DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR NITROGEN GAS GENERATION AND DISTRIBUTION SYSTEM (CAPACITY: 10 Nm^3/Hr)

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PROTOCOL CONTENTS

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1.0 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)			

2.0 OBJECTIVE:

- To prepare the Design Qualification document for **Nitrogen gas Generation & Distribution system** on basis of URS and information given by Supplier.
- To ensure that all Critical aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of **Nitrogen gas Generation & Distribution System (Make: Mass Gas air Systems Pvt. Ltd.**) in utility block at …….
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings provided by Vendor shall be verified during Design Qualification.

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	• Initiation, Authorization and Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Co-ordination with Production &Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity. • Review of Design Qualification Protocol cum Report after Execution.
Production	• Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Design Qualification Protocol cum Report after Execution.
Engineering	• Review of the Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e. ➢ GA Drawing ➢ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/brochures. ➢ Details of utilities Required. ➢ Identification of components for calibration ➢ Material of construction of Product Contact Parts ➢ Brief Process Description ➢ Safety Features and Alarms • Review of Design Qualification Protocol cum Report after Execution.

5.0 BRIEF EQUIPMENT DESCRIPTION:

PSA (Pressure Swing Adsorption) Based Nitrogen Plant is to produce Nitrogen gas form Atmospheric compressed air. Air passes through Carbon Molecular Sieves (CMS) at a certain pressure, the moisture, Oxygen and CO_2 are selectively adsorbed, and balance nitrogen comes out and collects in the receiver. Compressed air first collects in air receiver at 7.0 kg/cm^2 pressure and then goes to PSA module through air filter module. The air receiver has been providing to avoid air pressure fluctuation so that a constant flow & pressure will 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 enter in 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 passed through PSA module, moisture from compressed air is adsorbed in Alumina Bed and oxygen & carbon dioxide are selectively adsorbed in CMS bed, balance Nitrogen collected in surge vessel at the outlet of PSA Module.
Surge Vessel is a vertical, cylindrical type vertical pressure vessel. Surge vessel has been provided to collect outlet nitrogen before send to storage tank / user point.

One Oxygen analyzer connected with this vessel to measure oxygen impurity in the product nitrogen. Nitrogen from surge vessel now goes to user point through flow meter and backpressure control valve at required flow and pressure. To avoid impure high oxygen content in nitrogen on 3-way vent valve has been provided with an interlock of oxygen analyzer. In case oxygen content high as purity limit nitrogen will vent out in the atmosphere till purity comes with in desired limit.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared by ……. The manufacturer of equipment ensures complies with User Requirement Specification.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 Process/Product Parameters:

Critical Variables		Acceptance Criteria	Reference
PSA Module	Activated alumina bed	Mounted on the base panel which traps moisture from the incoming gases in Activated Alumina bed.	Process Requirement
	Carbon molecular sieves bed	Mounted on the base panel which traps Carbon dioxide & oxygen.	
Pressure gauge for Activated Alumina Bed		Pressure gauges is attached before activated alumina bed (Moisture trap)	Process Requirement
Pressure gauge for Carbon Molecular Sieves bed		Pressure gauges is attached before Carbon molecular sieves bed (Oxy trap)	Process Requirement
Application: Nitrogen gas generation & Distribution system unit is capable of producing upto 99.5% pure nitrogen at generation point.		Nitrogen gas system Flow should meet the requirement to provide a up to 99.5% pure nitrogen	Process Requirement
Electrical Control Panel		The system should have Electrical Control Switch.	Design Requirement

7.2 Utility Requirements/Location Suitability:

Critical Variables	Acceptance Criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	• Voltage: 230 V • Phases: 1 Phase • 100Watts	cGMP Requirement
Non lube type Dry Compressed air:	• 40 CFM @ 7.0 Kg/cm²g Pressure & - 40 °C Temp.	cGMP Requirement

7.3 Technical Specifications/Key Design Features:

Critical Variables	Acceptance Criteria	Reference
Manufacturer	…….	Process Requirement
Type	PSA Based	Design Requirement
Capacity	10 $Nm^3/hr.$	Design Requirement
Activated alumina bed tower	For absorption of oxygen & carbon dioxide from atmospheric Compressed air	Design Requirement
CMS tower	For absorption of moisture from atmospheric Compressed air.	Design Requirement
Air receiver tank	Collection of atmospheric Compressed air at 7.0 Kg/cm^2g	Design Requirement
Nitrogen receiver tank	Storage of nitrogen @ 5.5 Kg/cm^2g for further distribution	Design Requirement
Surge vessel	Collect outlet nitrogen before send to nitrogen receiver	Design Requirement
oxygen analyzer	Analyze oxygen content before collection in nitrogen receiver tank.	Design Requirement
Exhaust silencer	Reduce noise pollution during exhaust	Design Requirement
Cartridge Filter	1 µ	Design Requirement
Oil trap filter	Activated Carbon Filter	Design Requirement
Oil trap filter	0.01 µ	Design Requirement
Bacteriological Filter	0.22 µ	Design Requirement
Outlet Pressure	5.5 Kg/cm^2g	Design Requirement
Max. Working Pressure	7.0 Kg/cm^2g	Design Requirement
Design Pressure	8.0 Kg/cm^2g	Design Requirement
Test Pressure	12.4 Kg/cm^2g	Design Requirement
MOC for Pressure vessels	IS 2062	Design Requirement

Critical Variables	Acceptance Criteria	Reference
MOC of Pipes	IS 1239 Cl. 'C'	Design Requirement
MOC of Change-over valves	Die Cast Aluminum (specially Design for PSA System).	Design Requirement

Checked By
(Engineering)
Sign/Date: _____

Verified By
Quality Assurance
Sign/Date: _____

Inference: _____

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Reviewed By
(Manager QA)
Sign/Date: _____

7.4 Material of Construction:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
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
(Engineering)
Sign/Date: _____

Verified By
Quality Assurance
Sign/Date: _____

Inference: _____

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Reviewed By
(Manager QA)
Sign/Date: _____

7.5 Safety:

Parameters	ACCEPTANCE CRITERIA	REFERENCE
Nitrogen gas cylinder	Gas leakage should be verified before installing Nitrogen Cylinder	Process Requirement

Checked By
(Engineering)
Sign/Date: _____

Verified By
Quality Assurance
Sign/Date: _____

Inference: _____

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Reviewed By
(Manager QA)
Sign/Date: _____

7.6 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for supplying the "Nitrogen Gas Generation plant "	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical know -how, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

Reference: (1) User Requirement Specifications (URS).

(2) Design & Functional Specifications provided by Vendor.

8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy.
- Any other relevant documents.

9.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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12.0 ABBREVIATIONS:

No.	:	Number
QA	:	Quality Assurance
PVT.	:	Private
Ltd.	:	Limited
ID	:	Identification
No.	:	Number
UB	:	Utility Block
PSA	:	Pressure Swing Adsorption
CMS	:	Carbon molecular sieve
Kg	:	Kilo gram
°C	:	Degree centigrade
Mg	:	Milligram
m^3	:	Meter cube

13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			