INSTALLATION 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

INSTALLATION QUALIFICATOIN PROTOCOL CUM REPORT FOR COMPRESSED AIR GENERATION AND DISTRIBUTION SYSTEM	PROTOCOL No.:
	EFFECTIVE DATE:
	PAGE No.: 3 of 28

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 provide documented evidence for the Installation Qualification of **Compressed Air Generation and Distribution System** for ……..
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of **Compressed Air Generation and Distribution System (Make – Chicago Pneumatics)** to be installed Utility Block at ……...
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Compressed Air Generation and Distribution System.

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, Approval and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity.
Production	• Review & Pre Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Qualification Protocol after Execution.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in Installation Qualification Activity. • Calibration of process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol after Execution

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^{0}C temperature and is sucked by the 2nd 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.

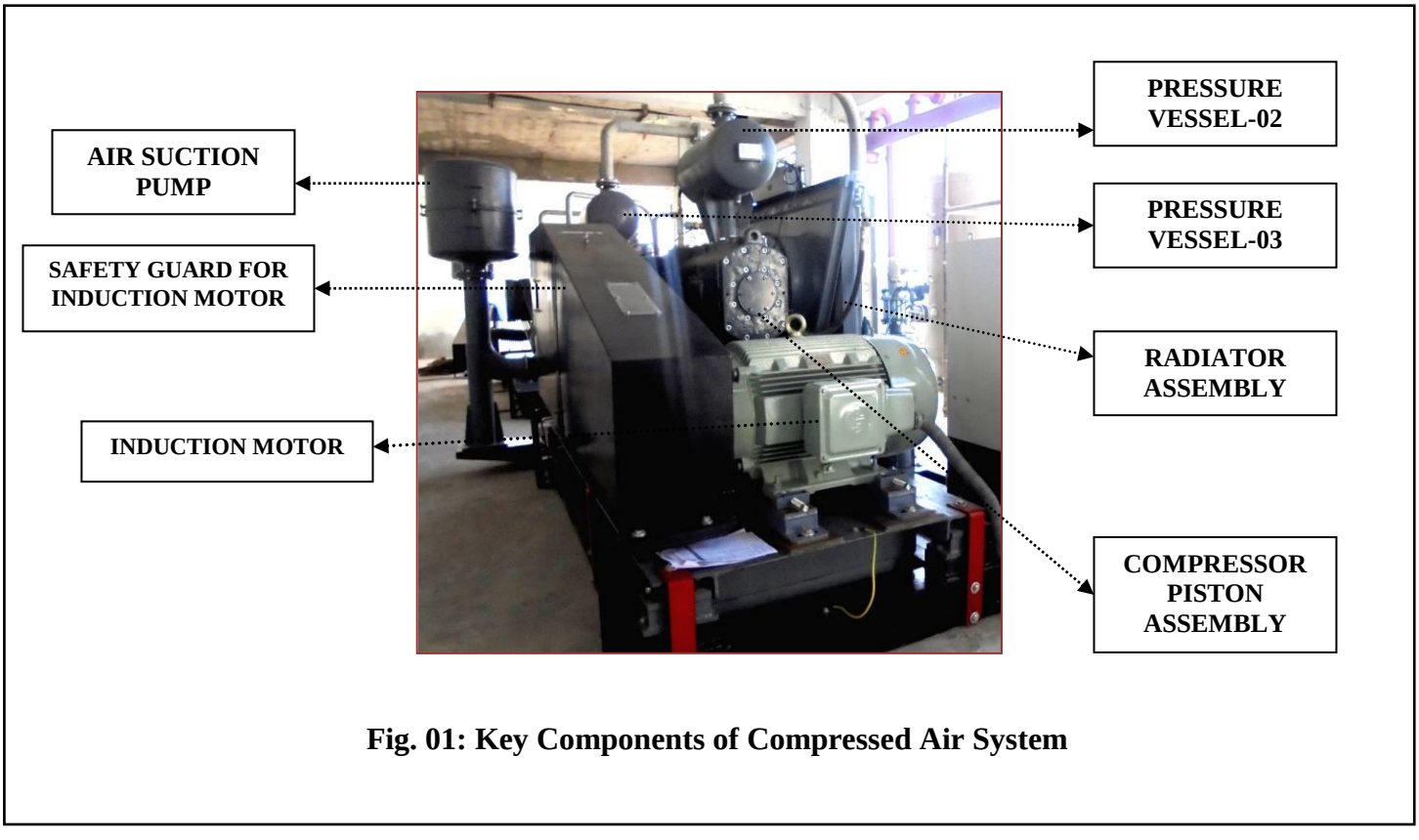

Fig. 01: Key Components of Compressed Air System

Fig. 02: Key Components of Compressed Air System

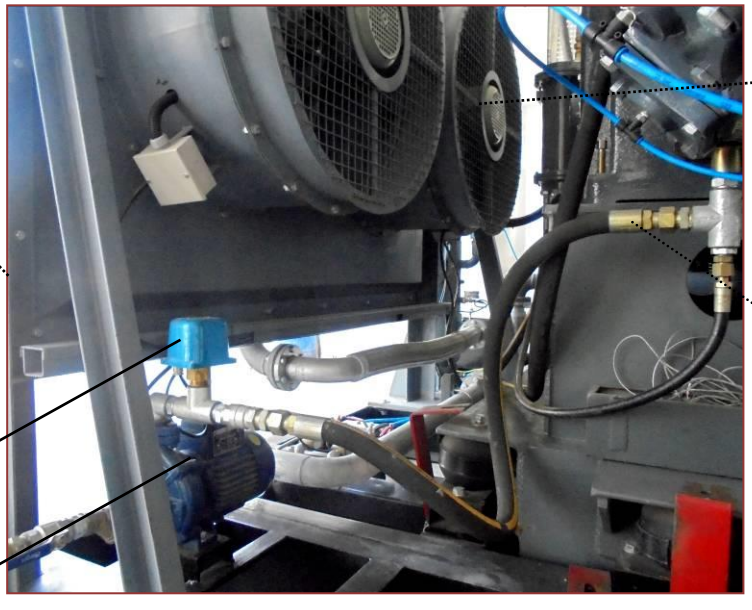

Fig. 03: Key Components of Compressed Air System

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document
- Piping and instrumentation diagram (P& ID)
- Electrical circuits diagram
- Technical specification of equipment
- Calibration / Test 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.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum report.

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 General Checks and Location Suitability:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Leveling	Should be properly balanced and leveled		
Edges of parts	Metal parts should be properly grind without any sharp edges		
Welding of Joints	Welding of joints should be without any welding burrs		
Place of Installation	Utility Block		
Room Condition	Ambient condition		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

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

Inference:

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

8.2 Equipment Verification:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Identification of Major Components:			
Air Compressor	Make: Chicago Pneumatic Model No.: HN2T-120 NPS Quantity: 01 No.		
Control Panel	Make: CP-Tronic III		
3 Phase Induction Motor	Make: Crompton Greaves		
Coolant Pump Motor	Make: Crompton Greaves		
Inter Cooler	Make: Chicago Pneumatic		
After Cooler Heat Exchanger (Radiator)	Make: Chicago Pneumatic		
Radiator Fan Motor	Make: Crompton Greaves		
Pressure Vessel	Make: Chicago Pneumatic Qty.: 04 Nos.		
Compressed Air Storage Tank-01	Make: United Engineering Works		
Compressed Air Storage Tank-02	Make: B-Tech Engineers		
Refrigerated Air Dryer	Make: GEM Equipment Ltd.		
Visual Inspection of all components for physical damage	No any component should be physically damaged		

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Sign/Date: ……

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(Manager QA)
Sign / Date: ……

8.3 Verification of Provided Utilities to the System:

Parameters	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
Utilities to Piston Assembly	• Earthing should be provided to complete system including the control panel. • Coolant supply should be provided to the compression vessels, piston assembly, heat exchangers and dryers. • Air supply should be provided to all components requiring air for functioning of pneumatic valves. • Electrical connections should be provided to the electrically operated valves and flow regulators. • Safety valves and inter-connections should be provided between components to facilitate proper functioning of the entire system.		
Utilities to Compression Vessel			
Utilities to Intercool Heat Exchanger			
Utilities to Heat Exchangers (Radiator Assembly)			
Utilities to Control Panel			
Utilities to Compressed Air Storage Tank			
Utilities to Air Dryer			

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(Quality Assurance)
Sign/Date: ……

Inference:

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

8.4 Installation Features of Key Components of the System:

Parameters	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
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		
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		
Layout and Arrangement	Should be as per GA drawing		
Presence of links between components	Star linking and power linking should be provided between components of control panel		
Connection of power and control wires	Control and power wires should be connected to all components properly		
Insulation of Electrical Connection	All electrical connections should be insulated properly		

INSTALLATION QUALIFICATOIN PROTOCOL CUM REPORT FOR COMPRESSED AIR GENERATION AND DISTRIBUTION SYSTEM	PROTOCOL No.:
	EFFECTIVE DATE:
	PAGE No.: 14 of 28

Parameters	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
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		
Coolant Pump Motor:			
Make	Crompton Greaves Ltd.		
Type	MBD12		
KW	0.75		
HP	1.0		
Volt	220±6%		
Current	7.6 Amps		
Serial No.	42916		
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		

Parameters	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
After Cooler Heat Exchanger (Radiator):			
S. No.	A135079		
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		
Pressure Vessel - 01			
Make	Chicago Pneumatics		
Serial No.	19032283-01 KE		
Design Pressure	6 Bar		
Hydro Test Pressure	9 Bar		
Design Temperature	100ºC		
Pressure Vessel - 02			
Make	Chicago Pneumatics		
Serial No.	19032284-01 KE		
Design Pressure	16 Bar		
Hydro Test Pressure	24 Bar		
Design Temperature	100ºC		
Pressure Vessel - 03			
Make	Chicago Pneumatics		
Serial No.	19032285-01 KE		
Design Pressure	6 Bar		
Hydro Test Pressure	9 Bar		

Parameters	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
Design Temperature	250ºC		
Pressure Vessel - 04			
Make	Chicago Pneumatics		
Serial No.	19032286-01 KE		
Design Pressure	14 Bar		
Hydro Test Pressure	21 Bar		
Design Temperature	250ºC		
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		
Connection to other components of system	Compressed Air Storage Tank should be properly connected to the other components of the system		
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		

INSTALLATION QUALIFICATOIN PROTOCOL CUM REPORT FOR COMPRESSED AIR GENERATION AND DISTRIBUTION SYSTEM	PROTOCOL No.:
	EFFECTIVE DATE:
	PAGE No.: 17 of 28

Parameters	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
Connection to other components of system	Compressed Air Storage Tank should be properly connected to the other components of the system		
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		
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.		
Compressed Air Distribution System:			
Compressed Air Distribution Line	Compressed air pipelines and other components should be properly identified, fixed and labeled		
Supply Points	All the supply points should be properly identified and labeled.		
Safety Features:			
Vacuum Indicator	Should be provided at air suction site to indicate the service level		

INSTALLATION QUALIFICATOIN PROTOCOL CUM REPORT FOR COMPRESSED AIR GENERATION AND DISTRIBUTION SYSTEM	PROTOCOL No.:
	EFFECTIVE DATE:
	PAGE No.: 18 of 28

Parameters	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
Safety Valve	Specifications: Size: 2" and 3.3 Bar Should be provided at pressure vessel.		
Overload Tripping	Overload relay drive motor should be provided with control panel		
Earthing	Earthing should be provided to control panel and entire system		
Electrical Insulation	All electrical connections provided to the system should be properly insulated		
Safety Guards for Moving Parts	All moving parts of entire system should be provided with safety guards for moving components.		

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

Inference:

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

8.5 Identification and Verification of Compressed Air Supply Points:

S.No.	Area / Location	No. Sampling Points	ID. No.	Critical / Non Critical
1.	**Granulation 01**			
	Paste room			
	FBD			
	FBD			
	RMG			
2.	**Granulation 02**			
	Paste room			
	FBD			
	RMG			
3.	**Granulation 03**			
	Paste room			
	FBD			
	RMG			
4.	**Granulation 05**			
	Paste room			
	FBD			
	RMG			
5.	**Granulation 06**			
	Paste room			
	FBD			
	FBD			
	RMG			
	Octagonal Blender			
6.	**Granulation 07**			
	Paste room			
	FBD			
	FBD			
	RMG			

S.No.	Area / Location	No. Sampling Points	ID. No.	Critical / Non Critical
	Octagonal Blender			
7.	**Granulation 10**			
	FBD			
8.	**Compression-01**			
9.	**Compression-02**			
10.	**Compression-03**			
11.	**Compression-04**			
12.	**Compression-05**			
13.	**Compression-06**			
14.	**Compression-07**			
15.	**Compression-08**			
16.	**Compression-09**			
17.	**Compression-10**			
18.	**Compression-11**			
19.	**Compression-12**			
20.	**Compression-13**			
21.	**Compression-14**			
22.	**Compression 15**			
23.	**Compression 16**			
24.	**Compression 17**			
25.	**Compression 18**			
26.	**Coating 01**			
27.	**Coating 02**			
28.	**Coating 03**			
29.	**Coating 04**			
30.	**Coating 05**			
31.	**Coating 06**			
32.	**Coating 07**			

S.No.	Area / Location	No. Sampling Points	ID. No.	Critical / Non Critical
33.	Coating 08			
34.	Coating 09			
35.	Coating 10			
36.	Coating 11			
37.	Coating 12			
38.	Coating 13			
39.	Capsule filling 01			
40.	Capsule filling 02			
41.	Capsule filling 03			
42.	Soft Gel Section Encapsulation-01			
43.	Soft Gel Section Medicament Preparation			
44.	Soft Gel Section Gelatin Preparation			
45.	Soft Gel Section Equipment Washing			
46.	Packing Line 01 (BLM)			
47.	Packing Line 02 (BLM)			
48.	Packing Line 03 (ABB)			
49.	Packing Line 04 (BLM)			
50.	Packing Line 05 (BLM)			
51.	Packing Line 06 (ABB)			
52.	Packing Line 07			

S.No.	Area / Location	No. Sampling Points	ID. No.	Critical / Non Critical
	(BLM)			
53.	Packing Line 08 (BLM)			
54.	Packing Line 09 (ABB)			
55.	Packing Line 10 (BLM)			
56.	Packing Line 11 (BLM)			
57.	Packing Line 12 (STP)			
58.	Packing Line 13 (BLM)			
59.	Packing Line 14 (STP)			
60.	Packing Line 15 (STP)			
61.	Packing Line 16 (STP)			
62.	Packing Line 17 (ABB)			
63.	Packing Line 18 (ABB)			
64.	Packing Line 19 (STP)			
65.	Packing Line 20 (STP)			
66.	Packing Line 21 (BLM)			

INSTALLATION QUALIFICATOIN PROTOCOL CUM REPORT FOR COMPRESSED AIR GENERATION AND DISTRIBUTION SYSTEM	PROTOCOL No.:
	EFFECTIVE DATE:
	PAGE No.: 23 of 28

S.No.	Area / Location	No. Sampling Points	ID. No.	Critical / Non Critical
67.	Packing Line 22 (BLM)			
68.	Packing Line 23 (BLM)			
69.	Packing Line 24 (FFS)			
70.	Packing Line 25 (PFM)			
71.	Packing Line 26 (BLM)			
72.	Packing Line 27 (BLM)			
73.	RM Liquid			
74.	Filter Cleaning			
75.	QC Department			
76.	Water System			
	Water System			

Checked 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 to give 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:

- Technical details for Equipment Requirement with Engineering Drawings.
- Electrical Circuit Diagram
- Test / 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:

Sr.	:	Senior
No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
cGEP	:	Current Good Engineering Practices
EU	:	European Union
QA	:	Quality Assurance
IQ	:	Installation Qualification
Amp.	:	Ampere
IPR	:	Intellectual property right
HP	:	Horse power
KW	:	Kilo watt
SS	:	Stainless steel
PLC	:	Programmable logical control
ID.	:	Identification
Kg	:	Kilo gram
Ltrs	:	Liters
mm	:	Millimeter
MCB	:	Miniature circuit break

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)			