PERFORMANCE QUALIFICATION PROTOCOL FOR PHARMA CODE READER

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

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PROTOCOL CONTENTS

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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
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 provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all test parameters meet the pre-defined acceptance criteria

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the pharma code reader installed in the Batch coding area .
- This Protocol will define the methods and documentation used to qualify the pharma code reader for Performance Qualification.

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.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and Compilation of the Performance Qualification. • Protocol Training. • Co-ordination with Production and Engineering to carryout PQ Activity. • Monitoring of Performance Qualification.
Production	• Review and approval of Protocol. • To co-ordinate and support Performance Qualification Activity.
Engineering	• Reviewing of qualification protocol for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

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5.0 EQUIPMENT DETAILS:

Equipment Name	Pharma code reader
Equipment	
Manufacturer's Name	Banner Engineering
Model	GMP Model
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 LED's 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 REASON FOR QUALIFICATION:

- New equipment in batch coding area.
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

Batch coding area.

9.0 FREQUENCY OF QUALIFICATION:

- After any major breakdown or after major modification.
- After Change of Location.

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10.0 PRE - QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- Calibration of all critical Components of Equipment.
- Preparation of SOP for Operation & Cleaning of Pharma code reader.
- Preparation of SOP for Preventive Maintenance Pharma code reader.

11.0 TESTS AND CHECKS:

11.1 Verification of Documents:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

- Executed and approved Design Qualification document.
- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operation & Cleaning of Pharma code reader.
- SOP for Preventive Maintenance of Pharma code reader.

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.
- Supporting documents would form a part of the PQ report.

Acceptance Criteria:

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

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11.2 Evaluation of Performance Using Product:

Objective:

- To verify the performance of equipment in the range of operational parameters established in Performance Qualification Activity.

Checks:

Challenge test perform for barcode on carton:

- Read the barcode on carton.
- Mixup different product carton.

Method:

- **Read the barcode on carton.**
  - Take 100 cartons and pass product barcode by the iVu Plus BCR. Repeat this activity three times at three different conveyer speeds for carton.
  - Take 10 cartons and put one extra bar and mixed with 90 good cartons and read the barcode by the iVu Plus BCR. Repeat this activity three times at three different conveyer speeds.
  - Take 10 cartons and merge two bars and mixed with 90 good cartons and read the barcode by the iVu Plus BCR. Repeat this activity three times at three different conveyer speeds.
- **Mixup different product carton.**
  - Take 100 cartons and pass product barcode by the iVu Plus BCR. Repeat this activity three times at three different conveyer speeds for carton.
  - Take 90 cartons and put 10 cartons of different product carton and read the barcode by the iVu Plus BCR. Repeat this activity three times at three different conveyer speeds.
- Record the observations in the report.

Acceptance Criteria:

- Read the barcode challenge test, all manipulated barcode shell be fail.
- Mixup different product carton challenge shell be fail.

12.0 CHECKLIST OF ALL TESTS & CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

- Verification of DQ, IQ & OQ & other documents.
- Verification of performance using product.

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13.0 REFERENCES:

The Principle References are as 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.

14.0 DOCUMENTS TO BE ATTACHED:

- Any other relevant document.

15.0 NON COMPLIANCE:

All the Non-compliances of procedure, specifications, and sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

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18.0 ABBREVIATIONS:

WHO	:	World Health Organization
GMP	:	Good Manufacturing Practices
cGMP	:	Current Good Manufacturing Practices
QA	:	Quality Assurance
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance qualification
SOP	:	Standard operating procedure
PCR	:	Pharma code reader
LCD	:	Liquid crystal displays
LED	:	Light emitting diode
BCR	:	Batch code reader