PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling and Sterility testing of Nitrogen Gas & Compressed Air	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure forSampling and Sterility Testing of Nitrogen Gas & Compressed Air.

2.0 SCOPE:

This SOP is applicable for Sampling and Sterility Testing of Nitrogen Gas & Compressed Air by Membrane Filtration Methodin Microbiological Laboratory of Quality Control Area.

3.0 RESPONSIBILITY:

Officer / Executive - Microbiologist

4.0 ACCOUNTABILITY:

Head – QC

5.0 PROCEDURE:

5.1 Take a 500 ml Suction Flask containing 200 ml of 0.9 % Normal Saline Solution and cover it with rubber plug with one hole from which a silicon pipe is attached. Attach one vent filter 0.2 µ connected with silicon tube to the beak of solution flask.

5.2 Put a Cotton Plug in the other end of Silicon Pipe that is sample receiving part and wrap Membrane Filter to Suction Tube of Vacuum Flask and then with Aluminum Foil.

5.3 Sterilize the Filtration Assembly, Membrane Filter of Pore Size 0.45µm, Forceps and Sampling Flask as per SOP, Titled **"Operation & Cleaning of Double Door Steam Sterilizer"**.

5.4 For collection of sample remove the Cotton Plug from the one end of Silicon Pipe and connect to the user point and allow the purging Nitrogen Gas or Compressed Airfor 10 min in 0.9 % Normal Saline Solution at optimum pressure.

5.5 After collection disconnect the pipe from the user point and transfer to Microbiology Lab for analysis. The samples should be taken by appropriate precautions to avoid contamination.

5.6 Operate the LAF as per SOP, Titled **"Procedure for Cleaning and Operation of Laminar Air Flow unit"**and transfer the filtration assembly, sample and other required materials to LAF room.

5.7 Dissemble the filtration assembly and wet the membrane filter with approx. 10 ml of 0.9 % Normal Saline Solution and filter the sample, after filtration wash the membrane filter with 100 ml of 0.1% peptone water.

5.8 After complete filtration process lift the assembly carefully and cut the membrane filter into two halves and transfer the membrane filter, one half to pre sterilized SCM tube and incubate at 22.5^0 $\pm 2.5^0$C for 14 days and other half to pre sterilized FTM tube and incubate at 32.5^0 $\pm 2.5^0$C for 14 days.

5.9 Wash the separate membrane filter with 100 ml of 0.1% of peptone water and cut the filter into two halves, transfer one half to SCM tube and other half to FTM tube. Incubate the tubes at above temperature and period. This serves as negative control.

5.10 Record the Nitrogen gas samples receiving details in **Annexure-I**, Titled **"Nitrogen GasSample Receiving Log"**.

5.11 Record the results of Nitrogen gas in **Annexure-II**, Titled**"Sterility Test Report of Nitrogen Gas"**.

5.12 **Frequency for Nitrogen Gas Sampling:** Once in a month all points Covered As per **Annexure-III**, Titled **"Sampling Schedule of Nitrogen Gas"**.

5.13 Record the Compressed Air samples receiving details in **Annexure-IV**, Titled **"Compressed Air Sample Receiving Log"**.

5.14 Record the results in **Annexure-V**, Titled **"Sterility Test Report of Compressed Air"**.

5.15 **Frequency for Compressed Air Sampling:** During Media fill Study.

5.16 **ACCEPTANCE CRITERIA:**

5.16.1 During the incubation period observe the medium for growth by means of turbidity. If noevidence of growth is found, sample being examined passes the test for sterility.

5.16.2 If evidence of Microbial Growth is found Investigate the cause of Failure as follows:

5.16.2.1 Check the Membrane Filter which is connected to Filtration Line and Sampling Procedure for collecting the sample.

5.16.2.2 Observe the Negative Control Tube for Growth by means of Turbidity.

5.16.3 If the above parameters are found to comply then sample being examined doesn't passes the test for sterility.

6.0 **REFERENCES:**

Not Applicable

7.0 **ANNEXURES:**

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Nitrogen Gas Sample Receiving Log	
Annexure-II	Sterility Test Report of Nitrogen Gas	
Annexure-III	Sampling Schedule of Nitrogen Gas	
Annexure-IV	Compressed Air Sample Receiving Log	
Annexure-V	Sterility Test Report of Compressed Air	

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ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

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

9.0 ABBREVIATIONS:

FTM	Fluid Thioglycollate Medium
LAF	Laminar Air Flow
Ltd.	Limited
No.	Number
QA	Quality Assurance
QC	Quality Control
SCM	Soyabean Casein Digest Medium
SOP	Standard Operating Procedure

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Details of Changes	Reason for Change	Effective Date	Updated By
00	New SOP	Nil		

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ANNEXURE-I
NITROGEN GAS SAMPLE RECEIVING LOG

Date of Sampling:

S.No.	Sampling Point No.	Details of Sampling Point	Sampled By (Sign & Date)	A.R. No	Tested By (Sign & Date).	Checked By (Sign & Date)	Remarks

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ANNEXURE – II

STERILITY TEST REPORT OF NITROGEN GAS

Sampling Point ID No.		**Report No.**	
Sampling Location		**Testing Shift**	
Date of Sampling		**Date of Testing**	
Date of Release		**Tested By**	

MEDIA CONTROL

Medium Used	**Fluid Thioglycollate Medium (FTM)**	**Soyabean Casein Digest Medium (SCM)**
Autoclave Media Ref. No.		
Incubation Temperature		
Incubator ID No.		
GPT Report No.		

OBSERVATIONS:

Date	**Fluid Thioglycollate Medium**			**Soyabean Casein Digest Medium**			**Observed By (Sign & Date)**	**Checked By (Sign & Date)**
	Sample	**Negative Control**		**Sample**	**Negative Control**			
		Test	**Media**		**Test**	**Media**		

+ ve= Growth observed –ve = No Growth observed

Remarks: The Sterility test complies / does not comply as per specification.

Microbiologist:
Sign &Date

Reviewed By:
Sign &Date

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ANNEXURE III
SAMPLING SCHEDULE OF NITROGEN GAS

S.No.	Area	Location	Sampling Point No.	Frequency
1	**Three Piece Line**	Manufacturing room -1		**All Points Covered once in a Month**
2		Manufacturing room -2		
3		Filtration room-1		
4		Filtration room-2		
5		Filling Room		
6		Disinfectant Preparation Room		
7	**Dry Powder Line**	Filling Room		
8	**Ampoule Line**	Manufacturing		
9		Filtration		
10		Ampoule filling room		
11		Disinfectant preparation		

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ANNEXURE-IV
COMPRESSED AIR SAMPLE RECEIVING LOG

Date of Sampling:

S.No.	Sampling Point No.	Details of Sampling Point	Sampled By (Sign & Date)	Tested By (Sign & Date)	A.R. No.	Checked By (Sign & Date)	Remarks

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ANNEXURE – V

STERILITY TEST REPORT OF COMPRESSED AIR

Sampling Point ID No.		**Report No.**	
Sampling Location		**Testing Shift**	
Date of Sampling		**Date of Testing**	
Date of Release		**Tested By**	

MEDIA CONTROL

Medium Used	Fluid Thioglycollate Medium (FTM)	Soyabean Casein Digest Medium (SCM)
Autoclave Media Ref. No.		
Incubation Temperature		
Incubator ID No.		
GPT Report No.		

OBSERVATIONS:

Date	Fluid Thioglycollate Medium			Soyabean Casein Digest Medium			Observed By (Sign & Date)	Checked By (Sign & Date)
	Sample	Negative Control		Sample	Negative Control			
		Test	Media		Test	Media		

+ve = Growth observed –ve = No Growth observed

Remarks: The Sterility test complies / does not comply as per specification.

Microbiologist:
Sign &Date

Reviewed By:
Sign &Date