



Name of the Department: Microbiology

Sample Size: Trend Monitoring for last three months period. (If any discrepancy observes than the review shall be extend to more 3 months data from previous period)

# Details of Record under review along with the established procedure:

Month:

	.No. Description of Compressed Air				Review Details		
	testing No. of Selected day: No. of Selected date		Day 1	Day 2	Day 3	Day 4	Day 5
1.	Name of Sample						
2.	<b>Pressure During san</b>	npling					
	Lot no. of Sodium c medium	asein Digest agar					
4.	Date of Sampling						
5.	Analytical report N	).					
	Incubator ID						
7.	Activity start on						
8.	<b>Activity Completed</b>	on					
9.	<b>Activity done By</b>						
10	Sampling details						
	A. a) Sampling F	oint					
	b) Sampling I	ocation					
	c) Sampling t	ime From					
		То					
	d) Sampling I	one By					
	e) Total Fung Count (cfu/m³)		Should be absent				
		Results	Nil	Nil	Nil	Nil	Nil
	f) Total bacte Count (cfu/m³)	_	NMT 100 cfu/m <sup>3</sup>				
		Results					
	B. a) Sampling F	oint					
	b) Sampling Location						
	c) Sampling t	ime From					
		То					
	d) Sampling I	one By					
	e) Total Fung Count (cfu/m3		Should be absent				





Description of Compressed Air testing No. of Selected day: No. of Selected date:		ed Air	Review Details					
		<b>→</b>	Day 1	Day 2	Day 3	Day 4	Day 5	
		Results	Nil	Nil	Nil	Nil	Nil	
	f) Total bacterial Count (cfu/m3)	Acceptance criteria	NMT 100 cfu/m <sup>3</sup>					
		Results						
C.	a) Sampling Point							
	b) Sampling Locati	ion						
	c) Sampling time	From						
		То						
	d) Sampling Done l	Ву						
	e) Total Fungal Count (cfu/m3)	Acceptance criteria	Should be absent					
		Results	Nil	Nil	Nil	Nil	Nil	
	f) Total bacterial Count (cfu/m3)	Acceptance criteria	NMT 100 cfu/m <sup>3</sup>					
		Results						
D.	a) Sampling Point							
	b) Sampling Location							
	c) Sampling time	From						
		То						
	d) Sampling Done l	Ву						
	e) Total Fungal Count (cfu/m3)	Acceptance criteria	Should be absent					
		Results	Nil	Nil	Nil	Nil	Nil	
	f) Total bacterial Count (cfu/m3)	Acceptance criteria	NMT 100 cfu/m <sup>3</sup>					
<b>E.</b>		Results						
	a) Sampling Point							
	b) Sampling Locati	ion						
	c) Sampling time							
		То						
	d) Sampling Done l	Bv						





o. Description of Compressed Air		ed Air	Review Details					
No.	ting . of Selected day: — . of Selected date: —	<b></b>	Day 1	Day 2	Day 3	Day 4	Day 5	
e)	e) Total Fungal Count (cfu/m3)	Acceptance criteria	Should be absent					
		Results	Nil	Nil	Nil	Nil	Nil	
	f) Total bacterial Count (cfu/m3)	Acceptance criteria	NMT 100 cfu/m <sup>3</sup>					
		Results						
F.	a) Sampling Point							
	b) Sampling Locati	on						
	c) Sampling time	From						
		То						
	d) Sampling Done	Ву						
	e) Total Fungal Count (cfu/m3)	Acceptance criteria	Should be absent					
		Results	Nil	Nil	Nil	Nil	Nil	
	f) Total bacterial Count (cfu/m3)	Acceptance criteria	NMT 100 cfu/m <sup>3</sup>					
		Results						
G.	a) Sampling Point							
	b) Sampling Locati	on						
	c) Sampling time	From						
		То						
	d) Sampling Done	Ву						
	e) Total Fungal Count (cfu/m3)	Acceptance criteria	Should be absent					
		Results	Nil	Nil	Nil	Nil	Nil	
	f) Total bacterial Count (cfu/m3)	Acceptance criteria	NMT 100 cfu/m <sup>3</sup>					
		Results						
Н.	a) Sampling Point							
	b) Sampling Locati	on						
	c) Sampling time	From						
		To						





Description of Compressed		ed Air			Review Details		
No	sting o. of Selected day: – o. of Selected date: –	<b>→</b>	Day 1	Day 2	Day 3	Day 4	Day 5
	d) Sampling Done	Ву					
e) Total Fungal Count (cfu/m3)	Acceptance criteria	Should be absent	Should be absent	Should be absent	Should be absent	Should be absent	
		Results	Nil	Nil	Nil	Nil	Nil
	f) Total bacterial Count (cfu/m³)	Acceptance criteria	NMT 100 cfu/m <sup>3</sup>				
		Results					
I.	a) Sampling Point						
	b) Sampling Locati	on					
	c) Sampling time	From					
		То					
	d) Sampling Done	Ву					
	e) Total Fungal Count (cfu/m³)	Acceptance criteria	Should be absent				
		Results	Nil	Nil	Nil	Nil	Nil
	f) Total bacterial Count (cfu/m³)	Acceptance criteria	NMT 100 cfu/m <sup>3</sup>				
		Results					
J.	a) Sampling Point						
	b) Sampling Locati	on					
	c) Sampling time	From					
		То					
	d) Sampling Done	By					
	e) Total Fungal Count (cfu/m³)	Acceptance criteria	Should be absent				
		Results	Nil	Nil	Nil	Nil	Nil
	f) Total bacterial Count (cfu/m³)	Acceptance criteria	NMT 100 cfu/m <sup>3</sup>				
		Results					
K.	a) Sampling Point						
	b) Sampling Locati	on					
	c) Sampling time	From					





No. Description of Compressed Air testing		ed Air	Review Details				
No	ting  o. of Selected day: —  o. of Selected date: —	<b>→</b>	Day 1	Day 2	Day 3	Day 4	Day 5
		To					
	d) Sampling Done	Ву					
	e) Total Fungal Count (cfu/m³)	Acceptance criteria	Should be absent				
		Results	Nil	Nil	Nil	Nil	Nil
	f) Total bacterial Count (cfu/m³)	Acceptance criteria	NMT 100 cfu/m <sup>3</sup>				
		Results					
L.	a) Sampling Point						
	b) Sampling Locati	on					
	c) Sampling time	From					
		To					
	d) Sampling Done By						
	e) Total Fungal Count (cfu/m³)	Acceptance criteria	Should be absent				
		Results	Nil	Nil	Nil	Nil	Nil
	f) Total bacterial Count (cfu/m³)	Acceptance criteria	NMT 100 cfu/m <sup>3</sup>				
		Results					
M	a) Sampling Point						
	b) Sampling Location						
	c) Sampling time	From					
		To					
	d) Sampling Done	Ву					
	e) Total Fungal Count (cfu/m³)	Acceptance criteria	Should be absent				
		Results	Nil	Nil	Nil	Nil	Nil
	f) Total bacterial Count (cfu/m³)	Acceptance criteria	NMT 100 cfu/m <sup>3</sup>				
		Results					
An	nalyzed By:						
Da	ite						





S.No.	Description of Compressed Air	Review Details					
	No. of Selected day:  No. of Selected date:	Day 1	Day 2	Day 3	Day 4	Day 5	
12.	Checked By:						
12.	Date						
13.	Approved By:						
13.	Date						

Review of Attendance data of the person signing the Specific record:

Particular involved in activity	Day 1	Day 2	Day 3	Day 4	Day 5
Name	Present	Present	Present	Present	Present
Name	Present	Present	Present	Present	Present
Name	Present	Present	Present	Present	Present
Name	Present	Present	Present	Present	Present

Review of the training records of the persons involved in particular activity.

Topic	Document no.	Name	Name	Name	Name
Preparation, evaluation, storage, use and disposal of cultural media	-	Trained	Trained	Trained	Trained
Operation, cleaning and performance of horizontal laminar air flow bench	-	Trained	Trained	Trained	Trained
Preparation, storage and use of standardized stable suspensions of test strains of micro-organisms.	-	Trained	Trained	Trained	Trained
Indenting, Receipt and Approval of dehydrated culture media	-	Trained	Trained	Trained	Trained
Operation & cleaning of vertical steam sterilizer used for media sterilization in microbiology section.	-	Trained	Trained	Trained	Trained
Operation, monitoring and cleaning of bacteriological incubators.	-	Trained	Trained	Trained	Trained
Operation and calibration of PH meter	-	Trained	Trained	Trained	Trained
Operation, Cleaning, Verification and Calibration of Analytical Weighing Balance.	-	Trained	Trained	Trained	Trained





		Compressed Air Trend Verification	
3.0 Do	cumentation of any discrepancies identifie	d during verification along with action taken:	
3.1	Details of discrepancy identified		
Quality	Assurance	<b>Quality Control</b>	
(Signatu	ure/Date):	(Signature/Date):	
3.2	Impact assessment		
Quality	Assurance(Signature/Date):		
3.3	Corrective Action taken		
<b>5</b>			
Date of	completion of actions outlined:		
Quality	Assurance	Quality Control	
(Signati	ure/Date):	(Signature/Date):	
4.0			
4.0	<b>Evaluation and Conclusion:</b>		
Quality	Assurance	Quality Control	
(Signati	ure/Date):	(Signature/Date):	