DESIGN QUALIFICATION

PROTOCOL CUM REPORT

FOR

COMPRESSED AIR GENERATION AND DISTRIBUTION SYSTEM

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

PROTOCOL 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 prepare the Design Qualification document for **Compressed Air Generation and 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 **Compressed Air Generation and Distribution System (Make: Chicago Pneumatics)** for ……
- The drawings and P & IDs 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	• Preparation, Authorization and Approval of the Protocol cum Report. • Assist in the verification of Critical Parameters, Drawings as per the Specification. • Review of Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Production	• Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Post Approval of 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 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 Qualification Protocol after Execution.

5.0 BRIEF EQUIPMENT DESCRIPTION:

Make	Chicago Pneumatic, Chicago
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

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.

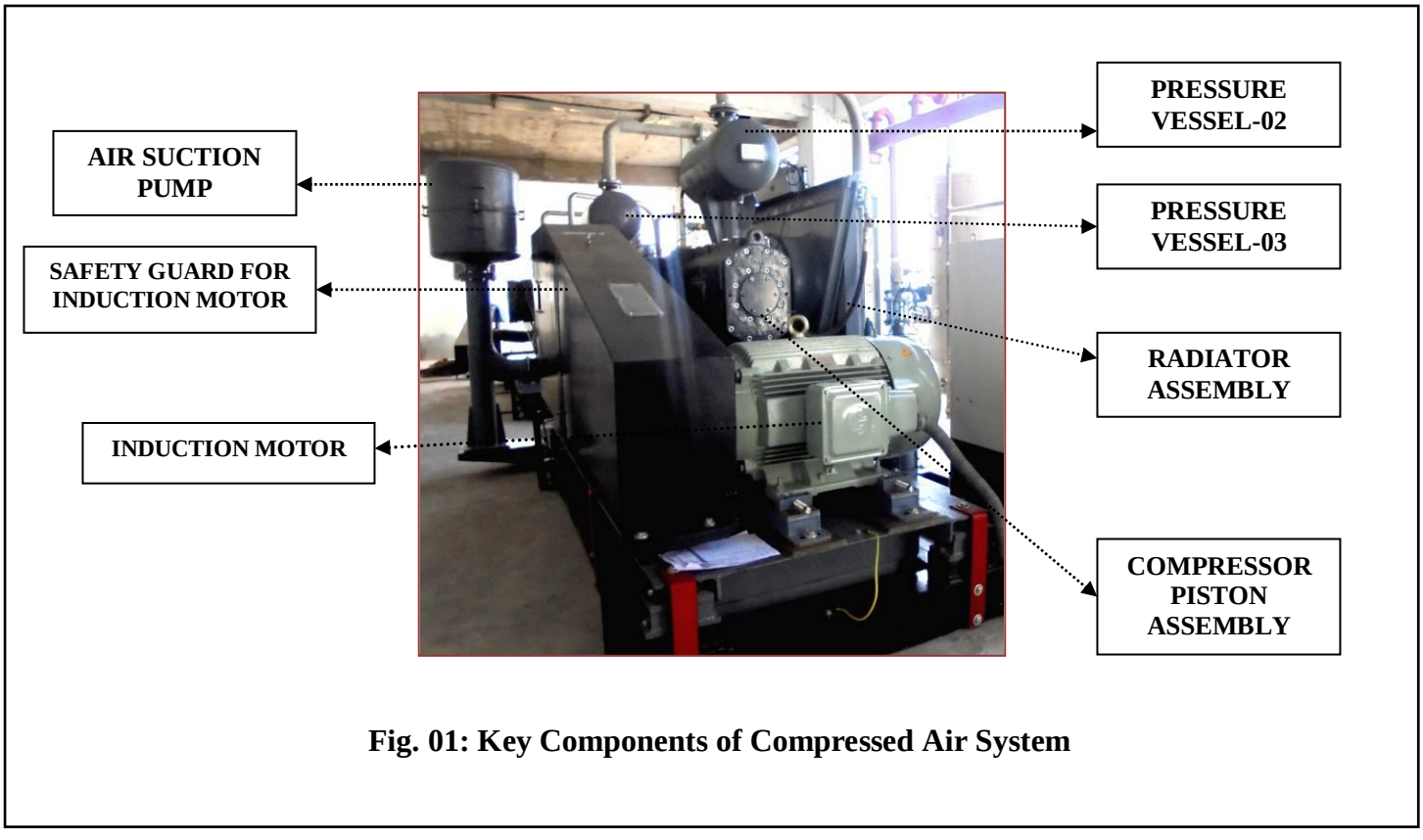

Fig. 01: Key Components of Compressed Air System

Fig. 02: Key Components of Compressed Air System

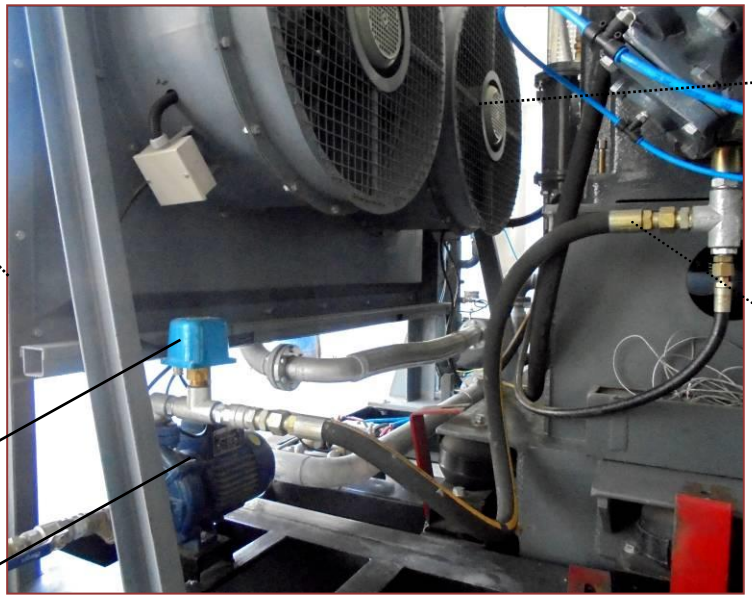

Fig. 03: Key Components of Compressed Air System

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on Technical Specification as mentioned in the purchase order prepared by ……. and functional specifications of system as provided by manufacturer of equipment.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Application: Compressed Air Generation and Distribution System	Compressed Air Generation and Distribution System should be capable of providing the compressed air of desired quality to all the processes, equipments and system as per the requirement.	Process Requirement
Working: Working of Compressed Air Generation and Distribution System	The system should be capable of providing compressed air to meet the specifications of air for oil content, water content, non-viable particulate, viable particulate and other contaminants.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	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	The electrical system of the equipment shall be housed as per the cGMP and cGEP standards, with adequate safety. Electrical panel and electro pneumatic panel is to be installed is service area.	cGMP Requirement
Room Condition	The system should be capable of working efficiency in the ambient conditions.	Design Requirement

7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

S.No.	Component / Parameters	Parameters	Technical Specification
1.	Air Compressor	Equipment	Air Compressor
		Make	Chicago Pneumatic
		Model No.	HN2T-120 NPS
		Quantity	1 No.
		No. of stages	2 Nos.
		Type	Non-Lubricated, Reciprocating, Horizontal, Balanced opposed
		Capacity	644 CFM each @ 8 Kg / cm^2
2.	Control Panel	Control Panel Serial No.	SMT-1432-120/211
		PLC	Make: CP-Tronic III
		Serial No. of PLC Screen	81931330005
		Supply Voltage	24 V AC, 50 Hz
3.	3 Phase Induction Motor	Make	Crompton Greaves
		Motor No.	NADV490SF_Nasik
		Frame	ND280M
		Voltage	415±10%
		Rating	90 KW (120 HP)
		Speed	1480 RPM
		Ampere	181 Amps
		Hertz	50±5%
		IP	55
4.	Coolant Pump Motor	Type	MBD12
		KW	0.75
		HP	1.0
		Volt	220±6%
		Current	7.6 Amps

S. No.	Component / Parameters	Parameters	Technical Specification
5.	Inter Cooler	S. No.	1903041311
		Make	Chicago Pneumatic
		Design Code	G.E.P. B-6062
		Specified Pressure	Shell: 4.0 Tube: 4.0
		Specified Hydro Test Pressure	Shell: 6.0 Tube: 6.0
6.	After Cooler Heat Exchanger (Radiator)	Make	Chicago Pneumatic
		Design Pressure	1.4 mPa
		Medium	Air
		Radiator Fan Motor	Make: Crompton Greaves Ltd. Quantity: 02 Nos. HP: 3.0 HP KW: 2.2 KW
		Flow Switch for Coolant	Make: Mukund Electricals Normal Flow Rate: 120 LPM Pipe Size: 40NB
7.	Pressure Vessel - 01	Make	Chicago Pneumatics
		Serial No.	19032283-01 KE
		Design Pressure	6 Bar
		Hydro Test Pressure	9 Bar
		Design Temperature	100ºC
8.	Pressure Vessel - 02	Make	Chicago Pneumatics
		Serial No.	19032284-01 KE
		Design Pressure	16 Bar
		Hydro Test Pressure	24 Bar
		Design Temperature	100ºC

S. No.	Component / Parameters	Parameters	Technical Specification
9.	Pressure Vessel - 03	Make	Chicago Pneumatics
		Serial No.	19032285-01 KE
		Design Pressure	6 Bar
		Hydro Test Pressure	9 Bar
		Design Temperature	250ºC
10.	Pressure Vessel - 04	Make	Chicago Pneumatics
		Serial No.	19032286-01 KE
		Design Pressure	14 Bar
		Hydro Test Pressure	21 Bar
		Design Temperature	250ºC
11.	Compressed Air Storage Tank-01	Make	United Engineering Works
		Capacity Volume	3.0 m^3
		Design Pressure	11.0 kg/cm^2
		Max. Operating Pressure	10.0 kg/cm^2
		Hydro Test Pressure	16.5 kg/cm^2
		Working Temperature	60ºC
		Design Temperature	100ºC
12.	Compressed Air Storage Tank-02	Make	B-Tech Engineers
		Capacity Volume	4.0 m^3
		Max. Operating Pressure	10.0 kg/cm^2
		Hydro Test Pressure	16.5 kg/cm^2
13.	Refrigerated Air Dryer	Make	GEM Equipment Ltd.
		Quantity	02 Nos.
		Capacity	600 CFM
		Model	2KDF060B
		Electrical Supply	415 V AC
		Working Pressure	16.0 kg/cm^2

S. No.	Component / Parameters	Parameters	Technical Specification
		Power	3.6 KW
		Compressor	Make: Danfoss
		Switch	Low Pressure Switch: 01 No. High Pressure Switch: 01 No. Fan Control Switch: 01 No.
		Pressure Gauge	Low Pressure Gauge: 01 No. High Pressure Gauge: 01 No.

7.4 SAFETY:

Critical Variables	Acceptance Criteria	Reference
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips	Safety Requirement
Mechanical Guard	Mechanical guard for all rotating parts.	Safety Requirement
Joints	Welding of joints without any welding burrs	Safety Requirement
Metal Parts	All the metal parts should be Properly grind without any sharp edges.	Safety Requirement
Leveling And Balancing	Equipment should be properly balanced & leveled	Safety Requirement
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Single external Earthing to control machine (panel and motors) and operator should be provided	Safety Requirement
Noise Level	Below 80 db	GMP & Safety Requirement
Emergency Switch	Provided easy access position	GMP & Safety Requirement
Vacuum Indicator	Should be provided at air suction site to indicate the service level	GMP & Safety Requirement
Safety Valve	Should be provided at pressure vessel.	GMP & Safety Requirement
Overload Tripping	Overload relay drive motor should be provided with control panel	GMP & Safety Requirement

7.5 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Compressed Air System	Selection of Vendor is done on the basis of review of vendor. Criteria for review includes vendor background (general/financial), technical knowhow, 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.
- 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:

URS	:	User Requirement Specification.
cGMP	:	Current Good Manufacturing Practice
cGEP	:	Current Good Engineering Practice
Pvt.	:	Private
IPR	:	Intellectual Property Right
Ltd.	:	Limited
QA	:	Quality Assurance
PO	:	Purchase Order
Kg	:	Kilogram
Hr	:	Hour
cm	:	Centimeter
V	:	Volt
Hz	:	Hertz
AC	:	Alternate Current
Amps	:	Amperes
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
STD	:	Standard
mPa	:	Millipascal
CFM	:	Cubic Feet per Meter
KW	:	Kilowatt
HP	:	Horse Power
RPM	:	Revolution Per Minute
MCB	:	Miniature Circuit Breaker
NB	:	Nominal Bore
LPM	:	Litre Per Minute

13.0 REVIEWED BY:

INITIATED BY:

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