



**PHARMA DEVILS**

PRODUCTION DEPARTMENT

**USER REQUIREMENT SPECIFICATION**

**NAME OF ITEM:** Compressed Air System

**PROTOCOL No.....**

**FUNCTIONAL AREA:** Production

**Page No.:** 1 of 15

# **USER REQUIREMENT SPECIFICATIONS**

## **COMPRESSED AIR SYSTEM**

**Document Reference:** Nil

**Issue Date:** Nil



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## USER REQUIREMENT SPECIFICATION

**NAME OF ITEM:** Compressed Air System

**PROTOCOL No.....**

**FUNCTIONAL AREA:** Production

**Page No.:** 2 of 15

### CONTENTS

S. No.	Title of sections	Page No.
1.0	Approval	4
2.0	Objective	5
3.0	Scope	5
4.0	Reason for URS	5
5.0	Responsibility	6
6.0	Equipment Description	7
7.0	Information of Input Material	7
8.0	Information of Output Material	7
9.0	Environment	7- 8
10.0	Equipment Design and Principle of Working	8
11.0	Process Description	8 - 9
12.0	Functional Requirements of Equipment	9
12.1	Functionality of the Equipment	9 - 10
12.2	Instrumentation Requirements	10
12.3	Data Collection and Reporting	10
12.4	Recipe Provision/ Data Saving/ Data Back-up/ Data Security	11

**Continued...**



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## USER REQUIREMENT SPECIFICATION

**NAME OF ITEM:** Compressed Air System

**PROTOCOL No.....**

**FUNCTIONAL AREA:** Production

**Page No.:** 3 of 15

S. No.	Title of sections	Page No.
13.0	Performance Features	11
14.0	Capacity/Speed	11
15.0	Automation and Safety Features	12
16.0	System Boundaries	12
17.0	Material of Construction	12
18.0	Surface Finish	13
19.0	Electrical and Control Equipment Philosophy	13
20.0	cGxP Considerations	13
21.0	Expected Documents and Drawings	13 - 15
22.0	Available Utilities	15
23.0	Maintenance Requirements	15
24.0	Delivery, Installation and Commissioning Requirements	15 - 16
25.0	Other Specific Requirements	16
26.0	Reference Documents	16
27.0	Abbreviations	16 - 17
28.0	Attachments	17



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## USER REQUIREMENT SPECIFICATION

**NAME OF ITEM:** Compressed Air System

**PROTOCOL No.....**

**FUNCTIONAL AREA:** Production

**Page No.:** 4 of 15

### 1.0 Approval:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution.

Functional area	Name	Designation	Signature	Date
<b>PREPARED BY</b>				
Validation QA				
<b>REVIEWED BY</b>				
User Dept. Head				
Engineering Dept. Head				
Environment, health and safety				
Quality Control (if applicable)				
Quality Assurance				
<b>APPROVED BY</b>				
QA Head				
Plant Head				



## USER REQUIREMENT SPECIFICATION

**NAME OF ITEM:** Compressed Air System

**PROTOCOL No.....**

**FUNCTIONAL AREA:** Production

**Page No.:** 5 of 15

**2.0 Objective:** The objective of this document is to provide the requirement and appropriate design to support the prospective supplier to identify company needs, price quote for the subject equipment and performance requirements for procurement of equipment including major ancillary component or fabrication of the area so as to meet the in-house requirements as well as compliance with cGMP.

The supplier shall abide by the information and conditions set forth by this document as well as the standard purchasing terms and conditions of company.

**3.0 Scope:** This user requirement specification (URS) is applicable for the procurement of Compressed Air System with 230 CFM @ 8.5 Bar(g) capacity.

**4.0 Reason for URS:** To procure Compressed Air System with 230 CFM @ 8.5 Bar (g) capacity for installation in B2 block for generation of Compressed Air.

**The reason for preparing this document is:**

Please tick any one (or multiple) option(s) from the following (☑):

- New or refurbished premises/equipment
- Purchase of Utility Systems
- Purchase of Process Equipment
- Purchase of Laboratory Equipment
- Bespoke or user configured computer systems
- In-Use Systems that don't have a URS
- Others (Specify)



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## USER REQUIREMENT SPECIFICATION

**NAME OF ITEM:** Compressed Air System

**PROTOCOL No.....**

**FUNCTIONAL AREA:** Production

**Page No.:** 6 of 15

### 5.0 Responsibility: Personnel involved in qualification activity.

Department	Name	Activity
Validation QA		To provide the User Requirement Specification (URS)
Engineering		To provide requirements with respect to utilities, components, based on the location of use and desired system parameters
Health Safety and Environment		To provide the safety requirements of system and facility
Quality Assurance		To be a part of qualification team
QA Head		To review and approve the requirement and Qualification document
Plant Head		To review and approve the requirement and Qualification document



## USER REQUIREMENT SPECIFICATION

**NAME OF ITEM:** Compressed Air System

**PROTOCOL No.....**

**FUNCTIONAL AREA:** Production

**Page No.:** 7 of 15

### 6.0 Equipment Description:

**Compressed Air Generation System:** The generation system is horizontal, Air cooled, two stage and oil free (Rotary screw type).

**Air System:** this is the heart of the unit and it is responsible for delivering quality compressed air at outlet. It starts from the suction filter of the compressor and ends at the usage points. The capacity of the air compressor is 230 CFM.

**Compressed Air Storage and Distribution System:** Compressed air storage and distribution system consist of Air Receiver tank, Air dryer (Refrigerated) and in distribution system contains safety valves, pressure gauges, reducer, auto drain traps, filter regulator, non return valve, moisture separator with regulator.

**Air Dryer:** The gaseous refrigerant coming from the receiver is sucked by the refrigeration compressor and it is pumped into the condenser. This allows condensation, eventually with the help of fan. The condensed refrigerant passes through the dewatering filter and it expands through the capacity tube and goes back to the evaporator where it produces the refrigerating effect. Due to the heat exchange with the compressed air which passes through the evaporator against the stream, the refrigerant evaporators and goes back to the compressor for a new cycle. The circuit is equipped with by system for the refrigerant; this intervenes to adjust the available refrigerating capacity to the actual cooling load.

**7.0 Information of Input Material:** This section mentions in brief the minimum requirement for Air quality that will be used as Compressed Air system.

**8.0 Information of Output Material:** Final Compressed Air Quality Specification as per ISO 8573

**9.0 Environment:** This section gives a brief summary of the layout and physical condition of the proposed site of the system. This includes (but not limited to), the data sheet of the room where proposed system is to be placed with proposed placement drawing showing room dimensions etc.

S.No.	Parameter	Specifications/Dimension
1.	Available area	<ul style="list-style-type: none"><li>➤ Area allocated for installation in Service floor of Block-2.</li><li>➤ Area grade/class: Uncontrolled/Ambient</li><li>➤ As Built Area Layout attached as attachment</li></ul>



## USER REQUIREMENT SPECIFICATION

**NAME OF ITEM:** Compressed Air System

**PROTOCOL No.....**

**FUNCTIONAL AREA:** Production

**Page No.:** 8 of 15

		No. _____ ➤ Should be able to accommodate in utility and service area.
2.	Maximum Expected size of equipment	Machine shall be of suitable size which can be able to install in the specified area with sufficient operating and cleaning space.

### 10.0 Equipment Design and Principle of Working:

The Compressed Air Distribution System is designed to provide Quality compressed Air, which is used, for the process, non-process and instrumentation and control applications. The term 'Quality Air' is applied to the air, which is free from Water Vapour, Oil Mist, Carbon Di-oxide, Carbon Monoxide, Nitric Oxide (NO) and Nitrogen Di-oxide, Sulphur Dioxide, Hydrocarbons, Dew Point, Oxygen Non-viable and Viable Particle Counts should be found within limit.

The Compressed Air Distribution System comprises of following units.

- Non-Lubricated Air Compressor
- Reservoir
- Compressed Air storage
- Refrigerated Air Dryer
- Filter Assembly
- Distribution Network.

**11.0 Process Description:** Air Compressor is horizontal, Air cooled, two stage and oil free (Rotary screw type). Ambient air is sucked by L.P. air end through suction filter and compressed. Compressed air is then discharge to H.P. air end through intercooler and moisture separator where air is cooled down in inter cooler and moisture is removed out in moisture separator before air enters into H.P air end. Air is further compressed and its pressure increased in H.P air end. After cooler where air gets cooled. Both inter cooler is fin-blade type. Air then from after cooler passed through Discharge line.

### 12.0 Functional Requirements of Equipment:

**12.1 Functionality of the Equipment:** The desired functional requirements and how it operates are listed under this section.

Sr. No.	Parameter	Specifications
---------	-----------	----------------





# PHARMA DEVILS

PRODUCTION DEPARTMENT

## USER REQUIREMENT SPECIFICATION

**NAME OF ITEM:** Compressed Air System

**PROTOCOL No.....**

**FUNCTIONAL AREA:** Production

**Page No.:** 9 of 15

Sr. No.	Parameter	Specifications
1.	Use / Purpose	➤ The equipment should be able to generate Compressed Air of the required quality complying to ISO 8573
2.	Generation Capacity	➤ 230 CFM @ 8.5 Bar(g)
3.	Model	➤ cGMP Model
4.	Suction Filter	➤ Suction air filter shall be provided
5.	Motor for compressor	➤ Shall be provided
6.	Motor for cooler	➤ Shall be provided
7.	Inter Cooler	➤ Fin-blade type Air cooled shall be provided.
8.	After Cooler	➤ Fin-blade type Air cooled shall be provided.
9.	Moisture Separator	➤ Shall be provided
10.	Oil Cooler	➤ Fin-blade type Air cooled shall be provided.
11.	Safety interlock pressure Transmitters	➤ Shall be provided
12.	Control panel	➤ Control panel should have switches for ON & OFF
13.	Microprocessor	➤ Shall be provided
14.	Lubricant	➤ Ultra Coolant shall be provided
15.	Low pressure air end	➤ Shall be provided
16.	High pressure air end	➤ Shall be provided

**12.2 Instrumentation Requirements:** This section mentions in brief the minimum requirement for measuring instrumentation for controlling and monitoring of process parameters. e.g. pressure gauge.

Sr. No.	Parameter	Specifications
1.	Pressure Gauge	➤ Shall be provided
2.	Temperature Sensor	➤ Shall be provided



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## USER REQUIREMENT SPECIFICATION

**NAME OF ITEM:** Compressed Air System

**PROTOCOL No.....**

**FUNCTIONAL AREA:** Production

**Page No.:** 10 of 15

**12.3 Data Collection and Reporting:** This section mentions in brief the data that is expected from the equipment with the respective unit of measurement. Need for printouts are also mentioned, if applicable e.g. temperature, flow rate, pressure, etc.

Sr. No.	Parameter	Specifications
1.	Flow	➤ In CFM
2.	Pressure	➤ In bar or kg/cm <sup>2</sup> (as applicable)
3.	Temperature	➤ In °C

**12.4 Recipe Provision/Data Saving/Data Back-up/Data Security:** This section specifies the requirements (as applicable) for recipe provision, data saving facility, data back-up facility, data security facilities, etc.

Sr. No.	Parameter	Specifications
1.	NA	NA

**13.0 Performance Features:** The parameters that are planned to be evaluated during performance qualification and validation activities are mentioned.

Sr. No.	Parameter	Specifications
1.	Performance of the system according to operation.	➤ The machine is intended to be operated regularly: 24 hours, 7 days per week with cleaning and sanitization in between.
3.	Cleaning Requirements	➤ Easy accessible for cleaning.
4.	Validation Parameters	➤ System Shall be able to produce Compressed Air of required quality complying to ISO 8573

**14.0 Capacity / Speed:** The desired capacity/speed with the UOM is specified in this section.

Sr. No.	Parameter	Specifications
1.	Working Capacity of	➤ 230 CFM @ 8.5 Bar (g)



## USER REQUIREMENT SPECIFICATION

**NAME OF ITEM:** Compressed Air System

**PROTOCOL No.....**

**FUNCTIONAL AREA:** Production

**Page No.:** 11 of 15

Sr. No.	Parameter	Specifications
	Compressed Air	

**15.0 Automation and Safety Features:** The minimum required as well as desired automation and safety features (alarms, interlocking, etc.) are listed in this section. e.g. for handling/Cleaning activities, etc.

Sr. No.	Parameter	Specifications
1.	Earthing	➤ Positive earthing with low voltage relay
2.	Equipment safety interlock switches	➤ A Pressure Transmitter (Switch) should be provided for low oil pressure
3.	Microprocessor	➤ It should be enclosed in a panel.
4.	MCB's	➤ Should be provided
5.	Emergency stop	➤ Should be provided
6.	Noise level	➤ Sound level of Blower should be NMT 80 db

**16.0 SYSTEM BOUNDARIES:** Nil.

**17.0 Material of Construction:** Specifications for material of construction of contact parts, non-contact parts, etc. are listed here.

Sr. No.	Parameter	Specifications
1.	Micron cartridge filter	➤ Base polymer- Poly ether sulfone ➤ Cartridge- PP
2.	Compressed Air Reservoir	➤ MS with powder coated
3.	Distribution pipe	➤ MOC of Contact Parts- SS316

**18.0 Surface Finish:** Specifications for surface finish of contact parts, non-contact parts, etc. are listed here.



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## USER REQUIREMENT SPECIFICATION

**NAME OF ITEM:** Compressed Air System

**PROTOCOL No.....**

**FUNCTIONAL AREA:** Production

**Page No.:** 12 of 15

Sr. No.	Parameter	Specifications
1.	Internal Surface finish (Contact Parts)	➤ Smooth finish inside surface with no welding burrs and crevices.
2.	Outer Surface finish (Non-contact Parts)	➤ Smooth finish outer surface with no welding burrs and Crevices.

**19.0 Electrical and Control Equipment Philosophy:** A brief detail of the control requirements and whether the equipment is to be controlled using electrical system/ microprocessor/ PLC/ computers or a combination of these are mentioned in this section.

Sr. No.	Parameter	Specifications
1	PLC System	➤ Shall be provided with Both Manual and Auto mode.

**20.0 cGxP CONSIDERATIONS:** The requirements for electronic compliance of the equipment.

Sr. No.	Parameter	Specifications
1.	Security Levels	➤ Operator: Only operation at auto/manual mode.

**21.0 Expected Documents and Drawings:** Requirement of documents to be delivered by the suppliers during the procurement life cycle. A suggestive list (but not limited to), is as listed below:

Sr. No.	Document details	Required (✓ / ✗)
1.	Design Specifications	✓
2.	Functional Specifications	✗
3.	PLC Alarm/ Interlock/ Safety/ communication/ power failure test procedures	✓
4.	Piping and Instrumentation Diagram (P&ID)	✗
5.	Instrument Listing	✓



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## USER REQUIREMENT SPECIFICATION

**NAME OF ITEM:** Compressed Air System

**PROTOCOL No.....**

**FUNCTIONAL AREA:** Production

**Page No.:** 13 of 15

Sr. No.	Document details	Required (✓ / ✗)
6.	Control Panel Assembly Drawings	<input checked="" type="checkbox"/>
7.	Machine Assembly Drawings	<input checked="" type="checkbox"/>
8.	Bill of Materials	<input checked="" type="checkbox"/>
9.	Calibration certificates of instruments	<input checked="" type="checkbox"/>
10.	Electrical drawings/ Schematic Diagram	<input checked="" type="checkbox"/>
11.	P & ID	<input checked="" type="checkbox"/>
12.	Functional Design Specification	<input checked="" type="checkbox"/>
13.	PLC specification	<input checked="" type="checkbox"/>
14.	Electrical Specification	<input checked="" type="checkbox"/>
15.	Hardware Specification	<input checked="" type="checkbox"/>
16.	Operation & Maintenance Manual	<input checked="" type="checkbox"/>
17.	Spare Parts List	<input checked="" type="checkbox"/>
18.	Other (Specify)	<input checked="" type="checkbox"/>

✓ : Applicable & required      ✗ : Not applicable

### 22.0 AVAILABLE UTILITIES:

Sr. No.	Parameter	Specifications
1.	Electricity	Electrical supply three Phase/ 415 volts $\pm$ 10% 50 Hz with neutral and earthing will be provided.

**23.0 Maintenance Requirements:** Maintenance related requirements like accessibility for easy maintenance, required spares, etc. are listed here.



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## USER REQUIREMENT SPECIFICATION

**NAME OF ITEM:** Compressed Air System

**PROTOCOL No.....**

**FUNCTIONAL AREA:** Production

**Page No.:** 14 of 15

Sr. No.	Parameter	Specifications
1.	Maintenance	Easy accessibility for maintenance
2.	Spare parts	List of spare parts and spare parts should be provided

### 24.0 DELIVERY, INSTALLATION AND COMMISSIONING REQUIREMENTS:

24.1 Should be delivered in disassembled condition and to be assembled at the site by the manufacturer/supplier service engineer.

24.2 Manufacturer should provide support in case of problems, which may not be able to rectify at the user end.

24.3 FAT if any required by the customer then, same to be performed jointly by the nominated persons from both the side at the manufacturer's site.

24.4 The manufacturer should install, qualify and commission the equipment at the user site.

24.5 Training to be provided by the manufacturer for the necessary critical steps involved in the operation, cleaning, maintenance, safety and handling of equipment.

25.0 **OTHER SPECIFIC REQUIREMENTS:** To provide the necessary servicing at the site at defined intervals. Language requirements in manual should be in English.

26.0 **REFERENCE DOCUMENTS:** Nil.

27.0 **ABBREVIATIONS:** Full forms of all abbreviations are listed here.

#### Abbreviation

#### Full form

cGMP : Current Good Manufacturing Practice

dB : Decibel

HZ : Hertz

Kg/cm<sup>2</sup> : Kilogram per centimetre square



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## USER REQUIREMENT SPECIFICATION

<b>NAME OF ITEM:</b> Compressed Air System	<b>PROTOCOL No.....</b>
<b>FUNCTIONAL AREA:</b> Production	<b>Page No.:</b> 15 of 15

- MOC : Material of Construction
- Nos : Number
- Sr. No. : Serial Number
- SS : Stainless Steel
- URS : User Requirement Specification
- °C : Degree Celsius
- % : Percentage
- mm : Millimetre
- PLC : Programmable logic controller

**28.0 Attachments:** This section contains a list of all attachments referenced if any in the protocol.

Sr. No.	Attachment Details	Attachment No.