PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Monitoring of Compressed Air in Manufacturing Area

SOP No.:		**Department:**	Microbiology	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	1 of 4	

1.0 OBJECTIVE

To lay down procedure for monitoring of compressed air in manufacturing areas.

2.0 SCOPE

This SOP is applicable for monitoring of compressed air .

3.0 RESPONSIBILITY

Prepared by - Executive Microbiology

Checked by - Assistant Manager Microbiology / QC

Approved by - Head QA, QC

4.0 PROCEDURE

4.1 Sampling of Compressed Air (filtered through 0.2µ membrane filter) by Liquid impingement method.

4.1.1 Take two 250ml glass bottles.

4.1.2 In one bottle take 100 ml of 0.1% peptone water for bioburden and in another bottle take 100ml-filtered particle free purified water for Liquid borne particle count.

4.1.2 Triple wrap the bottles with butter paper and sterilize them in autoclave.

4.1.3 Sterilize all the required accessories in autoclave.

4.1.4 Transfer the sterilized bottles and accessories to the respective manufacturing areas through pass box.

4.1.5 Enter the manufacturing area, as per the respective entry and exit procedure SOP, where compressed air sampling is to be done.

4.1.6 After reaching on the sampling site open the valve of sampling point and allow the gas to flow through the tube for about one minute.

4.1.7 Carefully open the lid of the bottle and purge compressed gas into each of the two bottles for about 10 minutes.

4.1.8 Close the lid of the bottle and label the bottles respectively.

4.1.9 Cover both the bottles with Aluminium foil and exit from the manufacturing area.

4.1.10 Bring both the samples to the microbiology laboratory and perform the bioburden and Liquid borne particle count test as per the respective test procedures.

4.1.11 Note down the observations and results as per Annexure - I for bioburden and Annexure - II for Liquid borne particle count.

4.2 Sampling of Compressed Air (filtered through 0.2µ membrane filter) by sieve impaction using M Air T Isolator

4.2.1 Perform the sampling of compressed air for bioburden by using M Air T Isolator System, SOP.

4.2.2 Note down the observations and results as per Annexure - I.

4.3 Acceptance criteria

4.3.1 For Bioburden Test - Nil CFU/CUM/10 minute

4.3.2 For Liquid borne particle test –

- For 10 µ particle - Not more than 10 particle.
- For 25 µ particle - Not more than 2 particle.

5.0 SAFETY & PRECAUTIONS

5.1 Sampling of compressed air is to be carried out aseptically.

5.2 All the accessories use for sampling of sterile compressed air should be autoclaved.

6.0 REVISION HISTORY

Revision No.	Reason for Revision	Superseded from & date
00	First Issue	--------

7.0 REFERENCES

SOP

8.0 ABBREVIATIONS

SOP : Standard Operating Procedure

µ : Micron

mL : Milliliter

°C : Degree Centigrade

9.0 ANNEXURES

Annexure - I : Bioburden test report of compressed air

Annexure - II : Liquid borne particle test report of compressed air

ANNEXURE - I
BIOBURDEN TEST REPORT OF COMPRESSED AIR

Date of Monitoring:_____ Date of Report: _____

Media used: _____ Sterilized medium lot No: _____

Equipment ID: _____

Method Used: Liquid impingement method/ Sieve impaction using M Air T Isolator.

Membrane used: _____ Membrane Lot No: _____

Sampling Done by: _____ Testing Done by: _____

Incubation conditions: 30 - 35°C for 48hrs followed by 20 - 25°C for next 72hrs.

S.No.	Sampling Location	Observation		Checked by
		CFU / CUM/10minute	Done by	

Remarks: The samples Complies / Does not complies with the laid down specifications.

ANNEXURE - II

LIQUID BORNE PARTICLE TEST REPORT OF COMPRESSED AIR

Date of Monitoring:_____ **Date of Report:** _____

Sampling Done by: _____ **Testing Done by:** _____

Equipment ID: _____

S.No.	Sample location	Observation			Checked by
		No. of Particle of size 10µ	No. of Particle of size 25µ	Done by	

Remarks: The samples Complies / Does not complies with the laid down specifications.