



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

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
BAR CODE TRACK AND TRACE
SYSTEM
LOCATION: PACKING AREA
(GENERAL BLOCK)**

DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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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 prepare the Design Qualification document for Bar Code Track & Trace System on basis of URS and information given by Supplier.
- To ensure that all Critical Aspects of Process / Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification for **Bar Code Track & Trace System with cGMP Model**.
- The Drawings and P & IDs provided by Vendor shall be verified during Design 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	<ul style="list-style-type: none">• Preparation, Approval and Authorization of the Protocol cum Report.• Assist in the verification of Critical Process Parameters & Drawings as per the Specification.• Post Approval of Qualification Protocol cum Report after Execution.• Co-ordination with Production and Engineering to carryout Design Qualification.• Monitoring of Design Qualification Activity.
Production	<ul style="list-style-type: none">• Review of the Protocol cum Report.• Assist in the verification of Critical Process Parameters & Drawings as per the Specification.• Post Approval of Qualification Protocol cum Report after Execution
Engineering	<ul style="list-style-type: none">• Review of the Protocol cum Report.• Assist in the Preparation of the Protocol cum Report.• To co-ordinate and support the Design Qualification Activity.• To assist in Verification of Critical Process Design Feature & Drawings as per the Specification.• Specification of the sub-components/ bought out items, their Make, Model, Quantity and backup records / brochures.• Details of utilities• Material of construction of all components• Brief Process Description• Safety Features and Alarms• Post Approval of Qualification Protocol cum report after Execution



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5.0 PROJECT REQUIREMENTS:

To confirm the safe delivery of the equipment from the supplier. To ensure that no unauthorized and/or unrecorded design modification shall taken place.

If at any point in time, any change is desired in the mutually agreed design, change control procedure shall be followed and documented.

6.0 BRIEF PROCESS DESCRIPTION:

The **JP NANO model Single Pen Plus** is a Machine in which the printing batch code and 2D barcode as per the DGFT on the cartons. The printer is consisting of electronic devices which incorporate to each other to fulfill the requirement of printing of boxes easily. The body of the machine is made of SS steel with 2.5mm thickness sheet. High speed Twin belt stacker with conveyor and air rejection system

6.1 EQUIPMENT SPECIFICATION:

Equipment Specification document is provided to manufacturer for engineering equipment & some critical variables to be met during designing the equipment.



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7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS / PRODUCT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application: Bar code printing and reading	Bar Code Track & Trace System machine should be able for printing and tracking of 2D bar code on carton.	Process Requirement
Working: Working on Bar Code Track & Trace System	Bar Code Track & Trace System should be facilitate the easy & efficient working during the course of the printing and tracking of 2D bar code on carton	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Approved Design Requirement
Safety Feature	Various Safety Features Should be provided to the equipment	Process Requirement

7.2 UTILITY REQUIREMENTS / LOCATION SUITABILITY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	The electrical system of the equipment shall be housed as per the cGMP and cGEP standards, with adequate safety. Electrical panel and electro pneumatic panel is to be installed in the service area.	Approved Design Requirement
Compressed air supply	NA	NA
Room Condition	General working condition. As per GMP and production requirement.	Process Requirement



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7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		REFERENCE
Equipment	Bar Code Track & Trace System		Cyklop Packaging system
Model	Single pen plus		As Per Approved Design Requirement
Serial No.			As Per Approved Design Requirement
Capacity	150 carton / Minute		As Per Approved Design Requirement
Camera	Micro scan QX Hawk Vision camera		As Per Approved Design Requirement
PLC	Panasonic PLC with colour MMI		As Per Approved Design Requirement
Conveyor	High speed twin belt conveyor		As Per Approved Design Requirement
Motor	Make	Bonvario	As Per Approved Design Requirement
	Model No.	BM712-4	
	Sr. No.	12126914	
	RPM	1370	
	HP	1 Hp	
VFD	Make	Delta	As Per Approved Design Requirement
	Model	VFD007L21A	
	Frequency Range	1-400 Hz	
Gear Box	Make	Bonvario	As Per Approved Design Requirement
	Type	BLM 40	
	Ratio	1:10	
	Sr. No.	130610	



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7.4 MATERIAL OF CONSTRUCTION :

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION	REFERENCE
1.	Bar Code Track & Trace System	SS Steel	GMP Requirement
2.	PLC (“Panasonic”)	STD	Process requirement
3.	VFD (“Delta” Make)	STD	Process Requirement
4.	Gear box(“Bonvario” Make)	STD	Process Requirement
5.	Motor(“Bonvario” 1HP, 1370 RPM)	STD	Process Requirement

7.5 SAFETY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
MCB	MCB should be provided so that when there is an overload in current or any short circuit then the MCB trips.	Safety Requirement
Mechanical Guard	Mechanical guard for all rotating parts should be provided	Safety Requirement
Joints	Welding of joints should be Leaving without any welding burrs.	Safety Requirement
Metal Parts	All the metal parts should be properly grounded without any sharp Edges.	Safety Requirement
Leveling And Balancing	Equipment should be Properly balanced & leveled.	Safety Requirement
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 Requirement
Noise Level	Below 80 db.	cGMP Requirement
Emergency Switch	Provided easy access position.	Safety Requirement



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7.6 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for supplying the Bar Code Track & Trace System.	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feed back from market (customers already using the equipment)	Process Requirement

- Reference:**
- (1) The equipment shall conform to the specifications and requirements as specified in PO and URS
 - (2) Operating and service manual for Bar Code Track & Trace System.



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8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy
- Any other relevant documents

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

10.0 ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS:

11.0 RECOMMENDATION:



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12.0 ABBREVIATION:

URS	:	User Requirement specification
DQ	:	Design Qualification
PO	:	Purchase Order
cGMP	:	Current Good Manufacturing Practice
cGEP	:	Current Good Engineering Practice
Ltd.	:	Limited
QA	:	Quality Assurance
PO	:	Purchase Order
Kg	:	Kilogram
Hr	:	Hour
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
Db	:	Deci bel



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13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			