INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
PHARMA CODE READER

INSTALLATION QUALIFICATION

PROTOCOL CUM REPORT

FOR

PHARMA CODE READER

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

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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PROTOCOL CONTENTS

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PHARMA CODE READER

1.0 PROTOCOL PRE – APPROVAL:

INITIATED 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 carry out the Installation Qualification of Pharma code reader used in Batch Coding area.
- To confirm that the equipment and its components are as per the Specifications and Installed as per the Approved Design and complies with GMP practices.
- To prove that each Operation proceeds as per the Design Specification and the tolerances prescribed there in the document, are the same at utmost transparency.
- To ensure that there is sufficient information available to enable the equipment to operate and Maintain safely, effectively and consistently.

3.0 SCOPE:

- To verify the critical dimensions of the unit and record Serial Numbers / Model Number of critical components.
- To verify that the correct hardware has been installed, system initializes correctly.

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, Approval and Compilation of the IQ Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity.
Production	• Review & Pre Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Qualification Protocol cum Report after Execution.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in IQ Activity. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol cum Report after Execution

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5.0 EQUIPMENT DETAILS:

Equipment Name	Pharma code reader
Equipment	
Manufacturer's Name	Banner Engineering
Model	GMP Model
Supplier's Name	Banner Engineering
Location of Installation	Batch Coding area

6.0 SYSTEM 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)

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents :

- Executed and approved design qualification document.
- Technical Specification of Equipment.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Supporting documents would form a part of the IQ Protocol cum report.

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7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by respective authorities.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

S.No.	Installation Check	Observation Comply/not comply	Observed by Sign & Date
1.	Check the proper mechanical installation of Pharma code reader.		
2.	Check the proper electrical installation of Pharma code reader.		
3.	Check the parts are working properly.		
4.	Check the equipment is free from any defects.		
5.	Check the finishing of product contact parts.		

Checked By
Sign & Date: ……

8.2 General Checks and Location Suitability:

S.No.	Installation Checks	Acceptance Criteria	Observation (Comply/not comply)	Observed by Sign & Date
1.	Grouting and Mounting	Should be grouted and mounted properly.		
2.	Leveling	Should be properly balanced and leveled.		
3.	Edges of Parts.	Metal edges should be properly Rounded off without any sharp edges.		
4.	Room Condition	General working condition As per GMP and production requirement.		
5.	Illumination in area	NLT 300 Lux		
6.	Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

Checked By
Sign & Date: ……

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8.3 Equipment Verification:

Installation Checks	Specification	Observation (Comply/not comply)	Observed by Sign & Date
Manufacturer	Banner Engineering		
Screen Size	3.5 in. diagonal		
LCD Aspect Ratio	4:3		
Display Resolution	320 × 240 RGB		
Viewing Angle	60 degrees left, and 60 degrees right; 50 degrees up, and 55 degrees down		
Stylus	Delrin		
Display Weight	12 oz		
Bracket with Stylus Weight	1.1 oz		
Connection	8-pin M12 circular		
Operating Temperature	0° to 50° C (32° to 122° F)		

Checked By
Sign & Date: ……

8.4 SAFETY:

Checks	Acceptance Criteria	Observation (Comply/not comply)	Observed by Sign & Date
Well embedded equipment	For Proper mixing.		
Electrical wiring and Earthing.	Electrical wiring should be as per approved drawings. Double external earthing to control machine panel and motors should be provided.		
Start On/Off switch: To stop the process immediately.	Should be provided For equipment and operator safety.		

Checked By
Sign & Date: ……

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8.5 Utility Verification List:

S. No.	Utility Parameter	Specified	Observation (Comply/not comply)	Observed by Sign & Date
1.	**Electrical Supply**	3 phase plus earthing, Voltage-213 ± 10 % V		

Checked By
Sign & Date: ……

Inference:

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Reviewed By
Sign & Date: ……

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

10.0 DOCUMENTS TO BE ATTACHED:

- Any other relevant documents.

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11.0 DEVIATION FROM PREDEFINED 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 ABBREVIATIONS:

GMP	:	Good Manufacturing Practice
cGMP	:	Current Good Manufacturing Practice
mm	:	Mili meter
IQ	:	Installation 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
NLT	:	Not less than.

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17.0 PROTOCOL POST- 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)			