PERFORMANCE QUALIFICATION REPORT FOR COMPRESSED AIR GENERATION AND DISTRIBUTION SYSTEM

EQUIPMENT ID. No.	
LOCATION	**Utility Block**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

CONTENTS

PERFORMANCE QUALIFICATOIN PROTOCOL FOR COMPRESSED AIR GENERATION AND DISTRIBUTION SYSTEM	PROTOCOL No.:
	EFFECTIVE DATE:
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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 (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To provide documented evidence that the **Compressed Air System (Make- Chicago Pneumatics**) 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 **Compressed Air System** installed in the **Utility Block** at …….
- This report provides all the relevant information of the performance qualification activity, In-process 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 the Protocol:

Departments	Responsibilities
Quality Assurance	• Preparation, Authorization, Approval and Compilation of the Performance Qualification Protocol & Report. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification Activity.
Production	• Review of Protocol & Report. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Review of Protocol & Report. • Analytical Support (Microbiological Testing/Analysis)
Engineering	• Reviewing of qualification protocol for correctness, completeness and technical excellence • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

5.0 EQUIPMENT DETAILS:

Equipment Name	Compressed Air System
Equipment	
Manufacturer's Name	Chicago Pneumatics
Model	GMP Model
Supplier's Name	Chicago Pneumatics
Location of Installation	Utility Block

6.0 SYSTEM DESCRIPTION:

Air compressor produce air of 8.5 bars Pressure, which is utilized for all pneumatic valves, vial and ampoules washing machine, packing machines & autoclaves.

Make: Chicago Pneumatic, Chicago

Capacity: 644 CFM

Model No. (Compressor): HX-2T-100NP

Model No. (Air Dryer): D-200

Capacity (Air Receiver): 3000 liters

Air compressor unit has an air unit system which is responsible for delivering quality compressed air at the outlet. It starts from the suction filter of the compressor and ends at the final service valve of the unit. Air compressor provides a filter of superior grade at the suction of the compressor to avoid any ingress of solid particles. The compressor cylinder, during suction stroke, aspires atmospheric air through the filer and compresses it to the delivery pressure.

The delivery pressure is achieved by compressing the air in stages. Between successive stages a highly efficient heat exchanger is provided to remove the heat of compression. Air, before passing to the next stage is cooled to near about atmospheric temperature in the heat exchanger. This helps in reducing the final air discharge temperature as well as the power consumption of the compressor. Sterilizing grade 0.2 micron hydrophobic filter shall be fixed at critical user points to deliver sterilized compressed air supply, wherever required and filters with sufficient particulate and microbial retention efficiency may also be installed at the user points to improve the purity of supplied air.

The oil-free compressed air system consists of an oil-free compressor, storage tank and refrigerant dryer and distribution system.

Air compressor is double acting horizontal cross head type, it consists two cylinders each cylinder is fitted with suction and delivery valves. The suction air filter is connected at the middle of cylinders, so that air can enter, at both ends of the piston during the forward and backward strokes. Quantity of air sucked at the front side is compressed up to approx 2 Kg/cm^2 pressure.

After compression, the air from the first stage cylinder, passes through the delivery valves to the inter cooler provided between the first and second stage. There it is cooled approx 30 ± 5^0C temperature and is sucked by the 2^{nd} stage through the suction valves. In the next stage the compressed air up to the 8.0 ± 0.5 Kg/cm^2 pressure enters to the delivery header connected to the cooler and finally to the receiver.

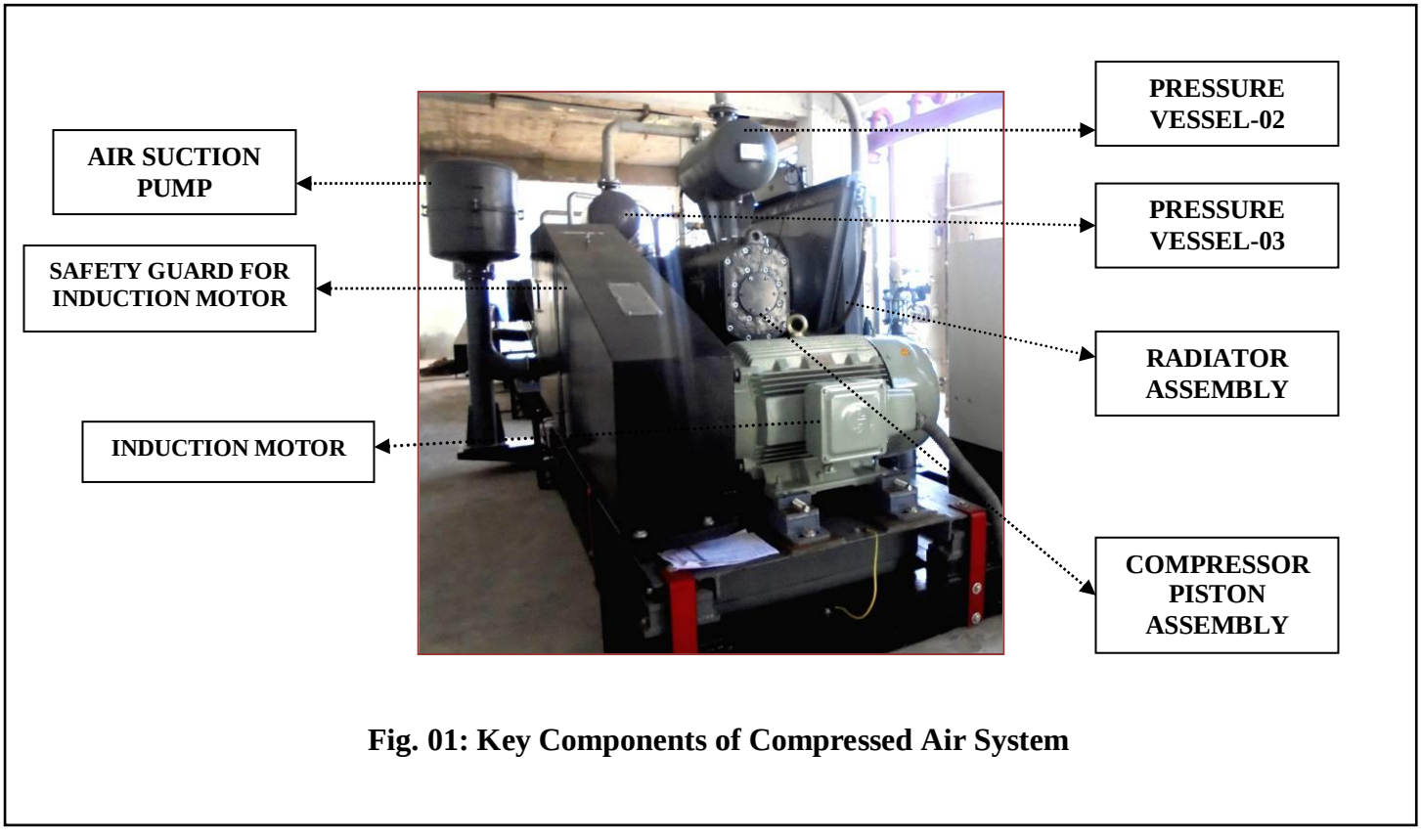

Fig. 01: Key Components of Compressed Air System

Fig. 02: Key Components of Compressed Air System

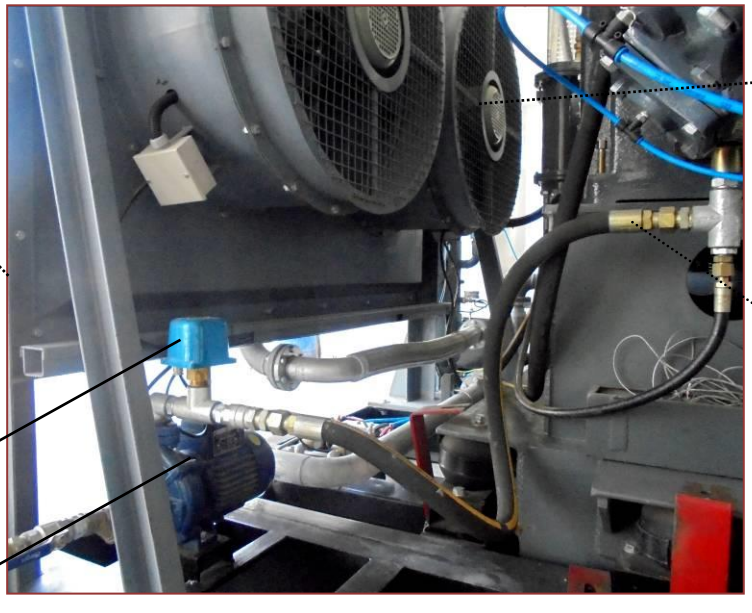

Fig. 03: Key Components of Compressed Air System

7.0 PRE – QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Completion of Design qualification activity.
- Completion of Installation qualification activity.
- Completion of Operational qualification activity.
- Preparation of SOP for Operating & Cleaning of Compressed Air System.

8.0 TESTS AND CHECKS:

8.1 Verification of Documents:

S.No.	Document	Document No.	Available (Yes / No)	Checked By (Sign / Date)
1.	Executed & Approved Design Qualification Documents			
2.	Executed & Approved Installation Qualification Documents			
3.	Executed & Approved Operational Qualification Documents			
4.	Approved Performance Qualification Protocol			
5.	SOP for Operating & Cleaning of Compressed Air System			

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

Inference:

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

8.2 Verification of Calibration of Test Instruments:

S.No.	Test Instruments	Make/Model	Calibrated On	Due On	Checked By (Sign/Date)
1.	Stopwatch				
2.	Pressure Gauze				
3.	Rota Meter				

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

Inference:

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

8.3 Oil & Water Content Analysis of Compressed Air:

S. No.	Date	Area/Location	ID. No.	Observed Oil Content (mg/m^3)	Observed Water Content (mg/m^3)
1.		**Granulation 02**			
		RMG			
2.		**Granulation 03**			
		RMG			
3.		**Granulation 06**			
		RMG			
4.		**Granulation 07**			
		RMG			
5.		**Coating 01**			
6.		**Coating 02**			
7.		**Coating 03**			
8.		**Coating 04**			
9.		**Coating 09**			
10.		**Coating 10**			
11.		**Coating 11**			
12.		**Capsule Filling 01**			
13.		**Capsule Filling 03**			
14.		**Soft Gel Section Encapsulation - 01**			
15.		**Soft Gel Section Medicament Preparation**			
16.		**Soft Gel Section Gelatin Preparation**			
17.		**Soft Gel Section Equipment Washing**			
18.		**Packing Line 06 (ABB)**			
19.		**Packing Line 09 (ABB)**			
20.		**Packing Line 12 (STP)**			

S. No.	Date	Area/Location	ID. No.	Observed Oil Content (mg/m^3)	Observed Water Content (mg/m^3)
21.		Packing Line 13 (BLM)			
22.		Packing Line 16 (STP)			
23.		Packing Line 18 (ABB)			
24.		RM Liquid			

Remarks:

Oil & Water content determination shall be performed for other remaining / new introduced critical compressed 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:

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

8.4 Determination of Viable Particle Count in Compressed Air:

S. No.	Date of Sampling	Area / Location	ID. No.	At 20-25°C for 72 Hrs (cfu)	At 30-35°C for 48 Hrs (cfu)	Total Microbial Count
1.		**Granulation 02**				
		RMG				
2.		**Granulation 03**				
		RMG				
3.		**Granulation 06**				
		RMG				
4.		**Granulation 07**				
		RMG				
5.		**Coating 01**				
6.		**Coating 02**				
7.		**Coating 03**				
8.		**Coating 04**				
9.		**Coating 09**				
10.		**Coating 10**				
11.		**Coating 11**				
12.		**Capsule Filling 01**				
13.		**Capsule Filling 03**				
14.		**Soft Gel Section Encapsulation - 01**				
15.		**Soft Gel Section Medicament Preparation**				
16.		**Soft Gel Section Gelatin Preparation**				
17.		**Soft Gel Section Equipment Washing**				
18.		**Packing Line 06 (ABB)**				

S. No.	Date of Sampling	Area / Location	ID. No.	At 20-25°C for 72 Hrs (cfu)	At 30-35°C for 48 Hrs (cfu)	Total Microbial Count
19.		Packing Line 09 (ABB)				
20.		Packing Line 12 (STP)				
21.		Packing Line 13 (BLM)				
22.		Packing Line 16 (STP)				
23.		Packing Line 18 (ABB)				
24.		RM Liquid				

Remarks:

Viable Particle Count Determination shall be performed for other remaining / new introduced critical compressed air supply points and observations for Viable Particle Count shall be enclosed as addendum with report.

Checked By
Sign/Date: ……

Verified By
Sign/Date: ……

Inference:

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

8.5 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	No. Sampling Points	ID. No.	Observed Pressure (Kg/cm^2) (1st to 5th Day)				
1.		**Granulation 01**							
		Paste room	01						
		FBD	01						
		FBD	01						
		RMG	01						
2.		**Granulation 02**							
		Paste room	01						
		FBD	01						
		RMG	01						
3.		**Granulation 03**							
		Paste room	01						
		FBD	01						
		RMG	01						
4.		**Granulation 05**							
		Paste room	01						
		FBD	01						
		RMG	01						
5.		**Granulation 06**							
		Paste room	01						
		FBD	01						

S. No.	Date of Observation	Area / Location	No. Sampling Points	ID. No.	Observed Pressure (Kg/cm^2) (1^{st} to 5^{th} Day)				
		FBD	01						
		RMG	01						
		Octagonal Blender	01						
6.		**Granulation 07**							
		Paste room	01						
		FBD	01						
		FBD	01						
		RMG	01						
		Octagonal Blender	01						
7.		**Granulation 10**							
		FBD	01						
8.		**Compression-01**	01						
9.		**Compression-02**	01						
10.		**Compression-03**	01						
11.		**Compression-04**	01						
12.		**Compression-05**	01						
13.		**Compression-06**	01						
14.		**Compression-07**	01						
15.		**Compression-08**	01						
16.		**Compression-09**	01						
17.		**Compression-10**	01						
18.		**Compression-11**	01						
19.		**Compression-12**	01						
20.		**Compression-13**	01						
21.		**Compression-14**	01						
22.		**Compression 15**	01						
23.		**Compression 16**	01						

S. No.	Date of Observation	Area / Location	No. Sampling Points	ID. No.	Observed Pressure (Kg/cm^2) (1^{st} to 5^{th} Day)				
24.		**Compression 17**	01						
25.		**Compression 18**	01						
26.		**Coating 01**	01						
27.		**Coating 02**	01						
28.		**Coating 03**	01						
29.		**Coating 04**	01						
30.		**Coating 05**	01						
31.		**Coating 06**	01						
32.		**Coating 07**	01						
33.		**Coating 08**	01						
34.		**Coating 09**	01						
35.		**Coating 10**	01						
36.		**Coating 11**	01						
37.		**Coating 12**	01						
38.		**Coating 13**	01						
39.		**Capsule filling 01**	01						
40.		**Capsule filling 02**	01						
41.		**Capsule filling 03**	01						
42.		**Soft Gel Section**	01						
43.		**Soft Gel Section**	01						
44.		**Soft Gel Section**	01						
45.		**Soft Gel Section**	01						
46.		**Packing Line 01 (BLM)**	01						
47.		**Packing Line 02 (BLM)**	01						
48.		**Packing Line 03 (ABB)**	01						

S. No.	Date of Observation	Area / Location	No. Sampling Points	ID. No.	Observed Pressure (Kg/cm^2) (1^{st} to 5^{th} Day)				
49.		**Packing Line 04 (BLM)**	01						
50.		**Packing Line 05 (BLM)**	01						
51.		**Packing Line 06 (ABB)**	01						
52.		**Packing Line 07 (BLM)**	01						
53.		**Packing Line 08 (BLM)**	01						
54.		**Packing Line 09 (ABB)**	01						
55.		**Packing Line 10 (BLM)**	01						
56.		**Packing Line 11 (BLM)**	01						
57.		**Packing Line 12 (STP)**	01						
58.		**Packing Line 13 (BLM)**	01						
59.		**Packing Line 14 (STP)**	01						
60.		**Packing Line 15 (STP)**	01						
61.		**Packing Line 16 (STP)**	01						
62.		**Packing Line 17 (ABB)**	01						
63.		**Packing Line 18 (ABB)**	01						
64.		**Packing Line 19 (STP)**	01						
65.		**Packing Line 20 (STP)**	01						
66.		**Packing Line 21 (BLM)**	01						

PERFORMANCE QUALIFICATOIN PROTOCOL FOR COMPRESSED AIR GENERATION AND DISTRIBUTION SYSTEM	PROTOCOL No.:
	EFFECTIVE DATE:
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S. No.	Date of Observation	Area / Location	No. Sampling Points	ID. No.	Observed Pressure (Kg/cm^2) (1st to 5th Day)				
67.		**Packing Line 22 (BLM)**	01						
68.		**Packing Line 23 (BLM)**	01						
69.		**Packing Line 24 (FFS)**	01						
70.		**Packing Line 25 (PFM)**	01						
71.		**Packing Line 26 (BLM)**	01						
72.		**Packing Line 27 (BLM)**	01						
73.		**RM Liquid**	01						
74.		**Filter Cleaning**	01						
75.		**QC Department**	01						
76.		**Water System**	01						
		Water System	01						

Remarks:

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

Checked By
Sign/Date: ……

Verified By
Sign/Date: ……

Inference:

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

8.6 RESULTS SUMMARY:

Tests	Sampling Location	No. of Samples Taken Each Day	Days	Acceptance Criteria	Accepted (Y/N)
Oil Content Analysis	Critical User Points	One sample from each point	01	Oil content should be less than 1 mg / m^3	
Water Content Analysis	Critical User Points	One sample from each point	01	Water content should be less than 500 mg / m^3	
Viable Particle Count	Critical User Points	One sample from each point	01	Should be less than 100 cfu/1 liters of Air	
System Supply Reliability Test	All User Points	One sample from each point	01	0.2 to 6.5 Kg/cm^2	

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Verified By
Sign/Date: ……

Inference:

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

9.0 DOCUMENTS TO BE ATTACHED:

- Oil and Water Content Testing Execution Record Sheets
- Copy of SOPs.
- Raw data of QC analysis
- Any Other Relevant Documents.

10.0 NON COMPLIANCE:

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11.0 DEVIATION FROM PREDEFINED 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:

Sr.	:	Senior
Asst.	:	Assistant
No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
QA	:	Quality Assurance
mm	:	Millimetre
Amp.	:	Ampere
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
SOP	:	Standard Operating Procedure
Kg	:	Kilogram
RSD	:	Relative Standard Deviation
No.	:	Number
Ltd.	:	Limited

17.0 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)			