OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BIOMETRIC SYSTEM

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

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BIOMETRIC SYSTEM	PROTOCOL No.:

CONTENTS

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BIOMETRIC SYSTEM	PROTOCOL No.:

1.0 PRE – 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)			

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set acceptance criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Biometric System and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this Operational qualification protocol cum report is limited to qualification of **Biometric System**.
- This Protocol will define the methods and documentation used to perform OQ activity of Biometric System successful, completion of this Protocol will verify that Biometric System meet all acceptance criteria and ready for Daily use.

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, Approval and Compilation of the Operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operational Qualification Activity. • Post approval of Operational Qualification Protocol Cum Report.
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.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in Biometric System Operational Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol Cum Report.

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 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol Cum Report
- IQ Protocol cum Report
- SOP For Operation And Handling Of Biometric System For Entry And Exit Procedure For Manufacturing And Filling Areas.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date
1.	DQ Protocol Cum Report			
2.	IQ Protocol Cum Report			
3.	SOP For Operation And Handling Of Biometric System For Entry And Exit Procedure For Manufacturing And Filling Areas.			

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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……
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Reviewed By
(Manager QA)
Sign/Date: ……

8.2 Operational and Functional Checks:

Operate the Biometric System as per Manufacturer's Manual/SOP and Check for the following functions of the equipment. The Equipment should function as desired.

S.No	Name of component /Accessory	Area	Physical Condition	Working	Discrepancy Yes/No	Checked by (Sign/Date)
1.	Electro-magnetic Lock					
2.						
3.						
4.	Biometric Systems					
5.						
6.						
7.	Display working Time / Date					
8.						
9.						
10.	Light glowing Green/ Red					
11.						
12.						
13.	Voice indicator					
14.						
15.						
16.	UPS check					
17.						
18.						
19.	Door Opening					
20.						
21.						

Acceptance Criteria: Access control gives beep with green light for authorized person. Unauthorized entry should be rejected with beep with red light. Light should glow.

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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……
……

Reviewed By
(Manager QA)
Sign/Date: ……

8.3 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power shut down	Equipment stops in safe and secure condition		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:
……
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……

Reviewed By
(Manager QA)
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."
- EU Guide to Good Manufacturing Practice, Part 4, 30 March 2015.

10.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents

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:

WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
QA	:	Quality Assurance
IQ	:	Installation Qualification
OQ	:	Operational Qualification
EQ	:	Equipment
BMT	:	Biometric System
CFM	:	Cubic feet per minute
SOP	:	Standard Operating Procedure

17.0 POST APPROVAL:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

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

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			