



PHARMA DEVILS

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
BIOMETRIC SYSTEM**

PROTOCOL No.:

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
BIOMETRIC SYSTEM**

EQUIPMENT ID. No.	
LOCATION	
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL



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1.0 PROTOCOL PRE – APPROVAL:

PREPARED 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 for the Installation Qualification of Biometric System.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of Biometric System to be installed.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Biometric System.



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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	<ul style="list-style-type: none">• Preparation, Review, Authorization and Compilation of the Installation Qualification Protocol cum Report.• Co-ordination with Production and Engineering to carryout Installation Qualification.• Monitoring of Installation Qualification Activity.• Post Approval of Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review & Pre Authorization of Installation Qualification Protocol cum Report.• To Co-ordinate and support for Execution of Qualification study as per Protocol.• Post Approval of Installation Qualification Protocol Cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Installation Qualification Protocol cum Report.• Co-ordination, Execution and technical support in Installation Qualification Activity.• Calibration of Process Instruments.• Responsible for Trouble Shooting (if occurs during execution).• Post Approval of Installation Qualification Protocol Cum report after Execution.



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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:

- 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.

7.1.2 Acceptance Criteria:

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



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	OBSERVED BY (ENGINEERING) SIGN/DATE
Application: Biometric System is capable to ensure that only authorized person shall access the critical area	Biometric System should meet the requirement to ensure that only authorized person access the critical area		
Working: Working of Biometric System	Instrument identified the personnel through the finger identification and allows opening the door through the magnetic control		
Electrical Control Panel	The system should have Electrical Control Panel.		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:
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Reviewed By
Manager QA
Sign/Date:



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8.1 VERIFICATION OF UTILITY REQUIREMENTS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	OBSERVED BY (ENGINEERING) SIGN/DATE
Utility connections should be available as per the manufacturer's specification.			
Electricity	220 V ± 10% / 50 Hz, Three Phase		
UPS	Should be Connected with UPS		
Room Condition	Should be able to meet the requirement of clean environment.		

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Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



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8.2 Installation Checks For Technical Specification:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	OBSERVED BY (ENGINEERING) SIGN/DATE
Magnet Lock	Door Mounted		
Access Control	Biometrics recognizes the finger print with real time monitoring		
Mounting applicability	Every Person can easily access		
Physical Condition	No physical damage to the instrument after locating on the final site of installation		
Cleanliness	All access parts are examined and cleared of any debris		
Leveling & anchoring	Instrument should be leveled properly.		
Earthing and connections	Loose unidentified wires should not be present		
	Required electric connections are connected properly (tight) and appropriately grounded and protected from shock		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



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8.3 SAFETY FEACHURE & ALARM :

Critical Variables	Acceptance Criteria	OBSERVATION (Complies /Not Complies)	OBSERVED BY (ENGINEERING) SIGN/DATE
Leveling and balancing	Biometric System should be properly balanced & leveled		
Electrical wiring	Electrical wiring should be proper		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
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Sign/Date:



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9.0 REFERENCES:

- Design Qualification
- Vendor Documents

10.0 DOCUMENTS TO BE ATTACHED:

- Calibration certificates.
- Any other relevant documents.

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:

- cGMP : Current Good Manufacturing Practice
- BMS : Biometric System
- HP : Horse Power
- Hz : Hertz
- IQ : Installation Qualification
- MCB : Miniature circuit breaker
- mm : Millimeter
- NLT : Not less than
- NMT : Not More Than
- RH : Relative Humidity
- RPM : Revolution per minute
- SS : Stainless steel



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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 (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			