PERFORMANCE QUALIFICATION REPORT FOR NITROGEN GAS GENERATION AND DISTRIBUTION SYSTEM CAPACITY: 10 Nm^3/Hr

EQUIPMENT ID. No.	
LOCATION	Utility Block
DATE OF QUALIFICATION	
SUPERSEDE REPORT No.	00

REPORT CONTENT

PERFORMANCE QUALIFICATOIN REPORT FOR NITROGEN GAS GENERATION & DISTRIBUTION SYSTEM	PROTOCOL No.: REPORT No.: EFFECTIVE DATE: PAGE No.: 3 of 22

1.0 REPORT PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To provide documented evidence that the **Nitrogen Gas Generation & Distribution System** is performing consistently, repeatedly and reproducibly within its established operating range and the results of all the test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The score of this report is limited for Qualification of **Nitrogen Gas Generation & Distribution System (Make- Mass Gas air Systems Pvt. Ltd)** installed in the Utility Block at …….
- This report provides all the relevant information of the performance Qualification activity, observations and analytical data of testing of collected samples.

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, Approval and Compilation of the Performance Qualification. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Report. • To co-ordinate and support Performance Qualification Activity. • Post Approval of Performance Qualification report after Execution.
Quality Control	• Review of Report. • Analytical Support (Microbiological Testing/Analysis) • Post Approval of Performance Qualification report after Execution.
Engineering	• Reviewing of Qualification Report for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Engineering assistance at the time of execution of PQ Study • Maintenance & preventive maintenance as per schedule. • Post Approval of Performance Qualification report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	**NITROGEN GAS SYSTEM**
Equipment ID No.	**…..**
Model	**PSA Based**
Manufacturer's Name	**MASS GASAIR SYSTEMS PVT. LTD.**
Supplier's Name	**MASS GASAIR SYSTEMS PVT. LTD.**
Capacity	**10Nm^3/hr.**
Outlet Pressure	**5.5 Kg/cm^2**
Location of Installation	**UTILITY BLOCK**

6.0 SYSTEM DESCRIPTION:

Type : PSA based Nitrogen Plant

Capacity : 10 Nm^3/hr

Purity : 99.5%

Outlet Pressure : 5.5 Kg/cm^2

Dew Point : (-) 40 °C

- 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.

7.0 REASON FOR QUALIFICATION:

- New user points added in FFS line & schedule requalification of DPI, Three Piece & Ampoule Line I-block at ……..

8.0 SITE OF STUDY:

Utility Block

9.0 FREQUENCY OF QUALIFICATION:

- Once in a six month.
- After any major breakdown or after major modification.
- After Change of Location.
- New User point added.

10.0 PRE – QUALIFICATION REQUIREMENTS:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance Qualification report.

10.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

S. No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	Executed and approved Design Qualification cum report				
2.	Executed and approved Installation Qualification cum report				
3.	Executed and approved Operational Qualification cum report				
4.	SOP for operation & Cleaning of Nitrogen Gas Generation & Distribution System				
5.	SOP for Preventive Maintenance Nitrogen Gas Generation & Distribution System.				

Checked By
Sign/Date: ……

Verified By
Sign/Date:……

Inference:

……

……

……

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

10.2 Training Record of Validation Team:

- All the persons involved in the execution of Qualification activity including the persons of outside agencies must be trained in all aspects of the Qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working at service floor.
- Verify the training records and record the details below mentioned table.

S.No.	Name of Person	Employee Code	Department	Status of Training	Verified By (QA) Sign/Date
1.0					
2.0					
3.0					
4.0					
5.0					
6.0					
7.0					

Training Given By:
Sign & Date……

Inference:

……

……

……

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

10.3 Calibration of Test Instruments:

- Calibration of all the instruments used for Qualification should be mentioned along with Calibration Certificates.

S.No.	Name of Test Instrument	Date of Last Calibration	Next Due on	Status	Availability of Calibration Certificate	Verified By (QA) Sign/Date
1.						
2.						
3.						
4.						
5.						

Checked By:
(Engineering)
Sign/Date: ……

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

Inference:

……

……

……

……

……

Reviewed By
(Manager QA)
Sign/Date:……

11.0 TESTS AND CHECKS:

Performance Qualification study shall be carried out using following tests:

11.1 Determination of Oil Content & Moisture content in Nitrogen gas:

S.No.	Date	Area/Location	ID. No.	Observed Oil Content (NMT1.0 mg/m^3)	Observed Water Content (NMT500 mg/m^3)
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					

Remarks:

Oil & Water content determination shall be performed for other remaining/new introduced critical Nitrogen air supply points and observations for Oil & Water content determination shall be enclosed as addendum with report and photographs of Under Test Gastec Tubes are enclosed as annexure-I with this report.

Checked By
Sign/Date: ……

Verified By
Sign/Date:……

Inference:

……

……

……

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

PERFORMANCE QUALIFICATOIN REPORT FOR NITROGEN GAS GENERATION & DISTRIBUTION SYSTEM	PROTOCOL No.:
	REPORT No.:
	EFFECTIVE DATE:
	PAGE No.: 12 of 22

11.2 CO_2, CO & SO_2 Content Analysis of Nitrogen:

S.No.	Date	Area/Location	ID No.	Observed CO_2Content (NMT500.0ppm)	Observed CO Content (NMT5.0ppm)	Observed SO_2 Content (NMT1.0ppm)
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						

Checked By
Sign/Date: ……

Verified By
Sign/Date: ……

Inference:

……

……

……

……

Reviewed By
Manager QA)
Sign/Date……

11.3 O_2, Hydrocarbon & NO_2 Content Analysis of Nitrogen:

S.No.	Date	Area/Location	ID. No.	Observed O_2Content (NMT0.5%)	Observed Hydrocarbon (NMT500 ppm)	Observed NO_2 Content (NMT2.0 ppm)
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						

Checked By
Sign/Date: ……

Verified By
Sign/Date:……

Inference:

……

……

……

……..…

Reviewed By
Manager QA)
Sign/Date:…….

11.4 Assay of Nitrogen, Dew Point & Sterility:

S.No.	Date	Area/Location	ID No.	Dew Point (NMT-40°C)	Sterility (no growth Observed)	Nitrogen content (NLT 99.5%)
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						

Checked By
Sign/Date: ……

Verified By
Sign/Date:……

Inference:

……

……

……

……..…

Reviewed By
Manager QA)
Sign/Date: ……

11.5 Non – Viable Particle Count:

Name of equipment :

Particle Counter ID :

Date of Calibration :

Due on Calibration :

Make :

Date of Performance Qualification :

Date	Area/Location	Observation		Acceptance Criteria
		At Rest		
		0.5µ < d ≤ 1.0µ	1.0µ < d ≤ 5.0µ	
				Confirms to ISO Class 2
				0.5µ < d ≤ 1.0µ ≤ 6000 particles
				1.0µ < d ≤ 5.0µ ≤ 100 particles

Checked By
Sign/Date: ……

Verified By
Sign/Date……..……

Inference:

……
……
……
……

Reviewed By
Manager QA)
Sign/Date: ……

11.6 System Supply Reliability Test:

Instrument Name	
Make	
Model No.	
Instrument ID. No.	
Calibration Date	
Calibration Due Date	
Calibration Certificate attached	

S.No.	Date of Observation	Area/Location	ID. No.	Observed Pressure (Kg/cm^2) (1^{st} to 5^{th} Day)				
1.0								
2.0								
3.0								
4.0								
5.0								
6.0								
7.0								
8.0								
9.0								
10.0								

Remarks:
Observations of System Supply Reliability Test for other remaining/new introduced Nitrogen supply points shall be enclosed as addendum with report.

Checked By
Sign/Date: ……

Verified By
Sign/Date:……

Inference:

……
……
……

Reviewed By
(Manager QA)
Sign/Date……

12.0 CHECKLIST OF ALL TESTS & CHECKS:

S.No.	Name of Test or Check	Execution (Yes/No.)	Remark	Verified By (Sign & Date)
1.0				
2.0				
3.0				
4.0				
5.0				
6.0				
7.0				
8.0				
9.0				
10.0				
11.0				
12.0				
13.0				

Checked By
Sign/Date: ……

Verified By
Sign/Date:……

Inference:

……

……

……

Reviewed By
Manager QA)
Sign/Date:……

13.0 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."
- WHO Technical Report Series 961, Annexure - 05.
- EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use Annex -1 Manufacture of Sterile Medicinal Products.- February 2008.
- ISO 14644-1 of Clean Rooms and Associated Controlled Environments.

14.0 DOCUMENTS TO BE ATTACHED:

- Copy of SOPs.
- Raw data of QC analysis
- Any Other Relevant Documents.

15.0 NON COMPLIANCE:

.....

.....

.....

.....

.....

16.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

.....

.....

.....

.....

.....

.....

17.0 CHANGE CONTROL, IF ANY:

.....

.....

.....

.....

.....

.....

.....

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

.....

.....

.....

.....

.....

.....

19.0 CONCLUSION:

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

20.0 RECOMMENDATION:

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

21.0 ABBREVIATIONS:

CFM	:	Cubic feet Meter
HEPA	:	High Efficiency Particulate Air Filter
ID.	:	Identification
DYP	:	Nitrogen Gas Generation & Distribution System
Ltd	:	Limited
mm	:	Millimeter
MOC	:	Material of construction
No.	:	Number
Pvt.	:	Private
QA	:	Quality Assurance
WHO	:	World Health Organization
GMP	:	Good Manufacturing practice
µ	:	Micron
%	:	Percent
FDA	:	Food & drug administration
IB	:	Injection block
µg	:	micro gram
ft^3	:	Cubic feet
min	:	Minute
m^3	:	meter cube
SCA	:	Soyabean casein agar
CFU	:	Colony forming unit
&	:	And
WFI	:	Water for injection
EU	:	European union
ISO	:	Indian standard of organization
SOP	:	Standard operating procedure
PPQ	:	Protocol performance qualification

22.0 REPORT POST-APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			