OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

COMPRESSED AIR GENERATION AND

DISTRIBUTION SYSTEM

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

CONTENTS

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 verify that the equipment operates in accordance with the design and user requirements as defined in set Acceptance Criteria and comply with cGMP Requirements.
- To verify the operational features of Compressed Air Generation and Distribution System and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user friendly point of view of the Machine, Cleaning Procedure and Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of **Compressed Air Generation and Distribution System (Make – Chicago Pneumatics)** installed in the Utility Block ……..
- This Protocol will define the methods and documentation used to perform OQ activity the Compressed Air Generation and Distribution System for OQ.

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, Approval, Compilation and Authorization of the Operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification.
Production	• Review of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol cum report after Execution.
Engineering	• Review of Operational Qualification Protocol cum Report. • To co-ordinate and support Operational Qualification Activity. • Calibration of Test Instruments.

5.0 EQUIPMENT DETAILS:

Equipment Name	Compressed Air System
Equipment	
Make	Chicago Pneumatic
Capacity	644 CFM
Model No. (Compressor)	HX-2T-100NP
Model No. (Air Dryer)	D-200
Capacity (Air Receiver -01)	3000 liters
Capacity (Air Receiver -02)	4000 liters
Location of Installation	Utility Block

6.0 SYSTEM DESCRIPTION:

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.

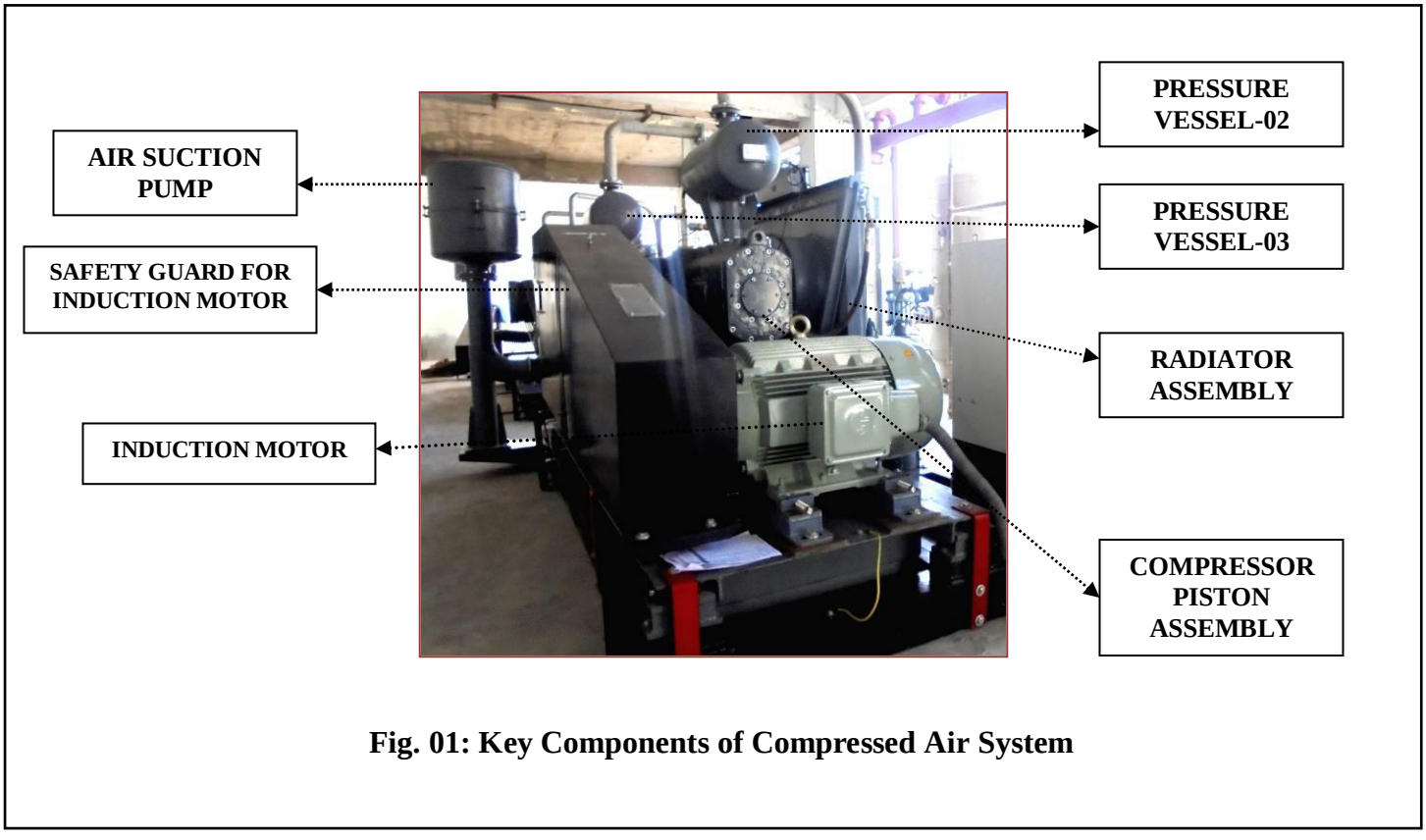

Fig. 01: Key Components of Compressed Air System

Fig. 02: Key Components of Compressed Air System

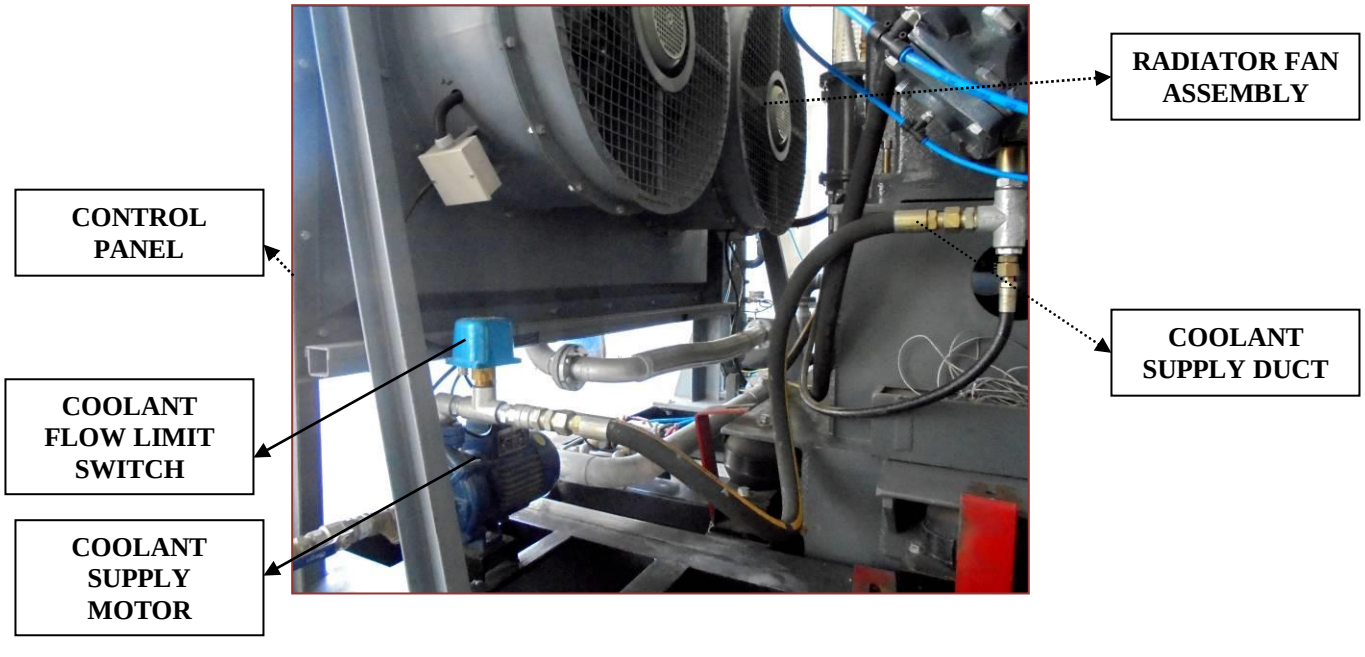

Fig. 03: Key Components of Compressed Air System

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved Design Qualification Document.
- Executed and approved Installation Qualification Document.
- Electrical Circuits Diagram.
- Calibration Certificate 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.

7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by respective authorities.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Documents Verification:

S.No.	Document Name	Document No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date
1.	DQ Protocol Cum Report			
2.	IQ Protocol Cum Report			
3.	Calibration Certificates of Test Instruments			
4.	Draft 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 Test Equipment Calibration:

- Verify that all critical instruments associated with the system and to be used for testing during operational qualification activity are in a calibrated state.
- All equipment / instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used.
- If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment / Instruments Name	Equipment / Instrument ID.	Calibration Done On	Calibration Due On	Observed By (Engineering) Sign / Date

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

Inference:

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

8.3 Operational and Functional Checks:

- Operate the Compressed Air System as per Manufacturer's Manual.
- Check operation of all major components of the system.
- Record the observations.

Component	Function	Acceptance Criteria	Observation	Observed By (Engineering) (Sign & Date)
Power Supply & Control Panel:				
Power Switch & MCB	Switch ON MCB to start electrical supply to control panel	Electrical supply should be connected to control panel		
ON Key of Control Panel	Press ON key on control panel	Control panel should start and display screen should show menu		
OFF Key of Control Panel	Press OFF key on control panel	Control panel should OFF and display screen should disappeared		
Control Panel	Switch OFF Power supply to control panel	System should shut down securely		
Control Panel	Restart Power supply to control panel	System should start normally		
Emergency Switch	Press emergency switch to STOP system	Entire system should STOP immediately		
Emergency Switch	Press ON key to Start system	Entire system should remain inoperative		
Emergency Switch	Press Emergency switch to restore system and press ON key of control panel	Entire system should become operative		

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Component	Function	Acceptance Criteria	Observation	Observed By (Engineering) (Sign & Date)
Function Keys of Control Panel	Press one by one F1, F2 & F3 keys and arrows on control panel	Display screen should show options in response to the function keys and selection of options should respond to movement according to the UP, DOWN, FORWARD & BACKWARD arrows		
Data Entry	Press keys to enter values for various parameters e.g. Loading pressure, unloading pressure	Values of parameters should be changed as per the input		
Display Screen	Start the system at set parameters	Display screen should show the system stage & parameter details such as Loading, Unloading, Pressure (Bar)		
Compressor Unit:				
Induction Motor	Speed Verification	1480 RPM ±2%		
Radiator Motor-1	Speed Verification	1430 RPM ±2%		
Radiator Motor-2	Speed Verification	1430 RPM ±2%		
Air Suction Pump	Air suction by pump during loading stage of cycle	Air should be suck in by pump throughout loading stage of cycle		
Air Suction Pump	Air suction by pump during Un-loading stage of cycle	Air should be thrown out by pump throughout Un-loading stage of cycle		

Component	Function	Acceptance Criteria	Observation	Observed By (Engineering) (Sign & Date)
Compressor	Loading stage activation at set loading pressure	Loading stage should be started by compressor at set pressure		
Compressor	Un-loading stage activation at set Un-loading pressure	Un-loading stage should be started by compressor after attaining the set pressure		
Solenoid Valves	Activation to start draining	During working water should be drain out by system		
Compressed Air Storage Tanks:				
Storage Tank	Air receiving	Pressure gauge should show increase in pressure during receiving of air by storage tanks		
Storage Tank	Air supply	Pressure gauge should show decrease in pressure during supply of air by storage tanks		
Storage Tank	Air holding	Pressure gauge should not show decrease in pressure during holding of air by storage tanks for 1 hour		
Pressure Gauge	Response to pressure of air in tank	Reading in Pressure gauge should change receiving and supply processes		
Refrigerated Air Dryer:				
Low Pressure Switch	Control of system operation	Compressor should start in response to set values of pressure in low pressure switch		
High Pressure Switch	Control of system operation	Compressor should stop in response to set values of pressure in high pressure switch		

Component	Function	Acceptance Criteria	Observation	Observed By (Engineering) (Sign & Date)
Fan Control Switch	Control of system operation	Operation of Fan should be controlled by the fan control switch		

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

Inference:

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

8.4 Verification of Pressure at Supply Points:

S. No.	Area / Location	No. Sampling Points	ID. No.	Observed Pressure (Kg/cm^2)
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		
	FBD	01		
	RMG	01		
	Octagonal Blender	01		
6.	**Granulation 07**			
	Paste room	01		
	FBD	01		
	FBD	01		
	RMG	01		

S. No.	Area / Location	No. Sampling Points	ID. No.	Observed Pressure (Kg/cm^2)
	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		
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		

S. No.	Area / Location	No. Sampling Points	ID. No.	Observed Pressure (Kg/cm^2)
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 Encapsulation-01	01		
43.	Soft Gel Section Medicament Preparation	01		
44.	Soft Gel Section Gelatin Preparation	01		
45.	Soft Gel Section Equipment Washing	01		
46.	Packing Line 01 (BLM)	01		
47.	Packing Line 02 (BLM)	01		
48.	Packing Line 03 (ABB)	01		
49.	Packing Line 04 (BLM)	01		
50.	Packing Line 05 (BLM)	01		
51.	Packing Line 06 (ABB)	01		
52.	Packing Line 07	01		

S. No.	Area / Location	No. Sampling Points	ID. No.	Observed Pressure (Kg/cm^2)
	(BLM)			
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		

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S. No.	Area / Location	No. Sampling Points	ID. No.	Observed Pressure (Kg/cm^2)
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		

Observed By
(Engineering)
Sign/Date: ……

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

Inference:

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

9.0 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 Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.

The following references are used for addition guidance:

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition / March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs, Beta. April 1, 1998.
- Code of Federal Regulations (CFR), Title 21, Part 211, Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals, April 1, 1998.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission's working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.
- GMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.

10.0 DOCUMENTS TO BE ATTACHED:

- Calibration Certificates.

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:

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
OQ	:	Operational Qualification
Ltd.	:	Limited
DQ	:	Design Qualification
IQ	:	Installation Qualification
No.	:	Number
IPR	:	Intellectual Property Right
HP	:	Horse power
KW	:	Kilo watt
PLC	:	Programmable Logical Controller
ID.	:	Identification
Kg	:	Kilogram
Ltrs	:	Liters
mm	:	Millimeter
MCB	:	Miniature Circuit Breaker

17.0 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)			