



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
NITROGEN GAS GENERATION & DISTRIBUTION SYSTEM**

PROTOCOL No.:

EFFECTIVE DATE:

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**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
NITROGEN GAS GENERATION AND
DISTRIBUTION SYSTEM
(CAPACITY: 10 Nm³/Hr)**

EQUIPMENT ID. No.	
LOCATION	UTILITY BLOCK
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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1.0 PROTOCOL PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

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 Nitrogen Gas Generation & Distribution System for Utility Block, at
- 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 **Nitrogen Gas Generation & Distribution System (Make – Mass Gas air Systems Pvt. Ltd.)** to be installed in utility block at
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of **Nitrogen Gas Generation & Distribution 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">• Initiation, Authorization, Approval 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 Installation Qualification Protocol Cum Report after Execution.
Production	<ul style="list-style-type: none">• Review & Pre Approval of 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 Protocol cum Report.• Co-ordination, Execution and technical support in Nitrogen gas Generation & Distribution System 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	Nitrogen Gas Generation & Distribution System
Equipment ID No.	
Model	PSA Based model
Manufacturer's Name	MASS GASAIR SYSTEMS PVT. LTD.
Supplier's Name	MASS GASAIR SYSTEMS PVT. LTD.
Capacity	10 Nm³/hr.
Outlet Pressure	5.5 Kg/cm²
Place of Installation	UTILITY BLOCK



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6.0 SYSTEM DESCRIPTION:

Type : PSA BASED NITROGEN PLANT

Capacity : 10 Nm³/hr

Purity : 99.5%

Outlet Pressure : 5.5 Kg/cm²

Dew Point : (-) 40 °C

- PSA (Pressure Swing Adsorption) Based Nitrogen Plant is to produce Nitrogen gas from Atmospheric compressed air. Air passes through Carbon Molecular Sieves (CMS) at a certain pressure, the moisture, Oxygen and CO₂ are selectively adsorbed, and balance nitrogen comes out and collects in the receiver.
- Compressed air first collects in air receiver at 7.0 kg/cm² pressure and then goes to PSA module through air filter module. The air receiver has been provided to avoid air pressure fluctuation so that a constant flow & pressure will be available during plant operation. One high efficient air filter has been provided at the outlet of air receiver to arrest dust particles from nitrogen gas before entering the PSA module.
- This is a specially designed composite bed type PSA module having two towers filled with special grade of Activated Alumina and second generation of high efficient Carbon Molecular Sieves (CMS) to produce 99.5% pure Nitrogen. As compressed air passes through the PSA module, moisture from compressed air is adsorbed in the Alumina Bed and oxygen & carbon dioxide are selectively adsorbed in the CMS bed, balance Nitrogen is collected in the surge vessel at the outlet of the PSA Module.
- Surge Vessel is a vertical, cylindrical type vertical pressure vessel. Surge vessel has been provided to collect outlet nitrogen before sending to storage tank/user point.
- One Oxygen analyzer is connected with this vessel to measure oxygen impurity in the product nitrogen. Nitrogen from the surge vessel now goes to the user point through a flow meter and backpressure control valve at the required flow and pressure. To avoid impure high oxygen content in nitrogen, a 3-way vent valve has been provided with an interlock of oxygen analyzer. In case oxygen content is high as the purity limit, nitrogen will vent out into the atmosphere until purity comes within the desired limit.



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7.0 PRE-QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Instrumentation diagram.
- Technical specification of equipment.
- Calibration certificate of components.
- Certificate of material of construction of components.

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.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum report.

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 General Checks and Location Suitability:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Leveling	Should be properly balanced and leveled.		
Edges of parts	All the parts should be properly grind without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Utility block Block		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

**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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8.2 Installation Checks:

S.No.	Specification	Observation	Observed By (Engineering) Sign/Date
1.	Check the Proper mechanical installation of Nitrogen Gas Generation & Distribution system		
2.	Check any physical damage to the equipment		
3.	Check the assembly of components as per the general arrangement drawing		
5.	Check the proper electrical installation Nitrogen Gas Generation & Distribution system		
6	Check the proper pipe line installation of Nitrogen Gas Generation & Distribution System		
7	Check that major components are protected from leakage and there is no physical damage		
8	Check that all piping have been done according to the drawing		

**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 MOC Verification List:

S. No.	Components	Acceptance Criteria	Observations	Observed By (Engineering) Sign/Date
1.	Moisture trap	Alumina bed		
2.	Oxy trap	CMS Bed		
3.	MOC for Pressure vessels	IS 2062		
4.	MOC of Pipes	IS 1239 Cl. 'C'		

**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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8.4 Equipment Verification:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Manufacturer	MASS GASAIR SYSTEMS PVT. LTD.		
Type	PSA Based		
Capacity	10 Nm ³ /hr.		
Activated alumina bed tower.	For absorption of Oxygen & Carbon dioxide from atmospheric compressed air.		
CMS tower	For absorption of moisture from atmospheric compressed air.		
Air receiver tank	Collection of atmospheric compressed air at 7.0 Kg/cm ² g		
Nitrogen receiver tank	Storage of nitrogen @ 5.5 Kg/cm ² g for further distribution		
Surge vessel	Collect outlet nitrogen before send to nitrogen receiver		
Oxygen analyzer	Analyze oxygen content before collection in nitrogen receiver tank.		
Exhaust silencer	Reduce noise pollution during exhaust		
Cartridge Filter	1 μ		
Oil trap filter	Activated Carbon Filter		
Oil trap filter	0.01 μ		
Bacteriological Filter	0.22 μ		
Outlet Pressure	5.5 Kg/cm ² g		
Max. Working Pressure	7.0 Kg/cm ² g		



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Design Pressure	8.0 Kg/cm ² g		
Test Pressure	12.4 Kg/cm ² g		
MOC for Pressure vessels	IS 2062		
MOC of Pipes	IS 1239 Cl. 'C'		
MOC of Change-over valves	Die Cast Aluminum (specially Design for PSA System).		

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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9.0 REFERENCES:

The Principle Reference is the following:

- Master Validation Plan
- 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.

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC
- Calibration certificates



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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:

No.	:	Number
WHO	:	World Health Organization
QA	:	Quality Assurance
PVT.	:	Private
Ltd.	:	Limited
ID	:	Identification
No.	:	Number
PC	:	Pure & Cure
UB	:	Utility Block
PSA	:	Pressure Swing Adsorption
CMS	:	Carbon molecular sieve
Kg	:	Kilo gram
°C	:	Degree centigrade
Mg	:	milligram
m ³	:	meter cube
IQ	:	Installation qualification



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17.0 PROTOCOL POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			