bar Code Track & Trace System serving.
- This Protocol will define the methods and documentation used to qualify the Bar Code Track & Trace System OQ. Successful completion of this Protocol will verify that the Bar Code Track & Trace System meet all acceptance criteria and is ready for Performance Qualification.

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4.0 RESPONSIBILITY:

The Validation Team, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol Cum Report.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Approval and Compilation of the Operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operation Process.
Production	• Review of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol after Execution
Engineering	• Review of Operational Qualification. • To co-ordinate and support Operational Qualification Activity. • Calibration of Process Instruments.

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5.0 EQUIPMENT DETAILS:

Equipment Name	**BAR CODE TRACK & TRACE SYSTEM**
Equipment ID No.	
Manufacturer's Name	**Cyklop Packaging system**
Supplier's Name	**Cyklop Packaging system**
Model	**$_C$GMP Model.**
Location of Installation	**Packing Area**
PO number	

6.0 SYSTEM DESCRIPTION:

6.1 BRIEF PROCESS 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.

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7.0 PRE-QUALIFICATION REQUIREMENTS:

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations or issues should be rectified and documented prior to OQ commencing.

7.1 SYSTEM PRE-REQUISITES:

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

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

Inference:_____

_____

_____

_____

Reviewed By:_____
(Manager QA)
Sign / Date

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8.0 CRITICAL VARIABLE TO BE MET:

8.1 OPEARATIONAL AND FUNCTIONAL CHECKS:

Operate the Bar Code Track & Trace System Machine as per Manufacturer's Manual / SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Power supply	Voltage: 125 to 250 V Ampere: 20 to 15 Amp		
Motor gear box	Check direction of motor shows on machine by direction arrow		
	Gear box transmit the speed to machine from motor.		
Earth	Proper earthing should be provided to machine		
ON Pressing Switch	Machine should be ON		
OFF Pressing Switch	Machine should be OFF		
Green indicator	Indicate machine is ON		
Red indicator	Indicate machine is OFF		
Main Switch knob ON	Control Panel should be ON		
Main Switch knob OFF	Control Panel should be OFF		

8.2 STARTUP VERIFICATION:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Turn on the main power switch	Machine should be ON		
Check the main indicator	Main indicator should be ON		
Check the LED display	Display should be ON		
Check the communication cable connection	Communication Cable should be connected		

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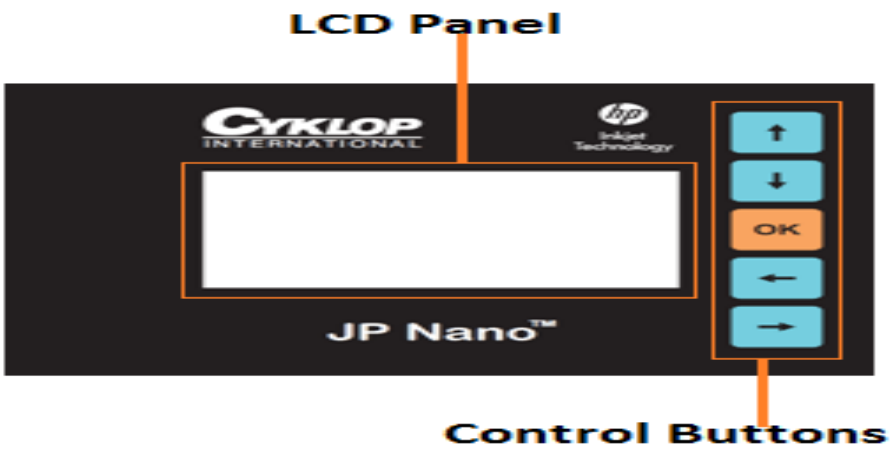
8.3 OPERATIONAL CHECKS FOR PLC:



↑	Press the button to change the value of the parameter selected.
↓	Press the button to change the value of the parameter selected.
OK	Confirms the operation currently selected through the menu.
←	Press the button to change the cursor position in the menu display towards left.
→	Press the button to change the cursor position in the menu display towards left

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

Inference:_____

_____

_____

_____

Reviewed By:_____
(Manager QA)
Sign / Date

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8.4 SAFETY TESTING / INTERLOCKING:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Electrical Wiring And Earthing	Must be inside the machine		
Motor Overload Relay	The switchgear shall trip if overloaded		
ELECTRICAL CHECK / CLEAN/ TIGHTEN			
Motor -1nos	Monthly once process		

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

Inference:_____

_____

Reviewed By:_____
(Manager QA)
Sign / Date

8.5 POWER FAILURE VERIFICATION:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

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

Inference:_____

_____

Reviewed By:_____
(Manager QA)
Sign / Date

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9.0 REFERENCES:

The Principle Reference is 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 Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.

10.0 DOCUMENTS TO BE ATTACHED:

- Operation And Maintenance Manual
- Any Other Relevant Documents

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

12.0 CHANGE CONTROL, IF ANY:

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

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14.0 CONCLUSION:

15.0 RECOMMENDATION:

16.0 ABBREVIATIONS:

Sr.	:	Senior
Asst.	:	Assistant
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
IQ	:	Installation Qualification
mm	:	Millimetre
Amp.	:	Ampere

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17.0 PROTOCOL 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)			