PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Microbiological Monitoring of Compressed Air	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a procedure for Microbiological Monitoring of Compressed Air.

2.0 SCOPE:

This SOP is applicable for Microbiological Monitoring of Compressed Air being used in manufacturing of product by Microbiology Section of Quality Control Area.

3.0 RESPONSIBILITY:

Officer / Executive – Microbiologist

4.0 ACCOUNTABILITY:

Head – QC

5.0 PROCEDURE:

5.1 Sterilize the component or accessories of compressed air sampler i.e. Stainless Steel conical head, two way air inlet connection (push-pull connector), Air inlet valve connection (tubing) for Air Flow Adjustment, Air Inlet Valve connection (tubing) for microbiological air analysis and stop watch.

5.2 Transfer all of the sterilized material to the production area, take a SS container of the desired size and sanitize its outer and inner surface with (0.2µ) filtered 70 % v/v of IPA.

5.3 Put all the required material for intended purpose and pre – incubated SCA media plates into the previously sanitized SS container, and transfer the loaded container into the desired production area.

5.4 All the above material required for sampling of Compressed air shall be shifted at the sampling points from the production area, and assembly of compressed air component.

5.5 Connect the unit to the desired point of sampling using suitable tubing. The inlet gas valve should be in a closed position.

5.6 Insert Petri dish with sterile medium in the housing and screw it to the conical head.

5.7 Open the line of compressed air. Adjust the air flow on the flow meter to 100 LPM (liters per minute) and pressure of 2 Bar or 2 kg/cm² supplied to wash the line.

5.8 Close the inlet.

5.9 Connect the regulated supply to compressed air sampler head through push-pull connector.

5.10 Open the inlet valve and start countdown of sampling for 10 minute.

5.11 Close the gas valve after 10 minutes for 100 LPM (1000 liters of air is collected).

5.12 Unscrew the head, remove the Petri dish, close the lid of the Petri dish and transfer it to the microbiology laboratory for incubation.

5.13 The Agar medium in the Petri dish should have impaction of holes.

5.14 Repeat the point 5.5 to 5.10 every time when new sample is taken.

5.15 Incubate the plate at 20-25 ^{0}C for 72 hours then transfer at 30-35 ^{0}C for 48 hours.

5.16 After completion of incubation, count the microbial colonies of each plate and report the results as CFU/1000 liters of Compressed air.

5.17 Acceptance Criteria:

For Compressed Air

Class	Alert Limit Cfu/ 1000 liters	Action Limit Cfu/1000 liters
100	‹ 1	‹ 1
1,000	‹ 06	‹08
10,000	‹ 60	‹ 80
100,000	‹120	‹ 160

5.18 FREQUENCY: Six monthly in Oral Dosage and Fortnightly in Parenteral.

5.19 CORRECTIVE AND PREVENTIVE ACTION:

S.No.	Observation (Alert Level)	Corrective Action
1.	If alert level is exceeded	Check the status of Vent filter installed and its installation date
2.	Repeatedly in the same area. For the three consecutive day.	Change the vent filter.
3.	Consecutively in the same area along with other area.	Stop the working and Install the new presterilised vent filter in the line.

6.0 REFERENCES:
Not Applicable

7.0 ANNEXURES:

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ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure – I	Compressed Air Sampling Log Book	
Annexure – II	Sampling Schedule of Compressed Air	
Annexure – III	Microbiological Monitoring Report of Compressed Air	

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:

QA	Quality Assurance
QC	Quality Control
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			

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ANNEXURE-I
COMPRESSED AIR SAMPLING LOG BOOK

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-II
SAMPLING SCHEDULE OF COMPRESSED AIR

Location	Sampling Point Details	Sampling Point	Frequency											
			Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sep	Oct	Nov	Dec
Granulation-01	RMG		**8**						**8**					
Granulation-05	Roll Compactor		**8**						**8**					
Granulation-06	RMG		**8**						**8**					
Coating-01	Coating-01		**8**						**8**					
Capsule Filling-01	Capsule Filling-01			**8**						**8**				
Soft Gel Section (Encapsulation-1)	Soft Gel Section (Encapsulation-1)				**8**						**8**			
Soft Gel Section (Medicament Preparation)	Soft Gel Section (Medicament Preparation)				**8**						**8**			
Soft Gel Section (Gelatin Preparation)	Soft Gel Section (Gelatin Preparation)				**8**						**8**			
Soft Gel Section (Equipment Washing)	Soft Gel Section (Equipment Washing)				**8**						**8**			
Soft gel section capsule polishing	Soft gel section capsule polishing				**8**						**8**			
Packing Line 01 (BLM)	Packing Line 01 (BLM)				**8**						**8**			
RM Liquid	RM Liquid							**8**						**8**
QC Department	QC Department							**8**						**8**

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Location	Sampling Point Details	Sampling Point	Frequency														
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
			16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Dry Powder	Vial Filling Area		√														
Dry Powder	Vial Washing & Sterilization Room			√													
Dry Powder	Autoclave cum bung processor				√												
Dry Powder	Equipment Washing room					√											
Dry Powder	Disinfectant Preparation room						√										
Dry Powder	Janitor room							√									
Dry Powder	Filter Cleaning room								√								
Three Piece	Garment wash & Preparation									√							
Three Piece	CIP/SIP										√						
Three Piece	Manufacturing - 1											√					
Three Piece	Filtration -01													√			
Three Piece	Unit preparation & sterilization															√	
Three Piece	Filling room																√
Three Piece	Equipment wash		√														
Ampoule line	Ampoule line (Garment Wash)			√													
Ampoule line	Ampoule line (CIP & SIP)				√												
Ampoule line	Ampoule line (Manufacturing)					√											
Ampoule line	Ampoule line (Filtration)						√										
Ampoule line	Ampoule line (Unit							√									

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	Preparation & Sterilization)																
Ampoule line	Ampoule line (Ampoule filling room)								√								
Ampoule line	Ampoule line (Equipment wash)									√							
Ampoule line	Ampoule line (Ampoule washing & Sterilization Area)										√						
Ampoule line	Ampoule line (Leak Test & Terminal Sterilization)											√					

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ANNEXURE-III
MICROBIOLOGICAL MONITORING REPORT OF COMPRESSED AIR

Date of Sampling						
Point No.						
Sampled By						
Sample Volume		**Date of Sampling**				
Media Used	Soybean casein digest agar	**Date of Observation:**				
Incubator ID No.		**Autoclave Media Ref. No.**				

OBSERVATION TABLE:

Area	Location	Observation	Observation	Total Microbial Count	Remark Complies Yes/No
		Incubation at $20^0 – 25^0$C for 72 hrs.	Incubation at $30^0 – 35^0$C for 48 hrs.		

LIMITS: Total Aerobic Microbial Count `

Grade	Alert Limits (cfu/1000 Liters)	Action Limits (cfu/1000 Liters)	Limits (cfu/1000 Liters)
Grade A	**<1**	**<1**	**<1**
Grade B	**06**	**08**	**10**
Grade C	**60**	**80**	**100**
Grade D	**120**	**160**	**200**

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Done By
Date

Checked By
Date