QUALIFICATION OF PROTOCOL CUM REPORT OF COMPRESSED AIR GENERATION AND DISTRIBUTION SYSTEM

PHARMAGUIDEHUB

Location

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1.0 Protocol Approval:

Protocol Prepared By:

Functional Area	Name	Signature	Date
Validation			

Protocol Reviewed By:

Functional Area	Name	Signature	Date
Head - Engineering			
Head - Quality Control			
Head - Validation			
Head - Quality Assurance			

Protocol Approved By:

Functional Area	Name	Signature	Date
Head - Manufacturing			
Head - Quality			

2.0 Objective:

The Objective of this protocol is:

- To evaluate and qualify the compressed air generation and distribution system after the installation of cartridge filter (0.01µ) on the outlet of compressed air Tank.
- To establish a documented evidence to provide a high degree of assurance that the cartridge filter (0.01µ) installed in the user points consistently produce prerequisite quality of compressed air and complies with the specifications.

3.0 Scope:

This protocol is applicable to evaluate and qualify:

The compressed air generation and distribution system after the installation of cartridge filter (0.01µ) on the user points.

4.0 Responsibilities:

4.1 Quality Assurance:

4.1.1 Prepares the Qualification Protocol.

4.1.2 Reviews the Qualification Protocol for technical adequacy.

4.1.3 Issues the Certified copy of Qualification Protocol for execution.

4.1.4 Monitors the Qualification activities.

4.1.5 Approval of Qualification Protocol.

4.2 Production:

4.2.1 Assists in the Preparation of Qualification Protocol.

4.2.2 Executes the Qualification activities.

4.2.3 Review and Approval of Qualification Protocol.

4.3 Engineering:

4.3.1 Executes Qualification activities.

4.3.2 Calibration of measuring devices.

4.3.3 Assists in the Qualification activities.

4.3.4 Review and Approval of Qualification Protocol.

4.4 Quality Control (Microbiology):

4.4.1 Identifies sampling points.

4.4.2 Analysis of Compressed air samples.

4.4.3 Preparation of reports and trends.

5.0 Validation Team:

Following Personnel from Quality Assurance, Quality Control, and Production and Engineering department shall be involved in the Qualification activities of compressed air generation and distribution system.

DEPARTMENT	NAME	SIGNATURE	DATE
Quality Assurance (Validation)			
Production			
Engineering			
Quality Control (Microbiology)			

6.0 Equipment Description:

Compressed Air Generator:

The air compressor cylinder is NL (non lubricated) cylinder type used for applications which prohibit air from being contaminated with oil, grease, glycerin or other lubricants. NL cylinder features the TFE (Tetrafluroethylene) rider ring on the piston to prevent metal contact of the piston with the cylinder bore, and TFE piston rings to maintain proper wall pressure. Compressed air generated from the Air Compressor is being stored in Air receiver of $1m^3$ X capacity, which is installed with required auto condensate drain valve, safety valve and pressure gauge. Compressed air is then passed through air dryer then dry air is distributed to various departments by Galvized Iron pipeline.

Storage and Distribution System

Compressed air is used for all pneumatic operation in various equipments and in process areas. Air coming in contact with the product is called as a process air, which is having a filtration of 0.01 µ at main line. Air required for instrumentation or for pneumatic actuator is having assembly of 0.01 µ Filter-Regulator-Lubricator at user point.

7.0 Validation Study Program:

The re-qualification study shall be performed to evaluate and qualify the compressed air generation and distribution system as mentioned below.

7.1 Samples shall be collected from the generation point once daily for three days.

7.2 Chemical and Microbiological quality of Compressed air shall be checked for the conformance with specification.

8.0 Acceptance Criteria:

The compressed air shall be checked for the following quality attributes

S. No	Name of Parameter	Acceptance Criteria
1	Non –viable count	**0.5micron-3520** **5.0 micron-29**
2	Presence of Water vapour	**5mg/metre^3 for +3°c dew point and** **0.01mg/meter^{3}for -70°c**
3	Presence of oil and mist	**0.1 mg /meter^3**
4	Carbon monoxide content	**5ppm**
5	Carbon dioxide content	**100ppm**
6	Sulphur dioxide content	**0.5ppm**
6	Hydrogen Sulphide content	**1ppm**
7	Nitrogen oxide content	**0.5ppm**

The compressed air sample must comply as per In House specification throughout the distribution system.

9.0 Procedure

9.1 Total viable and non viable particle count is carried out as per QC sop n**o--------**

For oil and mist content, water vapour, carbon mono oxide content, carbon dioxide content, sulphur di oxide content and nitrogen content follow the following procedure with the help of Gastec tube

9.2 Install a procedure reducer with gauge and FRL to sampling point and adjust the flow meter with the required setting.

9.3 Break the tip of the fresh Gastec detector tube with the help of tube tip breaker and insert a tube into the tube holder.

9.4 Attach the rubber tube holder to the FRL outlet. Make certain that the tube arrow G→ on the tube is pointing in the down ward direction.

9.5 Turn on the compressed air and confirm the FRL according to each Gastec detector tube specification.

9.6 Time the sampling time with the help of stop watch.

9.7 As soon as the sampling time has elapsed turn off the compressed air and remove the tube from the tube holder and read the colour change immediately.

10.0 Sampling Plan:

The compressed air shall be sampled as per the following sampling plan.

11.0 Record of Observations & results:

Table No: 11.1

Test: Sub – Non viable particle count
Acceptance Criteria: 0.5micron-3520 ,5.0 micron-29

Sampling Point	Date					
	≥.5 µ	≥5 µ	≥.5 µ	≥5 µ	≥.5 µ	≥5 µ
GP-01						

Compiled By: **Verified By:**

Table No: 11.2

Test: Water vapour content
Acceptance Criteria: 5mg/metre^3

Sampling Point	Date			Remark
GP-01				

Compiled By: **Verified By:**

Table No: 11.3

Test: content of oil &mist
Acceptance Criteria: 0.1 mg /meter^3

Sampling Point	Date			Remarks
GP-01				

Compiled By: **Verified By:**

Table No: 11.4

Test: content for carbon monoxide
Acceptance Criteria: 5ppm

Sampling Point	Date			Remark
GP-01				

Compiled By: **Verified By:**

Table No: 11.5

Test: content for carbon monoxide
Acceptance Criteria: 5ppm

Sampling Point	Date			Remark
GP-01				

Compiled By: **Verified By:**

Table No: 11.6

Test: content for carbon dioxide
Acceptance Criteria: 100ppm

Sampling Point	Date			Remark
GP-01				

Compiled By: **Verified By:**

Table No: 11.7

Test: content for sulphur dioxide
Acceptance Criteria: 0.5ppm

Sampling Point	Date			Remark
GP-01				

Compiled By: **Verified By:**

Table No: 11.8

Test: content for sulphur dioxide
Acceptance Criteria: 0.5ppm

Sampling Point	Date			Remark
GP-01				

Compiled By: **Verified By:**

Table No : 11.9

Test: content for hydrogen sulphide
Acceptance Criteria: 1.0 ppm

Sampling Point	Date			Remark
GP-01				

Compiled By: **Verified By:**

Table No : 11.10

Test: content for Nitrogen oxide
Acceptance Criteria: 0.5ppm

Sampling Point	Date			Remark
GP-01				

Compiled By: **Verified By:**

12.0 Deviation Sheet:

Report any deviation from the acceptance criteria or from protocol instructions in the Deviation report form of Annexure I. Record the total number of deviations reported during the performance qualification activities of this Protocol. Record the Deviation number and Title in the Table below. Include all Deviation Report Forms in Annexure I. Indicate the status of each variance as 'Closed' only when the Deviation is resolved.

Deviation No.	Deviation Title	Status

Total No. of Deviations: _____

Remarks (If any):

_____

_____

_____

_____

_____

Verified By & Date:

13.0 List of Annexure:

Annexure No.	Document Title

Remarks (If any):

_____

_____

_____

_____

Verified By & Date:

14.0 Summary & Conclusion:

Prepared By: _____ _____
Name & Department Sign. / Date

15.0 Post Approval Sheet:

Functional Area	Name	Signature	Date
Head Engineering			
Head Quality Control			
Head validation			
Head Quality Assurance			
Head Manufacturing			
Head Quality			

Annexure I: Deviation And Corrective Action Report Form

This Deviation and Corrective Action Report Form shall be completed for each result that does not meet the expected or as designed condition encountered during the execution of the protocol. Each form shall be numbered sequentially and tracked on the Deviation Sheet within the protocol.

Deviation Report Number:
Protocol Section No.: Date of Test
Description Of Test Result:
Corrective Action Taken / Planned:
Deviation Reported By: Name: Signature: Date:
Corrective action must be taken prior to approval of PQ:
Head-Engg. Signature Date
Head-User dept. signature Date:
QA signature Date:
Corrective Action Implemented:
Corrective Action Implemented By: Name: Signature: Date:
(Attach comments and supporting documentation as necessary)
Was a re-test or amendment necessary due to the Deviation? Date of re-test:
Is Deviation Closed (Yes/No): QA Signature: Date:

Compressed Air report

ANNEXURE – II
INCUBATION DETAILS

OBSERVATIONS:

S. No.	Sampling Location	Sampling Tag No.	Cfu per plate			Remarks
			1st Day	2nd Day	3rd Day	

Remarks:

Microbiologist /Date **Checked by/Date**