PERFORMANCE QUALIFICATION REPORT
FOR
PHARMA CODE READER

PERFORMANCE QUALIFICATION REPORT FOR PHARMA CODE READER

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

PERFORMANCE QUALIFICATION REPORT FOR PHARMA CODE READER

REPORT CONTENTS

PERFORMANCE QUALIFICATION REPORT FOR PHARMA CODE READER

1.0 REPORT 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)			

PERFORMANCE QUALIFICATION REPORT FOR PHARMA CODE READER

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 report provides all the relevant information of Performance Qualification Activity for Pharma code reader and all the observation of in-process checks and analytical results of analyzed samples.

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 Report.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, and Compilation of the Performance qualification Report. • Co-ordination with Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification Activity. • Post Approval of Performance Qualification Report after Execution.
Production	• Review & Pre Approval of Performance Qualification Report. • To co-ordinate and support Performance Qualification Activity. • Post Approval of Performance Qualification Report after Execution.
Engineering	• Review & Pre Approval of Performance Qualification Report. • Co-ordination, Execution and technical support in Qualification activity. • Responsible for Trouble shooting (if occurs during execution). • Post Approval of Performance Qualification 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
Location of Installation	Batch Coding area

6.0 PRE – QUALIFICATION REQUIREMENTS:

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 Pharma code reader.

7.0 TESTS AND CHECKS:

7.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By Sign & Date	Verified By Sign & Date
1.	Executed and approved DQ document				
2.	Executed and approved IQ document				
3.	Executed and approved OQ document				
4.	PQ Protocol approved				
5.	SOP for Operation & Cleaning of Pharma code reader.				
6.	SOP for preventive maintenance Pharma code reader.				

Reviewed By
Sign & Date:_____

PERFORMANCE QUALIFICATION REPORT FOR PHARMA CODE READER

7.2 OBSERVATIONS FOR EVALUATION OF PERFORMANCE USING PRODUCT:

7.2.1 TEST PRODUCT DETAILS:

S. No.	Product Name	Product Code	B. No.	B. Size	Mfg. Date	Exp. Date

7.2.2 CHALLENGE TESTS:

7.2.2.1 READ THE BARCODE BY THE iVU PLUS BCR:

Product Name		Batch No.	

Minimum speed …….

S. No.	Date	Time	Tests	Observations		Remarks (Pass/fail)
				Qty. of pass cartons	Qty. of fail cartons	
1.0			Pass product barcode of carton.			
2.0			Put one extra bar in carton.			
3.0			Merge two bars in carton.			

Checked By
Sign & date……

Verified By
Sign & date……

Product Name		Batch No.	

Optimum speed …….

S.No.	Date	Time	Tests	Observations		Remarks (Pass/fail)
				Qty. of pass cartons	Qty. of fail cartons	
1.			Pass product barcode of carton.			
2.			Put one extra bar in carton.			
3.			Merge two bars in carton.			

Checked By
Sign & date……

Verified By
Sign & date……

PERFORMANCE QUALIFICATION REPORT FOR PHARMA CODE READER

Product Name		Batch No.	
Maximum speed …….			

S.No.	Date	Time	Tests	Observations		Remarks (Pass/fail)
				Qty. of pass cartons	Qty. of fail cartons	
1.			Pass product barcode of carton.			
2.			Put one extra bar in carton.			
3.			Merge two bars in carton.			

Checked By
Sign & date……

Verified By
Sign & date……

7.2.2.2 MIXUP DIFFERENT PRODUCT CARTON:

Product Name		Batch No.	
Minimum speed …….			

S.No.	Date	Time	Tests	Observations		Remarks (Pass/fail)
				Qty. of pass cartons	Qty. of fail cartons	
1.			Pass product barcode of carton.			
2.			Pass different product barcode of carton.			

Checked By
Sign & date……

Verified By
Sign & date……

Product Name		Batch No.	
Optimum speed …….			

S.No.	Date	Time	Tests	Observations		Remarks (Pass/fail)
				Qty. of pass cartons	Qty. of fail cartons	
1.			Pass product barcode of carton.			
2.			Pass different product barcode of carton.			

Checked By
Sign & date……

Verified By
Sign & date……

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR PHARMA CODE READER

Product Name		**Batch No.**	
Maximum speed …….			

S.No.	**Date**	**Time**	**Tests**	**Observations**		**Remarks (Pass/fail)**
				Qty. of pass cartons	**Qty. of fail cartons**	
1.			Pass product barcode of carton.			
2.			Pass different product barcode of carton.			

Checked By
Sign & date……

Verified By
Sign & date……

Inference:

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Reviewed By
Sign & Date: ……

PERFORMANCE QUALIFICATION REPORT FOR PHARMA CODE READER

8.0 CHECKLIST OF ALL TESTS & CHECKS:

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

Tests or Checks	Executed (Yes/No)	Remarks
Verification of DQ, IQ & OQ & other documents.		
Verification of performance using product.		

Checked By
Sign & Date: _____

Verified By
Sign & Date: _____

Inference:

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Reviewed By
Sign & Date:_____

9.0 DOCUMENTS ATTACHED:

- Any other Relevant Documents.

10.0 NON COMPLIANCE:

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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 ABBREVIATIONS:

WHO	:	World Health Organization
GMP	:	Good Manufacturing Practices
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance qualification
SOP	:	Standard operating procedure
PCR	:	Pharma code reader
BCR	:	Batch code reader

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17.0 REPORT POST 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)			