



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT  
FOR  
BAR CODE TRACK & TRACE SYSTEM**

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

<b>EQUIPMENT ID No.</b>	
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>

**PROTOCOL CONTENTS**



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT  
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**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT  
FOR  
BAR CODE TRACK & TRACE SYSTEM**

**INITIATED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (QUALITY ASSURANCE)</b>			



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**2.0 OBJECTIVE:**

- To ensure that the Equipment/System conforms to the manufacturer's description and installation requirements.
- To ensure that the Equipment/System comply with relevant requirements of current manufacturing.
- To provide a record of key features of the equipment and components as currently installed.
- To ensure that there is sufficient documentation to enable the equipment to be operated and maintained safely, effectively and consistently.
- To ensure that the equipment is in a satisfactory state, to allow the OQ to be performed safely and with consistently repeatable results.
- To ensure that all instruments are calibrated prior to OQ.
- To carry out the Installation Qualification of **Bar Code Track & Trace System** with **cGMP Model** procured from **Cyklop Packaging system** which states that "The process to conforming that an item of equipment, or other system, as currently installed, meets its design qualification".
- To confirm that the equipment and its components are as per the Specifications and Installed as per the Approved Design and complies with cGMP and cGEP.

**3.0 SCOPE:**

- The scope of this installation qualification protocol cum report is limited to the installation qualification of the **Bar Code Track & Trace System** with **cGMP Model** procured from **Cyklop Packaging system** installed in the Packing area.
- To verify that the correct hardware has been installed, system initializes correctly.



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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.

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Approval, Authorization and Compilation of the Installation Qualification Protocol cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Installation Qualification.</li><li>• Monitoring of Installation Qualification Activity.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review of Protocol cum Report.</li><li>• Execution of Installation Qualification.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of Protocol cum Report.</li><li>• To co-ordinate and support Installation Qualification Activity.</li><li>• Calibration of Process Instruments.</li></ul>



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**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	<b>BAR CODE TRACK &amp; TRACE SYSTEM</b>
<b>Equipment ID No.</b>	
<b>Manufacturer's Name</b>	<b>Cyklop Packaging system</b>
<b>Supplier's Name</b>	<b>Cyklop Packaging system</b>
<b>Model</b>	<b>cGMP Model.</b>
<b>Location of Installation</b>	<b>Packing Area</b>
<b>PO number</b>	

**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.



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT  
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**7.0 PRE-QUALIFICATION REQUIREMENTS:**

The design qualification protocol cum Report of the Bar Code Track & Trace System must be executed & approved prior to IQ 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.	Verify that the DQ of the Bar Code Track & Trace System machine executed and approved. DQ Protocol			

**Verified By**  
**(Quality Assurance)**  
**(Sign/Date) .....**

**Inference:** \_\_\_\_\_

**Reviewed By:** \_\_\_\_\_  
**(Manager QA)**  
**Sign / Date**



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT  
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**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 GENERAL CHECKS AND LOCATION SUITABILITY:**

<b>INSTALLATION CHECKS</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION</b>	<b>OBSERVED BY (ENGINEERING) (SIGN/DATE)</b>
Grouting And Mounting of Equipment	Should be grouting and mounting proper.		
Equipment Should Be Properly Balanced & Leveled	Should be properly balanced and leveled.		
All The Metal Parts Should Be Properly Grounded Without Any Sharp Edges.	Metal parts should be properly grounded with any sharp edges.		
Welding of Joints Without Any Welding Burrs	Welding of joints should be without any welding burrs.		
Place of Installation	Packing area		
Room Condition	General working condition As per GMP and production requirement.		
Illumination in installed area	NLT 300 Lux.		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

**Verified By**  
**(Quality Assurance)**  
**(Sign/Date).....**

**Inference:** \_\_\_\_\_  
\_\_\_\_\_

**Reviewed By:** \_\_\_\_\_  
**(Manager QA)**  
**Sign / Date**





**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT  
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**8.2 EQUIPMENT VERIFICATION:**

**8.3 BAR CODE TRACK & TRACE SYSTEM MACHINE**

INSTALLATION CHECKS	ACCEPTANCE CRITERIA		OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Equipment	Bar Code Track & Trace System Single Pen Plus			
Model No.	Single Pen Plus cGMP Model.			
<b>ELECTRICAL INSTALLATION:</b>				
Electrical Supply	Voltage	125 to 250 V		
	Ampere	20 To 15 Amp		
Electrical connections.	Should be provided & secured.			
Components of Panel	Should be properly secured			
All terminals are tightened	Should be tightened			
Earthing connection to control panel & equipment	Earthing connection to control panel & equipment should be provided.			

S.No.	SPECIFICATION	OBSERVATION	OBSERVED (ENGINEERING) (SIGN/DATE)
1.	The machine has been positioned as per the room layout drawing		
2.	The machine has been leveled		
3.	The machine has been cleaned		
4.	Utility have been properly connected		
5.	Visually check the M/C for damage due to transportation. Etc		

**Checked By**  
**(Production)**  
**(Sign/Date)**

**Verified By**  
**(Quality Assurance)**  
**(Sign/Date).....**

**Inference:** \_\_\_\_\_

**Reviewed By:** \_\_\_\_\_  
**(Manager QA)**  
**Sign/Date**



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT  
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**8.4 INSTALLATION CHECKS:**

S.No.	Installation Checks	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
1.	Check the proper mechanical installation of Bar Code Track & Trace System		
2.	Check the proper electrical installation of bar code track & trace system		
3.	Check the parts are working properly		
4.	Check the equipment is free from any defects		
5.	Check the finishing of product contact parts		

**Verified By**  
**(Quality Assurance)**  
**(Sign/Date).....**

**Inference:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Reviewed By:** \_\_\_\_\_  
**(Manager QA)**  
**Sign / Date**



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**8.5 EQUIPMENT CHECK:**

COMPONENTS	ACCEPTANCE CRITERIA		OBSERVATION		OBSERVED BY (ENGINEERING) (SIGN/DATE)
Equipment	Bar code track & trace system				
Model No.	Single pen plus cGMP model				
Capacity	150 carton / Minute				
Camera	Micro scan QX Hawk Vision camera				
Conveyor	High speed twin belt conveyor				
Main motor	Make	Bonvario	Make		
	Model No.		Model No.		
	Sr. No.		Sr. No.		
	RPM	1370	RPM		
	HP	1 Hp	HP		
Gear box	Make	Bonvario	Make		
	Type	BLM 40	Type		
	Ratio	1:10	Ratio		
	Sr. No.	130610	Sr. No.		
VFD	Make	Delta	Make		
	Model	VFD007L21A	Model		
	Frequency Range	1-400 Hz	Frequency Range		
PLC	Make	Panasonic	Make		
	Model	Colour MMI	Model		



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**CONTROL PANEL**

ON/OFF Pressing Switch	Green	ON	Green		
	Red	OFF	Red		
ON/OFF indicator	ON	Green	ON		
	OFF	Red	OFF		
Main Switch knob	Control Panel on /off	On/Off control panel	Control Panel on /off		

**Verified By:** \_\_\_\_\_  
(Quality Assurance)  
(Sign/Date)

**Inference:** \_\_\_\_\_  
\_\_\_\_\_

**Reviewed By:** \_\_\_\_\_  
(Manager QA)  
Sign / Date

**8.6 SAFETY:**

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING (SIGN/DATE)
Electrical wiring and Earthing	Electrical wiring should be as per approved drawings. Double external earthing to control machine (panel and motors) and operator should be provided.		
Safety Features	Should be provided		

**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:**

- Technical details for Equipment Requirement with Engineering Drawings.
- Calibration certificates
- Operation and Maintenance Manual



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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 ABBREVIATION:**

DQ	:	Design Qualification
PO	:	Purchase Order
Asst.	:	Assistant
No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
cGEP	:	Current Good Engineering Practices
EU	:	European Union
QA	:	Quality Assurance
IQ	:	Installation Qualification
mm	:	Millimeter
Amp.	:	Ampere



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**17.0 PROTOCOL POST-APPROVAL**

Signing of this report indicates that Installation Qualification Protocol cum Report for **Bar Code Track & Trace System** has been completed.

**INITIATED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (QUALITY ASSURANCE)</b>			