PERFORMANCE QUALIFICATION PROTOCOL FOR BIOMETRIC SYSTEM

EQUIPMENT ID. No.	
LOCATION	
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR BIOMETRIC SYSTEM	PROTOCOL No.:

PROTOCOL CONTENTS

 PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR BIOMETRIC SYSTEM	PROTOCOL No.:

1.0 PROTOCOL APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

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 as per the parameter defined in operational qualification and that it gives result as per the predetermined acceptance criteria.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.
- The document also provides the observed and obtained values indicating compliance to the PQ Protocol.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the Biometric System.

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 cum Report. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity • Monitoring of Performance Qualification.
Production	• Review of Protocol cum Report. • To co-ordinate and support Performance Qualification Activity.
Engineering	• Review & Approval of Report. • Co-ordination, Execution and technical support in Biometric Qualification Activity. • Responsible for Trouble shooting (if occurs during execution).

5.0 EQUIPMENT DETAILS:

Equipment Name	Biometric System
Equipment ID.	
Manufacturer's Name	
Location of Installation	

6.0 SYSTEM DESCRIPTION:

The Biometric Authentication System based on biometric features (e.g. fingerprint). This system is to ensure that only authorized person shall access the critical area. This instrument identified the personnel through the finger identification and allows opening the door through the magnetic control.

7.0 REASON FOR QUALIFICATION:

New Equipment

8.0 SITE OF STUDY:

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9.0 FREQUENCY OF QUALIFICATION:

- Major maintenance of critical parts
- Any major modification in the existing system
- If the system is found to be malfunctioning/ after any major breakdown maintenance
- Relocation of the Equipment.

10.0 PRE-QUALIFICATION REQUIREMENTS:

10.1 Verification of Documents:

S.No.	Document Name	Document / SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
1.	PQ Protocol				
2.	SOP for Operation and Handling of Biometric System for Entry and Exit Procedure for manufacturing and Filling areas.				

10.2 Training of Qualification Team:

- All the persons involved in the execution of Qualification Protocol must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working at service floor.

10.3 Calibration of all Components of System and Test Instruments:

- Calibration of all the instruments used for Re-qualification should be mentioned along with Calibration Certificates.

11.0 TESTS AND CHECKS:

11.1 PERFORMANCE OF BIOMETRIC READER:

11.1.1 Objective:

- To verify the performance of Biometric Reader.

11.1.2 Acceptance Criteria:

Qualification shall be considered acceptable when requirements listed in below listed table has been fulfilled.

11.1.3 Observation:

- Record the observations in performance qualification report.

Test No.	Performance Qualification Test	Acceptance Criteria
1	After power ON reader showing Correct timing & Date	Biometric reader showing correct timing & Date
2	Open Menu option as user login.	It is not possible to login.
3	Open Menu by putting finger on sensor screen	It is not possible to login.
4	Open Menu as Admin login	Menu options will open.
5	Edit Admin roll as Admin login	Edited the Admin details.
6	Delete Admin roll as Admin login	Deleted the Admin roll.
7	Edit User data as Admin login	Edited the user details.

Test No.	Performance Qualification Test	Acceptance Criteria
8	Delete User data as Admin login.	Deleted User details.
9	Enroll user ID by as User login.	It is not possible to add user.
11	Verify user ID by finger print.	It is showing same user id at the time of verification of finger print
12	Verify user ID by different finger	It is not accepting other than enrolled finger
13	Edit Admin as an user	It is not possible to edit Admin as a user.
14	Delete Admin as an user	It is not possible to delete Admin as a user.
15	Enroll User as an user	It is not possible to enroll User as a user.
16	Storing log time and date	It is storing log time and date when user finger is verifying.
17	Unauthorized finger verification	It is not storing unauthorized log.
18	Checking IP Address of Biometric reader.	It is showing biometric IP Address.
19	Authorized finger verification	The door should be open through the magnetic control.
20	Unauthorized finger verification	The door should not be open through the magnetic control.
21	In normal condition	The door should not be open through the magnetic control.
22	Entry / Exit Emergency Button	All entry door should be open

11.2 CHALLENGE TEST:

11.2.1 Objective:

- To verify the performance of Biometric System.

11.2.2 Procedure:

- Operate the Biometric Machine as per SOP.
- Three authorized & unauthorized persons put their finger on scanning screen on Biometric machine.

11.2.3 Acceptance Criteria:

Qualification shall be considered acceptable when access is given to only authorized persons and stop the entry of unauthorized persons.

11.2.4 Observation:

- Record the observations in performance qualification report.

12.0 CHECKLIST OF ALL TESTS & CHECKS:

S.No.	Name of Test or Check	Acceptance Criteria
1.	Performance of Biometric Reade	The listed requirements in table should be fulfilled
2.	Challenge Test	Qualification shall be considered acceptable when access is given to only authorized persons and stop the entry of unauthorized persons.

13.0 REFERENCES:

The Principle Reference is the following:

- 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:

- List of Authorized Persons.
- Pictorials

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.

18.0 ABBREVIATIONS:

No.	:	Number
BMT	:	Biometric System
SOP	:	Standard Operating Procedure
WHO	:	World Health Organization
QA	:	Quality Assurance
PPQ	:	Protocol Performance Qualification