DESIGN QUALIFICATION PROTOCOL CUM REPORT
FOR
PHARMA CODE READER

DESIGN QUALIFICATION

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

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PROTOCOL CONTENTS

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1.0 PROTOCOL PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
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 on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product Requirement, GMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification for Pharma code reader with GMP Model procured from Banner Engineering.
- Equipment shall operate under the dust free environment and conditions as per the GMP Requirements.

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4.0 RESPONSIBILITY:

The Validation Group, 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 & Review of the Protocol cum Report. • Assist in the verification of Process Parameters, Drawings as per the Specification. • Review of Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Production	• Review of the Protocol cum Report. • Assist in the verification of Process Parameters, Drawings as per the Specification.
Engineering	• Review of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings, as per the Specification i.e. ➢ Specification of the sub-components/ bought out items, their Make, Model, Quantity and backup records / brochures. ➢ Identification of components for calibration ➢ Brief Process Description • Review of Qualification Protocol cum Report after Execution.

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5.0 BRIEF PROCESS DESCRIPTION:

Pharma code reader is designed to read Pharma code in batch accordance with cGMP principles. Qualification activities for the Pharma code reader incorporate the following system component.

- 89 mm (3.5 in) diagonal colour LCD flat-panel touch screen display.
- Connects directly to an iVu Remote Series sensor.
- Five cord set lengths available, ordered separately.
- Provides remote viewing of the iVu sensor image and user interface.
- Exceptionally wide viewing angle—60 degrees left and 60 degrees right; 50 degrees up, and 55 degrees down.
- Two LEDs provide feedback on the remote sensor operation—one for Power/Error, and the other indicating inspection Pass/Fail.
- Can be safely disconnected and reconnected to a live sensor.
- Mounting bracket and stylus included with cord set kit (ordered separately)

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared for the manufacturer of equipment ensures complies with User Requirement Specification.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 MAIN BODY ASSEMBLY:

Parameters	Acceptance Criteria	Reference
Manufacturer	Banner Engineering	Design Requirement
Type	Mountable Remote Display with sensor.	Design Requirement
Model	RDM35	Design Requirement
Description	89 mm (3.5 in) Diagonal Machine-Mountable Remote Touch Screen	Design Requirement

7.2 UTILITIY REQUIREMENTS / LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply:	3 phase plus earthing, Voltage-213 $\pm$ 10 % V (To be assured by Engineering department)	GMP Requirement

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7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

S.No.	Name of the Component	Technical Specification
1.	Manufacturer	Banner Engineering
2.	Screen Size	3.5 in. diagonal
3.	LCD Aspect Ratio	4:3
4.	Display Resolution	320 × 240 RGB
5.	Viewing Angle	60 degrees left, and 60 degrees right; 50 degrees up, and 55 degrees down
6.	Stylus	Delrin
7.	Display Weight	12 oz
8.	Bracket with Stylus Weight	1.1 oz
9.	Connection	8-pin M12 circular
10.	Operating Temperature	0° to 50° C (32° to 122° F)

7.4 MATERIAL OF CONSTRUCTION OF CONTACT PARTS:

S.No.	Parts Name	Material of Construction	Reference
1.	Housing Material	Zinc Zamac #3	Design Requirement
2.	Bracket Material	ABS	Design Requirement

7.5 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Pharma code reader.	Selection of Vendor is done on the basis of review of vendor. Criteria for review were vendor background (general/financial), technical knowhow, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

Checked By
Sign & Date……..

8.0 DOCUMENTS TO BE ATTACHED:

- Any other relevant documents.

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

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 REOMMENDATION:

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12.0 ABBREVIATIONS:

URS	:	User Requirement Specification
GMP	:	Good Manufacturing Practice
cGMP	:	Current Good Manufacturing Practice
mm	:	Mili meter
DQ	:	Design Qualification
V	:	Volt
PCR	:	Pharma code reader
Pvt	:	Private
Ltd	:	Limited
LCD	:	Liquid crystal displays
LED	:	Light emitting diode
RGB	:	Red, Green, Blue
OZ	:	Ounce
^{o}C	:	Degree centigrade
^{o}F	:	Degree Fahrenheit
ABS	:	Acrylonitrile, Butadiene and styrene.

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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)			