



PHARMA DEVILS

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

PROTOCOL No.:

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

EQUIPMENT ID. No.	
LOCATION	AMPOULE LINE
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 (QC-MICROBIOLOGY)			

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 to be installed at Ampoule line.
- 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 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 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 of Installation Qualification Protocol cum Report.• Co-ordination, Execution and technical support in Installation Qualification Activity.• 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	
Modal	
Location of Installation	Ampoule line

6.0 SYSTEM DESCRIPTION:

The NIYAMA HVAC BMS encompasses state-of-the-art technology with the vision of monitoring and controlling AHU parameters within the Concord environment where accurate temperature, humidity and CFM monitoring and controlling are essential. Niyama HVAC BMS supplied by Shree Aerodynamic Products having following basic components:

- Our modules in Ms powder Coated Control panel with necessary control outputs , supply and CFM ,Temperature ,Humidity Sensors and Real-time Display Console with Alert Indications
- Communication card for PC.
- HVAC BMS software

Distinctive Features

- Data monitoring, logging and notification using central base receiver.
- The Internet- and web-enabled remote diagnostics and maintenance
- Controlled access to **NIYAMA HVAC BMS software** based on allocated user privileges.
- Display current temperature ,humidity ,CFM Initiates alarm as per defined parameter limits for each parameters
- Real time monitoring, logging and reporting.
- Best-in-class data analysis tools, including ability to graph and report in standard and user-defined formats.
- Wired module connections to the central computer system.
- Modules are scalable and easy to integrate for fast time-to-market applications.



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7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 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 IQ commencing.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date
1.	DQ Protocol Cum Report			

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)	VARIFICARTION SOURCE	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
Engineering
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 VERIFICATION OF UTILITY REQUIREMENTS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	VARIFICATION SOURCE	OBSERVED BY (ENGINEERING) SIGN/DATE
Utility connections should be available as per the manufacturer's specification.				
Power	230 V, 1-phase, 50 Hz. Continues ups power supply			
Personal computer, For data logging & monitoring	Intel Core i5 Processor, 16 GB RAM Minimum, Ubuntu OS, 1TB Hard Drive, USB support			
Printer	Any printer.			
User	All the user list with Email ids			

**Checked By
Engineering
Sign/Date:**

**Verified By
Quality Assurance
Sign/Date:**

Inference:
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Sign/Date:**



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8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	VARIFICATION SOURCE	OBSERVED BY (ENGINEERING) SIGN/DATE
Body	Powder coated panels			
Dimensions	820 mm x 771 mm x 220.22 mm			
Weight	50 Kg Approx.			
Functions:				
Temperature	-40 to +125 °C with 2 decimal point			
CFM	CFM is Based on Delta P			
Relative Humidity	0 to 100% with 2 decimal point			
Accurate Monitoring	Locally, Centrally and Remotely.			
Display	Real Time Display ,Big LCD display			
Trends	Online and Historical			
Features	<ul style="list-style-type: none"> • Trends • Alarm set point configuration • Control parameter configuration 			
Measurements	CFM, Pressure, Temperature and RH			
High and low alarm	Upper and Lower limit			
Alarm output (Optional)	Dry contact or solid state			
Data printing	Individual or centralized module			
Communication	Hard wired / wireless			
Hooter	Potential free output			
User configurable	High & Low alarms setup			
Alarm output	Simple ON/OFF control			
Operator attention	Visual and Audible alarm notification			
Support	Multiple Windows			



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	VARIFICATION SOURCE	OBSERVED BY (ENGINEERING) SIGN/DATE
Major Components:				
General	Machine No. 1			
Controller Differential Bus Trans receiver	IC name: Atmega128 A Manufacturer : ATMEL Speed grades: 0 - 16 MHz Operating Voltages: 4.5-5.5 V Qty.: 1 No. IC number: SN75176B Manufacturer: Texas Instruments Bidirectional Transceivers Operating Voltages: 4.5-5.5 V Qty : 1 No.			
Real Time Clock	IC Number: DS1307 Manufacturer: Dallas semiconductor Operating Voltages: 4.5-5.5 V Two wire interface Auto power fail to detect and switch circuitry Qty : 1 No.			
Temperature Sensor	IC Number: SHT15 Manufacturer: Sensirion Two wire interface Operating range : -40 to +125 °C Operating Voltages: Qty: 1 No. In Each Module			



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RH Sensor	IC Number: SHT15 Manufacturer: Sensirion Two wire interface Operating range : 0 to 100% Operating Voltages: Qty: 1 No. In Each Module			
Differential Pressure Sensor	IC Number: 5852-003-D Manufacturer: Silicon Microstructures Two wire interface Operating range : 0.3 PSI to 1.5 PSI Operating Voltages: Qty: 1 No. In Each Module			
Digital Display Room Temperature Sensor	IC Number: HUT21D Manufacturer: Measurement Specialties, Inc. Two wire interface Operating range : -40 to +125 °C Operating Voltages: Qty: 1 No. In Each Module			



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	VARIFICATION SOURCE	OBSERVED BY (ENGINEERING) SIGN/DATE
Digital Display Room RH Sensor	IC Number: HUT21D Manufacturer: Measurement Specialties, Inc. Two wire interface Operating range : 0 to 100% Operating Voltages: Qty: 1 No. In Each Module			
Digital Display Room Differential Pressure Sensor	IC Number: SM9543 Manufacturer: Silicon Microstructures Two wire interface Operating range : 500 Pa Operating Voltages: Qty: 1 No. In Each Module			
Identification plate	Name of the equipment and/or suppliers name to be available on the equipment.			
Any physical damage to the equipment	No physical damage should be observed			



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	VARIFICATION SOURCE	OBSERVED BY (ENGINEERING) SIGN/DATE
General method of the electrical wiring	A. No loose hanging cables B. Well-insulated electrical wirings. C. Located in a safe place well protected from water seepage during machine or floor cleaning and also safe for operator during operation			

**Checked By
Engineering
Sign/Date:**

**Verified By
Quality Assurance
Sign/Date:**

Inference:

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**Reviewed By
Manager QA
Sign/Date:**



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8.4 SAFETY FEATURE & 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
Engineering
Sign/Date:**

**Verified By
Quality Assurance
Sign/Date:**

Inference:

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Sign/Date:**



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9.0 REFERENCES:

- Design Qualification

10.0 DOCUMENTS TO BE ATTACHED:

- 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
- IQ : Installation Qualification
- Pa : Pascal
- Qty. : Quantity
- % : Percentage
- V : Voltage
- CFM : Cubic Feet Minute
- LCD : Liquid Crystal Display
- °C : Degree Centigrade
- Kg : kilo gram
- P : Pressure
- mm : Mille Meter
- RH : Relative Humidity
- GB : Giga Byte
- TB : Tetra Byte
- RAM : Random Access memory
- Hz : hartz



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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 (QC-MICROBIOLOGY)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			