



STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Monitoring of Compressed Air/Nitrogen Gas Quality

Effective Date:

Supersedes: Nil

Review Date:

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1.0 OBJECTIVE:

To lay down the procedure for monitoring the quality of Compressed air/ Nitrogen gas in production, stores area and utility area.

2.0 SCOPE:

This SOP is applicable for monitoring the quality of Compressed air and Nitrogen gas used in production, stores area and utility area.

3.0 RESPONSIBILITY:

Microbiologist – Quality Control

Head – Quality Control

4.0 PROCEDURE:

4.1 Materials & Equipments:

4.1.1 Air Sampler.

4.1.2 Pre-incubated sterile Soyabean Casein Digest Agar Plate.

4.1.3 Incubator.

4.1.4 compressed air/nitrogen gas sampling accessory.

4.1.5 Compressed Air/Nitrogen Gas Sampler.

4.1.6 Aluminium foil, butter paper, Non-absorbent cotton, filtered 70 % v/v IPA.

4.2 Sampling and Testing procedure of Compressed air and Nitrogen gas for Non-sterile area for microbiological testing

4.2.1 Prepare Soyabean casein digest Agar plates as per SOP.

4.2.2 Prepare the 70 % v/v IPA as per SOP.

4.2.3 Transfer the air sampler to the location where sampling is to be done as per entry and exit procedure of man and material of respective area. Flush out compressed air/nitrogen for 15 seconds before sampling.

4.2.4 Place pre-incubated Soyabean Casein Digest Agar plate on plate holder removing the lid of the agar plate. SCDA plates shall be marked with location and date of exposure.



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- 4.2.5 Place sterile compressed air/nitrogen gas sampler accessory on plate holder and adjust the compressed air/nitrogen gas pressure of sampling point at 2.0 kg/cm^2 with the help of regulator with calibrated pressure gauge. After every air sampling location the sampler accessories shall be sanitized with 70 % v/v IPA.
- 4.2.6 Compressed air/nitrogen gas sampling shall be done as per the sampling plan. Compressed air, Nitrogen gas (Microbial) sampling should be done for three consecutive working days and half yearly once in Non sterile area.
- 4.2.7 The test is applicable only when compressed gas /Nitrogen gas is filtered through filter of less than or equal to 0.2 micron pore size.
- 4.2.8 Set the air sampling time of the sampler to sample 1000 liters of compressed air/nitrogen and operate the air sampler as per SOP.
- 4.2.9 Operate the air sampler as per respective standard operating procedure for cleaning and operation of air sampler and collect 1000 liters of compressed air/nitrogen gas sample from each location.
- 4.2.10 Close the sampling valve of the sampling point and remove compressed air/nitrogen gas sampling accessory. Remove the plates from the holder, cover with lid.
- 4.2.11 Mark the plate with location no, date and also perform the air sampling in the same way in other locations as per the frequency.
- 4.2.12 Transfer the plates to microbiology department and incubate at plate in inverted position along with control plate (unexposed) at 20°C - 25°C for 72 hours and at 30°C - 35°C for 48 Hours for the compressed air testing and at 30°C - 35°C for 72 hours under anaerobic conditions for nitrogen testing.
- 4.2.13 Control plate (unexposed) represents the medium sterility and carrier control of plate transportation.
- 4.2.14 After completion of incubation period of respective test , observe number of CFU per 1000 liters of gas on plate and record the results as per Annexure-1. For compressed air and Annexure –2 for Nitrogen Gas.



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4.3 Sampling point for Nitrogen Gas

S.No.	Area	Sampling Point (ID.No.)
1.		
2.		
3.		
4.		
5.		

4.4 SAMPLING POINT FOR COMPRESSED AIR

S.No.	Area	Sampling Point (ID.No.)

4.5 Frequency and limit

Area	Sample	Test	Method	Limits	Frequency
Non sterile	Nitrogen (Micro)	Anaerobic bacteria	By Air sampling method	NMT5 CFU/m ³	Half Yearly
	Compressed Air (Micro)	Bacteria	By Air sampling method	NMT 100 CFU/m ³	Half Yearly
		Fungi	By Air sampling method	Nil	Half Yearly

*Compressed air , Nitrogen Gas (microbial) sampling should be done for three consecutive working days, and half yearly once in Non-Sterile area (± 15 working days for the half yearly)

5.0 ANNEXURE (S):

Annexure-1: Test report of Compressed air

Annexure-2 : Test report of Nitrogen gas

6.0 REFERENCE (S):

SOP: Procedure for preparation of Disinfectant and cleaning of Microbiology Laboratory.

SOP: Cleaning and operation of Autoclave for media

SOP: Operation and Cleaning of Air Sampler Climate



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SOP: Procedure for preparation of media.

SOP: Preparation, Approval, Distribution control, revision and Destruction of Standard operating Procedure (SOP).

7.0 ABBREVIATION (S) / DEFINITION (S):

CFU : Colony Forming Unit

NMT : Not more than

NLT : Not less than

SOP : Standard Operating procedure

v/v : Volume per volume

IPA : Iso Propyl Alcohol

SCDA : Soyabean casein digest agar

QCM : Quality Control Microbiology

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
01	00	---	---	New SOP	---



PHARMA DEVILS
MICROBIOLOGY DEPARTMENT

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Annexure 1
TEST REPORT OF COMPRESSED AIR

Date of sampling		Date of Report	
Sampling time		Sampled By (Sign. & Date)	
A.R.No.:		Air Sampler ID. No.:	

Media Details	Incubation Temperature	Incubation Time	Incubator ID No.
Soyabean Casein Digest Agar	20°–25°C	72 hours	
Lot No.:	30°–35°C	48 hours	

S.No.	Location ID. No.	Sampling Location Description	Total Count(cfu/m³)	
			Bacteria	Fungi

Frequency: Half Yearly	Negative control:
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Limit: (cfu/m³)

Bacteria	Fungi
NMT 100	Nil

Remark: Area Complies / Does not Comply with specified limit.

Observed By: (Sign. & Date)	Date of Report	Checked By : (Sign. & Date)
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Annexure 2
TEST REPORT OF NITROGEN GAS

Date of sampling		Date of Report	
Sampling time		Sampled By (Sign. & Date)	
A.R.No.:		Air Sampler ID. No.:	

Media Details	Incubation Temperature	Incubation Time	Incubator ID No.
Soyabean Casein Digest Agar	30°–35°C	72 hours	
Lot No.:			

S.No.	Location ID. No.	Sampling Location Description	Total Count (cfu/m ³)
			Anaerobic Bacteria

Frequency: Half Yearly	Negative control:
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Limit: NMT 5 CFU/m³

Remark: Area Complies / Does not Comply with specified limit.

Observed By: (Sign. & Date)	Date of Report	Checked By : (Sign. & Date)
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