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| DOC NUMBER: 569-DB7A-PRO-500-005 | | CLIENT NUMBER: PRD-MEC-MDE-010 | |
| CLIENT: TAKEDA | | | |
| PROJECT BURITI EPCMV PROJECT | | | |

FINAL DRUG PRODUCT COMPRESSED AIR GENERATION SYSTEM DESCRIPTION REPORT

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1. REVISION HISTORY

| Rev | Reason For Change |
|-----|-------------------------|
| A | 90% DD ISSUE |
| 0 | ISSUED FOR CONSTRUCTION |
| 1 | AS PER N+1 UPDATE |

2. PURPOSE

This document is intended to describe the Compressed Air Generation System, Building 7A – Final Drug Product - FDP, intended to Buriti Project, located at Hermobrás site in Goiania – Pernambuco state, Brazil.

3. REFERENCE

The following documents were used as reference:

| Item | Number | Title |
|------|-------------|--|
| 01 | 7A-M-05-81 | P&I DIAGRAM - DRUG PRODUCT- COMPRESSED AIR GENERATION SYSTEM |
| 02 | 7A-Z-0-2-36 | P&I DIAGRAM - CLEAN COMPRESSED AIR DISTRIBUTION |
| 03 | 7A-Z-0-2-37 | P&I DIAGRAM - INSTRUMENT AIR DISTRIBUTION |

4. PROCESS DESCRIPTION





The building 7A has a Compressed Air Generation System, located on the utilities room (7A-1043) at the Ground floor to supply the demand of Instrument Air and Clean Compressed Air.

The Compressed Air Quality required shall be in accordance with ISO-8573-1 considering the following characteristics:

- Class 1 – Particles
- Class 2 – Dew Point (-40°C)
- Class 3 -Oil Free

The Compressed Air Generation System is a vendor package to produce 850 Nm³/h @ 9.0 bar(g) (design condition) to be supplied with the equipment indicated below:

- 1 Rotary Compressor - COMP-7A-1 (one operating).
- 1 Particulate Coalescing Filter – F-COMP-7A-1.
- 1 Twin adsorption Dryer – AD-7A-1.
- 1 Particulate Coalescing Filter – F-AD-7A-1.
- 1 Receiver – AR-7A-1 (capacity of 2.000 L).
- 1 Particulate Filter – F-AR-7A-1(installed after the receiver).
- 1 Main Control Panel

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After the compressed air generation, out of the vendor package, there are two different distribution headers, one to supply compressed air for instrumentation (line 1.1/2"-CA-840014-SS6-NI) with the maximum flow rate of 4,908.3 NLPM (294.5 NM3/HR) @ 6.0 bar(g) and another to supply Clean Compressed Air for Process (line 2.1/2"-CA-840015-SS6-NI) with the maximum flow rate of 5,373.3 NLPM (322.4 NM3/HR) @ 6.0 barG. The header for Process has two T-Style sanitary Filters (FGA-7000-1 / FGA-7000-2) before the consumers.

4.1 COMPRESSOR




The compressor (COMP-7A-1) type of rotary screw, oil-free and water-cooled with panel located near the equipment, work with variable speed, controlled by PIC- 840009. The set point pressure to be adjusted during startup. At the outlet of the compressor there is a Particulate Coalescing Filter (F-COMP-7A-1) for oil removal (0,01 ppm) and particle removal (0,01 µm).

The compressor has the following characteristics:

| ROTARY COMPRESSOR | |
|-------------------------------------|--------------------------|
| Capacity - NM3/H | 850 |
| Material | Carbon Steel / Cast Iron |
| Process gas | AIR |
| Cooling medium | Water |
| Size - Height x Length x Width (mm) | 2184 x 2180 x 1450 |

| MODEL PERFORMANCE | Operating point | Min Flow at Pressure | Max Flow at Pressure |
|-------------------------------------|-----------------|----------------------|----------------------|
| Discharge Pressure – bar(g) | 6 | 6 | 6 |
| Delivered flow (Nm ³ /h) | 850 | 237,09 | 933,11 |
| Power: Shaft - kW | 86,53 | 27,9 | 96,08 |
| Power: Package - kW | 96,84 | 32,95 | 106,56 |
| Motor Speed - rpm | 2976 | 1000 | 3250 |
| Stage isentropic eff.: Shaft - % | 80,63 | 69,77 | 79,71 |
| Stage isentropic eff.: Package - % | 72,05 | 59,08 | 71,87 |
| Air outlet temperature - °C | 34 | 29 | 36 |

The compressor is a water-cooled with cooling water from the Cooling Towers through a 2" line (line 2"-TWS-840016-CS1-NI) and it returns to the Cooling Towers through a 2" line (line 2"-TWR-840021-CS1-NI). The flow rate to feed this equipment at the same time is 180LPM (10.8 m3/hr), an inlet pressure of 3.2 barG and a differential of temperature of 15°C. The cooling water passes through the compressors even when they are not working. There is a static balancing valve to regulate the cooling water flow rate and a low flow switch at the inlet of the compressor (FSL- 840017 for compressor COMP-7A-1).

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4.2 TWIN ADSORPTION DRYER

The twin adsorption Dryer with hot regeneration (AD-7A-1) consists of two towers that contain activated alumina to remove moisture compresses air by adsorption.

The Twin Adsorption Dryer has a capacity to produce 850 Nm³/h to meet the flow rate compressor.

At the outlet of the twin adsorption dryer there is a Particulate Coalescing Filter (F-AD-7A-1) for particle removal (0,1 µm).

4.3 RECEIVER

After the Particulate Coalescing Filter (F-AD-7A-1) there is a receiver (AR-7A-1) with capacity of 2,000 L. The receiver has the function of control pressure system. Therefore, the pressure variation in the air system is equalized and the load and relief cycles in the compressor are minimized, they lower the compressed air temperature. The receiver also collect residual condense if necessary.

There is a pressure safety valve (PSV-840010) on top of the receiver preserving the receiver.




After the receiver there is another Particulate Filter (F-AR-7A-1) for particle removal (0,01 µm).

4.4 MAIN CONTROL PANEL

The panel located near the equipment has the function of controlling the pressure and temperature of all system, as well as the outlet dew point.

The vendor package has the following instruments:

| EQUIPMENT | INSTRUMENT | FUNCTION |
|----------------------------------|-------------------------|------------------------------------|
| COMP-7A-1 - Water Inlet line | PIT-840021 | Pressure Indication Transmitter |
| COMP-7A-1 - Water Inlet line | FSL-840017 | Low Flow Switch |
| M-COMP-7A-1 - Motor | SC-840001 | Control Speed |
| F-COMP-7A-1 - Inlet line | PI-840001 | Pressure indication |
| F-COMP-7A-1 - Outlet line | PI-840003 | Pressure indication |
| AD-7A-1 - Inlet line | TIT-840004 | Temperature Indication Transmitter |
| AD-7A-1 - Inlet line | XV-840004 / XV-840014 | On-off Valve |
| AD-7A-1 - Vent line | XV-840006 / XV-840007 | On-off Valve |
| AD-7A-1 - Inlet line | PIT-840024 / PIT-840014 | Pressure Indication Transmitter |
| AD-7A-1 | PSV-840004 / PSV-840014 | Pressure Safety Valve |
| AD-7A-1 - air blower Motor | SC-840005 | Control Speed |
| AD-7A-1 - Outlet Line air blower | PIT-840019 | Pressure Indication Transmitter |
| AD-7A-1 - Outlet Line air blower | TIT-840014 | Temperature Indication Transmitter |
| F-AD-7A-1 - Inlet line | PI-840005 | Pressure Indication |
| F-AD-7A-1 - Outlet line | PI-840007 | Pressure Indication |

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| EQUIPMENT | INSTRUMENT | FUNCTION |
|---|------------|---------------------------------|
| AR-7A-1 | PI-840010 | Pressure Indication |
| | PSV-840010 | Pressure Safety Valve |
| F-AR-7A-1 - Inlet line | PI-840011 | Pressure Indication |
| F-AR-7A-1 - Outlet line | PI-840012 | Pressure Indication |
| Outlet Compressed Air Generation System | AIT-840001 | Dew Point Analyzer |
| | PIT-840009 | Pressure Indication Transmitter |

4.5 CONSUMERS





The compressed air generation system has the following consumers in the Building 7A:

- Clean Compressed Air

| EQUIPMENT | FLOW RATE (Nm³/h) |
|------------------------------|----------------------|
| PARTS WASHER, LV-4601 | 25.5 |
| CIP/SIP STATION, STA-4701 | 6.84 |
| AUTOClave, AT-9001 | 60.0 |
| LYO N°2, LYO-1106 | 27.6 |
| LYO N°1, LYO-1105 | 27.6 |
| AUTO LOAD-UNLOAD, ALS 1105/6 | 0.18 |
| VIAL WASHER, ML-1101 | 228.0 |
| AREA UTIL. STATION, UP-3801 | 1.8 |
| AREA UTIL. STATIONS UP-3903 | 1.8 |
| AREA UTIL. STATIONS UP-3902 | 1.8 |
| AREA UTIL. STATIONS UP-3901 | 1.8 |
| STERILE FILT. SKID, FIL-3901 | 1.8 |
| CIP SKID, CIP-7701 | 16.98 |

- Instrument Air

| EQUIPMENT | FLOW RATE (Nm³/h) |
|---------------------------|----------------------|
| PARTS WASHER, LV-4601 | 3.6 |
| AUTOClave, AT-9001 | 3.6 |
| LYOPHILIZER N°1, LYO-1105 | 3.6 |
| LYOPHILIZER N°2, LYO-1106 | 3.6 |

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| EQUIPMENT | FLOW RATE (Nm³/h) |
|-----------------------------------|----------------------|
| DECON AUTOCLAVE, AT-9002 | 63.6 |
| FORMULATION TCU, TCU-3903 | 3.6 |
| CIP SYS. N°1, CIP-7701 | 3.6 |
| STERILE FILT. SKID, FIL-3901 | 3.6 |
| FILLING MACHINE, EV-1103 | 3.6 |
| DEPYRO. TUNNEL, TE-1102 | 54.0 |
| VIAL WASHER, ML-1101 | 0.6 |
| CAPPER, CTM-1104 | 6.0 |
| WFI DIST. HEAT EXCHANGER, TC-6402 | 3.6 |
| WFI DIST. HEAT EXCHANGER, TC-6403 | 3.6 |
| CIP CHEM. TOTE DIST., BD-4301 | 36.0 |
| PRETREATMENT SYSTEM, RO-6301 | 3.6 |
| WFI STILL, MES-6401 | 3.6 |
| HOT WFI SKID, SK-6401 | 3.6 |
| CLEAN STEAM GEN., CSG-6501 | 3.6 |
| PROC. WASTE SUMP, SK-8001 | 3.6 |