



DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Procedure for Validation of Compressed Air	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a Procedure to define the Standard Operating Procedure for “Validation of Compressed air”.

2.0 SCOPE:

This SOP is applicable for Validation of Compressed air at

3.0 RESPONSIBILITY :

Quality Assurance : Preparation & Execution of validation protocol & report compilation of Data.

Microbiologist : Sampling & Analysis of compressed air.

Manager QA : Review of validation protocol & report.

4.0 ACCOUNTABILITY:

Head-Quality shall be accountable for ensuring over all compliance of this Standard Operating Procedure.

5.0 DEFINITIONS:

- **SOP:** A **Standard Operating Procedure (SOP)** is a set of written instructions that document a routine or repetitive activity which is followed by employees in an organization.
- **Compressed air:** Compressed air is a gas, or a combination of gases, that has been put under Greater pressure than the air in the general environment.
- **Dew Point:** The temperature at which a condensable component of a gas (as, water vapor in The air) starts to condense into liquid.
- **Water Vapour:** Dispersion, in air, of molecules of water, especially as produced by evaporation a Ambient temperatures rather than by boiling.



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- **Total Viable Counts:** It gives a quantitative estimate of the concentration of microorganisms such as bacteria, yeast or mould spores in a sample. The count represents the number of colony forming units (cfu) per g (or per ml) of the sample.

6.0 PROCEDURE:

6.1 The Validation of the compressed air system shall be done by monitoring and testing of compressed air user points installed in Each Critical compressed air user points shall be tested for Validation of Air compressor system to ensure desired quality of compressed air.

The below tests are include for Validation of the Compressed air:

- Total Viable Count
- Non-Viable Particulate count
- Verification of Dew point
- Verification of water vapor content
- Verification of Oil mist content
- Verification of Carbon Mono-oxide (CO) content
- Verification of Carbon Dioxide (CO₂) content
- Verification of Nitrogen Monoxide/ Dioxide (NO/NO₂) Content
- Verification of Sulphur Dioxide (SO₂) content

6.2 The above-mentioned tests provide a documented verification of the intended revalidation of the compressed air distribution system and ensure that the system is performing adequately & will produce desired results in terms of quality and quantity when operated as per specification.

6.3 All the test shall be done as per given Annexure-I and accordingly protocol & report shall be prepared.

6.4 TOTAL VIABLE COUNT:

The test shall be carried out to determine the total viable count in the compressed air. The procedure is outlined below:

6.4.1 Take 500 ml of purified water in glass bottle, plug with cotton and wrap it with aluminum foil.



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Sterilize the glass unit as per SOP.

- 6.4.2** Keep all the sterile sampling bottles required for microbiological testing in a tray and carry the Tray to the concerned area (compressed air user point) to conduct sampling as described below.
- 6.4.3** Connect the compressed air point with silicon tube from which sample has to be withdrawn. Clean thoroughly the outer surface of the compressed air pipeline with 70 % IPA solution. Wait for 5 minutes.
- 6.4.4** Take the pre-sterilized glass bottle containing sterilized purified water, open the screw cap From glass bottle and dip the cleaned silicon tube of compressed air supply in to sterile water.
- 6.4.5** Open valve of the compressed air line gradually for 2 minutes so that the compressed air enters Into the glass bottle containing sterilized purified water. Ensure that the air bubbles generated Into the glass bottle do not cause spillover of the purified water.
- 6.4.6** After 2 minutes, close the valve of compressed air line and also close sterile glass bottle with Screw cap. Wrap the glass bottle with aluminum foil and bring it to microbiology lab for Analysis.
- 6.4.7** Transfer the above collected water sample containing compressed air from user point to a Sterilized filtration funnel fitted with sterile membrane of nominal pore size equal to 0.45 μ .
- 6.4.8** Filter it and after filtration, put the membrane filter on the media plate of Soyabean Casein Digest Agar (SCDA). Incubate the sampling plate for 72 hours at 20 to 25°C for fungal count Followed by 2 days at 30 to 35°C for bacterial count. Incubate a negative control which has Been treated in a similar way as test except the sample i.e. compressed air.
- 6.4.9** Perform the positive control as per SOP, Microbial monitoring of compressed air.

6.4.10 Acceptance Criteria:

S.No.	Test	Specification
1.	For sterile area	Bacteria: Nil Fungi: Nil
2.	For Non-sterile area	Bacteria: Not more than 5 cfu/m ³ Fungi: Nil



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6.5 NON-VIABLE PARTICULATE COUNT:

The test shall be carried out to determine the total non-viable particulate count in the compressed air.

The procedure is outlined below:

6.5.1 Connect the particle counter to compressed air user point with diffuser. Take one sample (one mtr³) of Compressed air at each user point.

6.5.2 Record the number of particles per cubic meter of air for different particle size range.

6.5.3 Acceptance Criteria:

Particle size between 0.5 to 1.0 micron ranges should not be more than 6000 in each cubic meter of compressed air.

Particle size between 1.0 to 5.0 micron ranges should not be more than 100 in each cubic meter of compressed air.

6.6 VERIFICATION OF DEW POINT:

The test shall be carried out to determine the dew point at the outlet of each compressed air user point.

6.6.1 Before the test, ensure air temperature between 0 to +40°C and relative humidity of air between 0 to 90%.

6.6.2 Open the compressed air valve and let the air to be drained out for 1 minute.

6.6.3 Connect the Compressed air outlet point to connection pipe of Dew Point Temperature Transmitter.

6.6.4 Insert the Dew Point Temperature Transmitter in the connection pipe.

6.6.5 Ensure that the probe of Transmitter is directly perpendicular to Compressed air flow.

6.6.6 Ensure that there is no leakage in the connections as the penetration of humidity from the Environment will affect the end results.

6.6.7 Switch on the power supply of transmitter.

6.6.8 Take the reading of dew point for each compressed air user point from transmitter once it is Stabilized.

6.6.9 Acceptance Criteria: The Pressure dew point should be $\leq - 40^{\circ}\text{C}$.



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6.7 VERIFICATION OF WATER VAPOR CONTENT:

The test shall be carried out to detect the absence or presence of water vapor in compressed air.

The procedure is outlined below:

- 6.7.1** Install a reducer pressure with gauge and flow meter to compressed air line and adjust the flow Meter to flow rate of 100 ml/min.
- 6.7.2** Break the tips off a fresh detector tube in the tube tip breaker and insert the tube into tube Holder. When breaking the tube ends, keep away from the eyes. Do not touch the broken glass Tube, pieces and reagent with bare hands. (Measuring range: 30-80 mg/m³)
- 6.7.3** Attach the rubber tube holder to the flow meter outlet. Make certain the tube arrow G> on the tube pointing in a down direction.
- 6.7.4** Turn on the valve and set the flow meter to 100 ml/min. Record the flow rate with stopwatch.
- 6.7.5** Pull handle all the way out until it locks on pump stroke (100 ml). Wait for 10 minutes. The Sampling time represents the time necessary to draw the required air sample of 1000 ml through the tube. The tube must be positioned in the desired sampling area for the entire sampling time or until the flow finish indicator indicates the end of the sample.
- 6.7.6** As soon as sampling time of 10 minutes has elapsed, turn off the valve and remove the tube From the tube holder and then read the colour change in layer immediately.
- 6.7.7** Observed the colour change of detector tube as per its specification, if water content present.
- 6.7.8 Acceptance Criteria:** No colour change should be observed in the detector tube and Compressed air should be moisture free. If observed, water vapor level should be less than 67 ppm.

6.8 VERIFICATION OF OIL MIST CONTENT:

The test shall be carried out to determine the content of total oil mist (mineral oils) in compressed air.

The procedure is outlined as following:

- 6.8.1** Install a reducer pressure with gauge and flow meter to compressed air line and adjust the flow Meter to sampling rate 1000 ml/min.
- 6.8.2** Break tips off a fresh detector tube in the tube tip breaker and insert a tube into tube holder.



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When breaking the tube ends, keep away from the eyes. Do not touch the broken glass tube, Pieces and reagent with bare hands. (Measuring range: 0.2-5.0 mg/m³)

- 6.8.3** Attach the rubber tube holder to the flow meter outlet. Make certain the tube arrow G> on the tube pointing in a down direction.
- 6.8.4** Turn on the valve and confirm the flow meter set to 1000 ml/min. Record the flow rate with stopwatch.
- 6.8.5** Pull handle all the way out until it locks on pump stroke (1000 ml). Wait for 20 minutes. The Sampling time represents the time necessary to draw the required air sample of 20000 ml through the tube. The tube must be positioned in the desired sampling area for the entire sampling time or until the flow finish indicator indicates the end of the sample.
- 6.8.6** As soon as sampling time of 20 minutes has elapsed, turn off the valve and remove the tube from the tube holder and then read the colour change of detector tube as per its specification, if oil mist present.
- 6.8.7** Correction for Pressure shall be done as per below formula:

$$\text{Oil content} = \frac{\text{Tube reading (mg/m}^3\text{)} \times 1013 \text{ (hpa)}}{\text{Atmospheric pressure (hpa)}}$$

- 6.8.8 Acceptance Criteria:** Total oil mist (mineral oils) content should be less than 0.1 mg/m³.

6.9 VERIFICATION OF CARBON MONOXIDE CONTENT:

The test shall be carried out to determine the carbon monoxide content in compressed air. The procedure is outlined as:

- 6.9.1** Install a reducer pressure with gauge and flow meter to compressed air line and adjust the flow meter to sampling rate 100 ml/min.
- 6.9.2** Break tips off a fresh detector tube in the tube tip breaker and insert a tube into tube holder. Attach the rubber tube holder to the flow meter outlet. Make certain the tube arrow G> on the tube pointing in a down direction. (Measuring range: 5-50 ppm)
- 6.9.3** When breaking the tube ends, keep away from the eyes. Do not touch the broken glass tube, pieces and reagent with bare hands.



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- 6.9.4** Turn on the valve and confirm the flow meter set to 100 ml/min. Record the flow rate with stopwatch.
- 6.9.5** Pull handle all the way out until it locks on pump stroke (100ml). Wait for 3 minutes. The sampling time represents the time necessary to draw the required air sample of 300 ml through the tube. The tube must be positioned in the desired sampling area for the entire sampling time or until the flow finish indicator indicates the end of the sample.
- 6.9.6** As soon as sampling time of 3 minutes has elapsed, turn off the valve and remove the tube from the tube holder and then read the colour change of detector tube as per its specification, if CO content present.

- 6.9.7** Correction for Pressure should be done as per below formula:

$$CO\ content = \frac{Tube\ reading\ (ppm) \times 1013\ (hpa)}{Atmospheric\ pressure\ (hpa)}$$

- 6.9.8 Acceptance Criteria:** Total carbon monoxide content in compressed air should be less than 5 ppm.

6.10 VERIFICATION OF CARBON DIOXIDE CONTENT:

The test shall be carried out to determine the content of carbon dioxide in compressed air. The procedure is outlined as following:

- 6.10.1** Install a reducer pressure with gauge and flow meter to compressed air line and adjust the flow meter to sampling rate 100 ml/min.
- 6.10.2** Break tips off a fresh detector tube in the tube tip breaker and insert a tube into tube holder. Attach the rubber tube holder to the flow meter outlet. Make certain the tube arrow G> on the tube pointing in a down direction. (Measuring range: 200-3000 ppm)
- 6.10.3** When breaking the tube ends, keep away from the eyes. Do not touch the broken glass tube, pieces and reagent with bare hands.
- 6.10.4** Turn on the valve and confirm the flow meter set to 100 ml/min. Record the flow rate with stopwatch.
- 6.10.5** Pull handle all the way out until it locks on pump stroke (100ml). Wait for 1.5 minutes. The



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sampling time represents the time necessary to draw the required air sample of 150 ml through the tube. The tube must be positioned in the desired sampling area for the entire sampling time or until the flow finish indicator indicates the end of the sample.

6.10.6 As soon as sampling time of 1.5 minutes has elapsed, turn off the valve and remove the tube from the tube holder and then read the colour change of detector tube as per its specification, if CO₂ content present.

6.10.7 Correction for Pressure should be done as per below formula:

$$CO_2 \text{ content} = \frac{\text{Tube reading (ppm)} \times 1013 \text{ (hpa)}}{\text{Atmospheric pressure (hpa)}}$$

6.10.8 Acceptance Criteria: Total carbon dioxide content in compressed air should be less than 500 ppm.

6.11 VERIFICATION OF NITROGEN MONOOXIDE/ DIOXIDE (NO/NO₂) CONTENT:

The test shall be carried out to determine the content of nitrogen oxide in compressed air.

The procedure is outlined as following:

6.11.1 Install a reducer pressure with gauge and flow meter to compressed air line and adjust the flow meter to sampling rate 100 ml/min.

6.11.2 Break tips off a fresh detector tube in the tube tip breaker and insert a tube into tube holder. Attach the rubber tube holder to the flow meter outlet. Make certain the tube arrow G> on the tube pointing in a down direction. (Measuring range: 0.2 - 5 ppm)

6.11.3 When breaking the tube ends, keep away from the eyes. Do not touch the broken glass tube, pieces and reagent with bare hands.

6.11.4 Turn on the valve and confirm the flow meter set to 100 ml/min. Record the flow rate with stopwatch.

6.11.5 Pull handle all the way out until it locks on pump stroke (100ml). Wait for 2 minutes. The sampling time represents the time necessary to draw the required air sample through the tube. The tube must be positioned in the desired sampling area for the entire sampling time or until the flow finish indicator indicates the end of the sample.

6.11.6 As soon as sampling time of 2 minutes has elapsed, turn off the valve and remove the tube from



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the tube holder then read then read the colour change of detector tube as per its specification, if Nitrogen oxide content present.

6.11.7 Correction for Pressure should be done as per below formula:

$$NO/NO_2 \text{ content} = \frac{\text{Tube reading (ppm)} \times 1013 \text{ (hpa)}}{\text{Atmospheric pressure (hpa)}}$$

6.11.8 Acceptance Criteria: Total nitrogen oxide (NO/NO₂) content in compressed air should be less than 2 ppm.

6.12 VERIFICATION OF SULPHUR DIOXIDE CONTENT:

The test shall be carried out to determine the content of sulphur dioxide in compressed air. The procedure is outlined as following:

- 6.12.1** Install a reducer pressure with gauge and flow meter to compressed air line and adjust the flow meter to sampling rate 100 ml/min.
- 6.12.2** Break tips off a fresh detector tube in the tube tip breaker and insert a tube into a tube holder. Attach the rubber tube holder to the flow meter outlet. Make certain the tube arrow G> on the tube pointing in a down direction. (Measuring range: 0.25 - 10 ppm)
- 6.12.3** When breaking the tube ends, keep away from the eyes. Do not touch the broken glass tube, pieces and reagent with bare hands. Turn on the valve and confirm the flow meter set to 100 ml/min. Record the flow rate with stopwatch.
- 6.12.4** Pull handle all the way out until it locks on pump stroke (100ml). Wait for 2 minutes. The sampling time represents the time necessary to draw the air sample through the tube. The tube must be positioned in the desired sampling area for the entire sampling time or until the flow finish indicator indicates the end of the sample.
- 6.12.5** As soon as sampling time of 2 minutes has elapsed, turn off the valve and remove the tube from the tube holder then read the colour change of detector tube as per its specification, if Sulphur dioxide content present.
- 6.12.6** Correction for Pressure should be done as per below formula:



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$$SO_2 \text{ content} = \frac{\text{Tube reading (ppm)} \times 1013 \text{ (hpa)}}{\text{Atmospheric pressure (hpa)}}$$

6.12.7 Acceptance Criteria: Total sulphur dioxide (SO₂) content in compressed air should be less than 1 ppm.

7.0 ABBREVIATION:

SOP	Standard Operating Procedure
QA	Quality Assurance
MI	Milliliter
%	Percent
Mg	Milligram
CFM	Cubic Feet per minute
°C	Degree Celsius
CFU	Colony Forming Unit
Min	Minimum
ppm	Parts per Million
CO	Carbon Monoxide

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Validation test parameters	

9.0 DISTRIBUTION DETAILS:

- Master Copy Quality Assurance Department
- Controlled Copy No. 01 Quality Assurance Department.
- Controlled Copy No. 02 Quality Control Department.
- Controlled Copy No. 03 Production Department.



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- Controlled Copy No. 04 Engineering Department.
- Controlled Copy No. 05 Quality Control Department.

10.0 REFERENCE:

- ISO 8573.1:2010 (E) Part 1 to Part 9.

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		



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ANNEXURE- I VALIDATION TEST PARAMETERS

S.No.	Tests
1.	Total Viable Count
2.	Non-Viable Particulate count
3.	Verification of Dew point
4.	Verification of water vapor content
5.	Verification of Oil mist content
6.	Verification of Carbon Mono-oxide (CO) content
7.	Verification of Carbon Dioxide (CO ₂) content
8.	Verification of Nitrogen Monoxide/ Dioxide (NO/NO ₂) Content
9.	Verification of Sulphur Dioxide (SO ₂) content