

#### MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE		
Department: Microbiology	SOP No.:	
Title: Environmental Monitoring of Non-Sterile Manufacturing Facility	Effective Date:	
Supersedes: Nil	Review Date:	
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#### 1.0 OBJECTIVE:

To lay down a procedure for Microbiological Environment Monitoring of Air by Settle Plate and Active Air Sampler Method.

#### 2.0 SCOPE:

This SOP is applicable for Microbiological Environment Monitoring of Air by Settle Plate and Active Air Sampler Method.

#### 3.0 RESPONSIBILITY:

Officer / Executive – Microbiology

#### 4.0 ACCOUNTABILITY:

Head - QC

#### **5.0 ABBREVIATIONS:**

Ltd. Limited

ML Microbiology Laboratory

No. Number

QA Quality Assurance QC Quality Control

SOP Standard Operating Procedure SCA Soyabean Casein Digest Agar

% Percentage μ Micron

IPA Isopropyl Alcohol
TFC Total fungal count
TBC Total bacterial count
TMC Total microbial count

NA Not applicable

CFU Colony forming unit

SS Stainless Steel

### **6.0 PROCEDURE:**

**6.1** After pre-incubation, label SCA plates under LAF as per given below Pattern.

#### L/M/PC/DD/MM/OS/G

L - Location

Method of monitoring such as **SP** for settle plate, **AS** for air sampling.

SN - Sr. No. of plates exposed

**DD** - Date



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MM - Month

OS Operating Shift A or B,C

**G** - Grade

For example:-GR/SP/AL-01/27/11/A/D

**GR** - Granulation area

**SP** - Settle plate

**AL-01** - Plate Code of exposed plates

27 - Date
 11 - Month
 A - Shift
 D - Grade

- **6.2** Sanitize the surface of aluminum foil with 0.22μ filtered 70% IPA and makes the set of plates and wrap in aluminum foil.
- **6.3** Put the set of plates in cleaned SS container sanitized with 0.22µfiltered70% IPA.
- 6.4 Transfer the S.S. container to the respective area. Ensure that container should not open during transit from Microbiology lab to Manufacturing area and Manufacturing area to Microbiology lab.
- **6.5** Place the containers having materials into pass box of respective area. Enter into the concern area through change room.
- 6.6 Environmental monitoring of area by settle plate method (passive air sampling):
  - **6.6.1** Transfer the media plates inside the respective area bypass box.
  - **6.6.2** Expose the SCA plates at each specified location as per annexure by opening the upper lid of the petri plate for 4 hours and write the start time on the first plate and end time on last plate.
  - 6.6.3 After completion of exposure time; close the lid of plate in the same sequence used for plate exposer and write the start time on the first plate and end time on the last plate and collect all exposed plates and wrap with aluminum foil. Place the plates in SS container and transfer the plates to microbiology lab for incubation and ensure that container should not open during transit and same time shall be transcribed on report.
  - **6.6.4** Incubate all the plates first at 20 to 25 °C for NLT 72 hours in inverted position.
  - **6.6.5** After completion of 72 hour at 20 to 25°C; transfer the plates at 30 to 35°C for NLT 48 hours in inverted position.
  - **6.6.6** For negative control incubate SCA plate as it is without exposer.
  - **6.6.7** Generally the height of Passive air sampling should not be not more than 1 feet below the working height and Plates should never be exposed directly on the floor.

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- **6.6.8** After the completion of the incubation period, count the CFU obtained on each Petri plate with the help of colony counter from both side of plates and record the results in respective format.
- 6.6.9 Note: If a holiday is there on the day of completion of incubation/transfer, the plates shall be observed/transfer on the next working day.
- 6.7 Environmental Monitoring of Air by Air Samplers (Active Air Sampling):
  - **6.7.1** Sanitize the air sampler with lint free cloth previously wetted with 0.22 µ filtered 70% IPA.
  - 6.7.2 Transfer the air sampler in to concern area pass box and again sanitize with lint free cloth previously wetted with 0.22µfiltered 70% IPA.
  - **6.7.3** At the location of air sampling; remove the Barrier paper or butter paper of perforated sieve, write the start time on first plate and keep the SCA plate after opening the top lid in air sampler head and set it with perforated sieve of air sampler over the SCA plate. Vertically put the air sampler at the location and carry out the air sampling of 1000 Liter.
  - **6.7.4** After air sampling, remove the plate (in the same area where it is sampled) from air sampler, close the lid immediately and Immediately clean the head cone of air sampler with lint free cloth previously wetted with filtered 70% IPA and carry out the air sampling for other specified locations and write the end time on the last plate.
  - **6.7.5** After air sampling; collect all the plates and wrap with aluminum foil. Place the plates in SS container and transfer the plates to microbiology lab for incubation and same time shall be transcribed on report.
  - **6.7.6** Incubate all the plates first at 20 to 25 °C for NLT 72 hours in inverted position.
  - **6.7.7** After completion of 72 hours at 20 to 25°C; transfer the plates at 30 to 35°C for NLT 48 hours in inverted position.
  - **6.7.8** For negative control; incubate SCA plate as it is without sampling.
  - 6.7.9 After the completion of the incubation period, count the CFU obtained on each Petri plate with the help of colony counter from both sides of plates and record the results in respective format and feller correction shall be applied as per defined in format, Titled "MPN conversion table for SAS air samplers" and format, Titled "MPN conversion table for hi air flow airsamplers (Himedia)".
  - 6.7.10 Note: If a holiday is there on the day of completion of incubation/transfer, the plates shall be observed/transfer on the next working day.
- 6.8 Acceptance Criteria for Total Aerobic Microbial Count:
  - 6.8.1 Settle plate (Diameter 90mm) (cfu/4hours)

Grade	Alert Level	Action Level	Limits



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Grade C	30 cfu	40 cfu	50 cfu
Grade D	60 cfu	80 cfu	100 cfu

### 6.8.2 Active Air Sampler (cfu/ meter<sup>3</sup> or 1000 liter of air)

Grade	Alert Level	Action Level	Limits
Grade C	60 cfu	80 cfu	100 cfu
Grade D	120 cfu	160 cfu	200 cfu

### **6.9** Frequency of Environmental Monitoring:

**6.9.1** Environmental monitoring shall be done as per given table:

Air Monitoring By	Air Monitoring By
Settle Plate	Active Air Sampler
Once in two month	Once in two month

Note: Environment Monitoring performed as per annexure-XXXXVII, Title: - "Environment monitoring schedule for settle plates & active air sampling".

#### 7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Environment Monitoring Report of Granulation by Settle Plate	
Annexure-IV	Environment Monitoring Report of Compression by Settle Plate	
Annexure-V	Environment Monitoring Report of Coating by Settle Plate	
Annexure-VII	Environment Monitoring Report Of Capsule Filling and Capsule Quarantine area by Settle Plate	
Annexure-VIII	Environment Monitoring Report of soft gelatin capsule area of General Block By Settle Plate	
Annexure-IX	Environmental Monitoring report for Qualification	
Annexure-X	Environment Monitoring Report of Packing area line by Settle Plate	
Annexure-XIV	Environment Monitoring Report of active air sampling For Qualification	
Annexure-XV	Environment Monitoring Log Book	
Annexure-XVI	Environment Monitoring Report of Granulation by Air Sampler	
Annexure-XIX	Environment Monitoring Report of Compression by Air Sampler	



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ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-XX	Environment Monitoring Report of Coating by Air Sampler	
Annexure-XXII	Environment Monitoring Report of capsule filling area of General Block by Air Sampler	
Annexure-XXIII	Environment Monitoring Report of soft gelatin capsule area of General Block by Air Sampler	
Annexure-XXIV	Environment Monitoring Report of Packing area line by air sampler	
Annexure-XXV	Environment Monitoring Report of Packing area line by air sampler	
Annexure-XXVI	Environment Monitoring Report of dispensing area General Block by air sampler	
Annexure-XXVII	Environment Monitoring Report of sampling area General Block by air sampler	
Annexure-XXVIII	Environmental Monitoring Report of Manufacturing area by Settle Plate and Air Sampling	
Annexure-XXX	Environmental Monitoring Report of Raw Material Store of Ointment Area by Settle Plate and Air Sampling	
Annexure-XXXI	Environment Monitoring Report of Granulation by settle plate	
Annexure-XXXII	Environment Monitoring Report of Compression by settle plate	
Annexure-XXXIII	Environment Monitoring Report of Granulation by Air Sampler	
Annexure-XXXIV	Environment Monitoring Report of Compression Air Sampler	
Annexure-XXXV	Environment Monitoring Report of Coating area and Hot Tray Dryer Room of General Block by settle plate	
Annexure-XXXVI	Environment Monitoring Report of Coating area by Air Sampler	
Annexure-XXXVII	Environment Monitoring Report of packing area by settle plate	
Annexure-XXXVIII	Environment Monitoring Report of packing area by air sampler	
Annexure-XXXIX	Environment Monitoring Report of granulation by settle plate	
Annexure-XXXX	Environment Monitoring Report of Compression by settle plate	
Annexure-XXXXI	Environment Monitoring Report of Compression by settle plate	



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ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-XXXXII	Environment Monitoring Report of Liquid Line in Q-Block by settle plate	
Annexure-XXXXIII	Environment Monitoring Report of Liquid Line in Q-Block by Air Sampler	
Annexure-XXXXIV	Environment Monitoring Report of Compression by Air Sampler	
Annexure-XXXXV	Environment Monitoring Report of Compression by settle plate	
Annexure-XXXXVI	Environment Monitoring Report of Compression by Air Sampler Method	
Annexure-XXXXVII	Environment Monitoring Schedule for Settle plates &Active air sampling	

**ENCLOSURES:** SOP Training Record

### 8.0 DISTRIBUTION:

Controlled Copy No. 01
 Controlled Copy No. 02
 Master Copy
 Quality Assurance
 Microbiology
 Quality Assurance

### 9.0 REFERENCES:

**EU-GMP** 

#### 10.0 REVISION HISTORY:

#### **CHANGE HISTORY LOG**

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By



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## ANNEXURE-I ENVIRONMENT MONITORING REPORT OF GRANULATION BY SETTLE PLATE

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle Plate	Soyabean Casein Digest Agar	Plate Exposure Time:	
Autoclave Media Ref. No	SCA/	Plate Collection Time	
1st Incubation Temp & Time.	20 – 25°C for NLT 72 hrs.	2 <sup>nd</sup> Incubation Temp & Time	30 – 35°C for NLT 48 hrs.
Incubator ID No.		Incubator ID No.	

S. No.	Area	Location	Plate Code	Gra de	ТВС	TFC	Total Microbial Count
1.	Men Entry			D			
2.	Material Entry			D			
3.	Equipment Drying			D			
4.	Paste Preparation Room			D			

#### LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	60 cfu/Plate	80 cfu/Plate	100 cfu/Plate

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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# ANNEXURE-II ENVIRONMENT MONITORING REPORT OF GRANULATION OF GENERAL BLOCK BY SETTLE PLATE

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle Plate	Soyabean Casein Digest Agar	Plate Exposure Time:	
Autoclave Media Ref. No	SCA/	Plate Collection Time:	
1st Incubation Temp & Time	20 – 25°CforNLT72 hrs.	2 <sup>nd</sup> Incubation Temp & Time	30 – 35°C for NLT48 hrs.
Incubator ID No.		Incubator ID No.	

S.No.	Area	Location	Plate Code	Grade	TFC	TBC	Total Microbial Count
1.	Man Entry			D			
2.	Buffer Room			D			
3.	Material Entry			D			
4.	Paste Preparation Room			D			
				D			
_	Granulation			D			
5.				D			
				D			

LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	60 cfu	80 cfu	100 cfu

<sup>-</sup>ve control .....

Observed By:	Reviewed By:
Date:	Date:



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sedes: Nil			Re	eview D	ate:	
Date:			Pa	ge No.:		
VIRONMENT MONITO	ORING REPORT OF	GRANULATIO	ON OF (	GENEI	RAL BLO	СК ВҮ
f Sampling		Date of Observ	ation			
ed By		Area Status			Static / Dy	namic
<b>Used For Settle Plate</b>	Soyabean Casein Digest Agar	Plate Exposure	Time:			
ave Media Ref. No	SCA/	Plate Collection	n Time			
ubation Temp & Time.	20 – 25°CforNLT72 hrs.	2 <sup>nd</sup> Incubation	Гетр &	Time.	30 – 35°C for NLT48 hrs.	
ntor ID No.		Incubator ID N	0.			
Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count
Man Entry			D			Count
			D			
			D			
Buffer Room			D			
FOR SETTLE PLATE: Tot	tal Aerobic Microbial com	nt				
Grade	Alert Level		evel		Specified	Limits
D	60 cfu	80 0	cfu		100	) cfu
ntrol				l.		
	Environmental Monitorin edes: Nil Date:  TRONMENT MONITO  Sampling ed By Used For Settle Plate ave Media Ref. No abation Temp & Time.  tor ID No.  Area  Man Entry Material Entry Paste Preparation Room Buffer Room  FOR SETTLE PLATE: Tot Grade D	Environmental Monitoring of Non-Sterile Manual edes: Nil  Date:  ANNEX  TRONMENT MONITORING REPORT OF SETTLI  Sampling End By  Used For Settle Plate  Ave Media Ref. No Bation Temp & Time.  Tor ID No.  Area  Location  Man Entry  Material Entry  Paste Preparation Room  Buffer Room  FOR SETTLE PLATE: Total Aerobic Microbial councils  Grade  Alert Level	Environmental Monitoring of Non-Sterile Manufacturing Facility edes: Nil  Date:  ANNEXURE-III  TRONMENT MONITORING REPORT OF GRANULATION SETTLE PLATE  Sampling Ed By Date of Observ Area Status  Used For Settle Plate Digest Agar  Ave Media Ref. No Date Of Observ Digest Agar  Area Status  Plate Exposure Digest Agar  Ave Media Ref. No Digest Agar  Area Location Digest Agar  Location Digest Agar  Plate Collection Digest Agar  Area Location Digest Agar  Plate Collection Digest Agar  Digest Agar  Digest Agar  Digest Agar  Digest Agar  Digest Agar  Plate Collection Digest Agar  Digest Agar	Environmental Monitoring of Non-Sterile Manufacturing Facility  edes: Nil  ANNEXURE-III  TRONMENT MONITORING REPORT OF GRANULATION OF OSETTLE PLATE  Esampling  ed By  Used For Settle Plate  ave Media Ref. No  state SCA/  plate Collection Time  ave Media Ref. No  stor ID No.  Area  Location  Area  Location  Plate  Grade  Man Entry  Material Entry  Paste Preparation Room  Buffer Room  FOR SETTLE PLATE: Total Aerobic Microbial count  Grade  ANNEXURE-III  Ref.  ANNEXURE-III  ANNEXURE-III  Pate of Observation  Area Status  Plate Exposure Time:  Plate Collection Time  2nd Incubation Temp & Tonubation Temp	Environmental Monitoring of Non-Sterile Manufacturing Facility edes: Nil  Review D Page No.:  ANNEXURE-III  TRONMENT MONITORING REPORT OF GRANULATION OF GENER SETTLE PLATE  Sampling Date of Observation Area Status  Used For Settle Plate Digest Agar Ave Media Ref. No SCA/ Plate Exposure Time: Digest Agar Ave Media Ref. No Digest Agar Area Location  Area Location  Man Entry Material Entry Paste Preparation Room Buffer Room  FOR SETTLE PLATE: Total Aerobic Microbial count Grade  ANNEXURE-III  Review D Page No.:  Annex Location Plate of Observation Area Status Plate Exposure Time: Digest Agar Area Location Plate Collection Time Digest Agar Area Location Plate Grade TBC Code Digest Agar Area Location Digest Agar Area Collection Time  Area Digest Agar Area Collection Time  Area Digest Agar Area Status  Plate Exposure Time:  Digest Agar Area Status  Digest Agar  Area Status  Digest Agar  Area Status  Digest Agar  Area Status  Digest Agar  Area Status  Digest Agar  Area Status  Digest Agar  Area Status  Digest Agar  Area Status  Digest Agar  Area Status  Digest Agar  Area Status  Digest Agar  Area Status  Digest Agar  Area Status  Digest Agar  Area Status  Digest Agar  Area Status  Digest Agar  Area Status  Digest Agar  Area Status  Digest Agar  Area Status  Digest Agar  Area Status  Digest Agar  Area Status  Digest Agar  Area Status	Environmental Monitoring of Non-Sterile Manufacturing Facility  edes: Nil Review Date:  Page No.:  ANNEXURE-III  TRONMENT MONITORING REPORT OF GRANULATION OF GENERAL BLOCK SETTLE PLATE  Sampling Date of Observation Area Status Static / Dy  Used For Settle Plate Soyabean Casein Digest Agar  ave Media Ref. No SCA/ Plate Exposure Time:  Incubation Temp & Time.  Area Location Plate Grade TBC TFC  Man Entry Date Plate Code  Man Entry Date Plate Pla



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#### **ANNEXURE-IV**

### ENVIRONMENT MONITORING REPORT OF COMPRESSION BY SETTLE PLATE

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle Plate	Soyabean Casein Digest Agar	Plate Exposure Time:	
Autoclave Media Ref. No	SCA/	Plate Collection Time	
1st Incubation Temp & Time.	20 – 25° C for NLT 72 hrs.	2 <sup>nd</sup> Incubation Temp & Time.	30 – 35°C for NLT 48 hrs.
Incubator ID No.		Incubator ID No.	

S.No.	Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count
1.	Man Entry			D			
2.	Material Entry			D			
3.	Compression			D			
3.	Compression			D			

LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	60 cfu	80 cfu	100 cfu

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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### ANNEXURE-V ENVIRONMENT MONITORING REPORT OF COATING BY SETTLE PLATE

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle Plate	Soyabean Casein Digest Agar	Plate Exposure Time:	
Autoclave Media Ref. No	SCA/	Plate Collection Time	
1st Incubation Temp & Time.	20 – 25° C for NLT 72 hrs.	2 <sup>nd</sup> Incubation Temp & Time.	30 – 35°C for NLT 48 hrs.
Incubator ID No.		Incubator ID No.	

S.No.	Area	Location	Plate Code	Grade	ТВС	TFC	Total Microbial Count
1.	Man Entry			D			
2.	Coating			D			

#### LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	60 cfu	80 cfu	100 cfu

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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### ANNEXURE-VI ENVIRONMENT MONITORING REPORT OF COATING BY SETTLE PLATE

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle Plate	Soyabean Casein Digest Agar	Plate Exposure Time:	
Autoclave Media Ref. No.	SCA/	<b>Plate Collection Time</b>	
1st Incubation Temp & Time	$20 - 25^{0}$ C for NLT 72 hrs.	2 <sup>nd</sup> Incubation Temp & Time	30 – 35°C for NLT 48 hrs.
Incubator ID No.		Incubator ID No.	

S.No.	Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count
1.	Man Entry			D			
				D			
2.	Coating			D			
				D			
3.	Man Entry			D			
4.	Solution Preparation Room			D			

LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits	
D	60 cfu	80 cfu	100 cfu	

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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# ANNEXURE-VII ENVIRONMENT MONITORING REPORT OF CAPSULE FILLING AND CAPSULE QUARENTINE AREA BY SETTLE PLATE

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle Plate	Soyabean Casein	Plate Exposure Time:	
Wedia Osed For Settle Flate	Digest Agar		
Autoclave Media Ref. No	SCA/	Plate Collection Time	
1 <sup>st</sup> Incubation Temp & Time.	$20 - 25^{\circ}$ C for	2 <sup>nd</sup> Incubation Temp & Time.	$30 - 35^{\circ}$ C for NLT 48
1 incubation remp & rime.	NLT 72 hrs.	2 incubation remp & rime.	hrs.
Incubator ID No.		Incubator ID No.	

S.No.	Area	Location	Plate Code	Grade	TFC	TBC	Total Microbial Count
1.	Man Entry			D			
2. Capsule Filling			D				
			D				

### LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	60 cfu	80 cfu	100 cfu

-ve control .....

Observed By:	Reviewed By:
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# ANNEXURE-VIII ENVIRONMENT MONITORING REPORT OF SOFT GELATIN CAPSULE AREA BY SETTLE PLATE

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle Plate	Soyabean Casein Digest Agar	Plate Exposure Time:	
Autoclave Media Ref. No		Plate Collection Time	
1st Incubation Temp & Time.	20 – 25 <sup>0</sup> C for NLT 72 hrs.	2 <sup>nd</sup> Incubation Temp & Time.	30 – 35°C for NLT 48 hrs.
Incubator ID No.		Incubator ID No.	

Incuba	tor ID 110.		incubator ID 11	<b>.</b>			
S.No.	Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count
1.	Man Entry			D			
2.	Capsule Sorting			D			
	1 0			D			
3.	Drying Zone			D			
J.	Drying Zone			D			
	Encapsulation			D			
4.				D			
				D			
5.	Gelatin Preparation			D			
J.	Area			D			
6.	Man Entry			D			
				D			
				D			
7.	Medicament Area			D			
				D			
				D			_
8.	Janitor Room			D			

LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	60 cfu	80 cfu	100 cfu

-ve control .....

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## ANNEXURE-IX ENVIRONMENTAL MONITORING REPORT BY SETTLE PLATE FOR QUALIFICATION

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle Plate	Soybean Casein Digest Agar	Plate Exposure Time:	
Autoclave Media Ref. No	SCA/	Plate Collection Time	
1st Incubation Temp & Time	20 – 25° C for NLT 72 hrs.	2 <sup>nd</sup> Incubation Temp & Time	30 – 35°C forNLT48 hrs.
Incubator ID No.		Incubator ID No.	

S.No.	Area	Location	Plate Code	Grade	ТВС	TFC	Total Microbial Count
1.							
2.							
3.							
4.							
5.							
6.							
7.							

<ul><li>ve control</li></ul>																											
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Rema	rks: The environmental	monitoring result by	Settle Plate	method for abov	e locations	complies /	does not c	omply
as per	prescribed limits.							

Observed By:	Reviewed By:
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ENVIRONMENT MON	ANNEXUI		A LINE BY	SETTLE PLATE
Date of Sampling		Date of Observatio	n	
Sampled By		Area Status	· · · · · · · · · · · · · · · · · · ·	Static / Dynamic
Media Used For Settle Plate	Soybean Casein Digest Agar	Plate Exposure Tir	ne:	
Autoclave Media Ref. No	SCA/	Plate Collection Ti	me	

S.No.	Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count
1.	Man Entry			D			
2	Blister			D			
2.	Diistei			D			

2<sup>nd</sup> Incubation Temp & Time.

**Incubator ID No.** 

 $30 - 35^{\circ}$ C for NLT 48

hrs.

 $20 - 25^{\circ}$  C for NLT 72

hrs.

LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

Grade	Alert Level	Action Level	<b>Specified Limits</b>
D	60 cfu	80 cfu	100 cfu

-ve control
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1st Incubation Temp & Time.

**Incubator ID No.** 

Observed By:	Reviewed By:
Date:	Date:



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#### **ANNEXURE-XII**

### ENVIRONMENT MONITORING REPORT OF DISPENSING AREA BY SETTLE PLATE

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle Plate	Soyabean Casein Digest	Plate Exposure Time:	
Media Used For Settle Flate	Agar		
Autoclave Media Ref. No	SCA/	Plate Collection Time	
1st Incubation Temp & Time.	$20 - 25^{\circ}$ C for NLT 72	2 <sup>nd</sup> Incubation Temp & Time.	$30 - 35^{\circ}$ C for NLT 48
1 incubation remp & time.	hrs.	2 incubation remp & rine.	hrs.
Incubator ID No.		Incubator ID No.	

S.No.	Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count
1.	Air lock-01			D			
2.	Air lock-02			D			
3.	Dispossing Room			D			
3.	Dispensing Room			D			
4.	Dispensing Booth			C			

### LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
С	30 cfu	40 cfu	50 cfu
D	60 cfu	80 cfu	100 cfu

-ve control							
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Observed By:	Reviewed By:
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## ANNEXURE-XIII ENVIRONMENT MONITORING REPORT OF SAMPLING AREA BY SETTLE PLATE

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle Plate	Soyabean Casein Digest Agar	Plate Exposure Time:	
Autoclave Media Ref. No	SAC/	Plate Collection Time	
1st Incubation Temp & Time	20 – 25 <sup>0</sup> C for NLT 72 hrs.	2 <sup>nd</sup> Incubation Temp & Time	30 – 35°C for NLT 48 hrs.
Incubator ID No.		Incubator ID No.	-

S.No.	Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count
1.	Air Lock-01			D			
2.	Air Lock-02			D			
3.	Compling Doom 01			D			
3.	Sampling Room-01			D			

LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
С	30 cfu	40 cfu	50 cfu
D	60 cfu	80 cfu	100 cfu

-ve control	
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Observed By:	Reviewed By:
Date:	Date:



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# ANNEXURE-XIV ENVIRONMENT MONITORING REPORT OF ACTIVE AIR SAMPLING FOR QUALIFICATION

Date of sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Air	Soybean Casein Digest	Area	
Monitoring	Agar		
Autoclave Media Ref. No	SCA/	Air sampling time	
1st Incubation Temp & Time	$20 - 25^{\circ}$ C for NLT 72	2 <sup>nd</sup> Incubation Temp & Time	$30 - 35^{\circ}$ C for NLT 48
	hrs.	-	hrs.
Incubator ID No.	-	Incubator ID No.	-

S.No.	Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count	Corrected Count ( Feller Correction)

-ve contro	l																								
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Remarks:	The environmental	l monitoring	result by	Active	Air S	Sample	r for a	ibove	location	ons com	plies	/ does not	compl	y
	as per prescribed li	imits.												

Observed by:	Reviewed by:
Date:	Date:



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## ANNEXURE-XVI ENVIRONMENT MONITORING REPORT OF GRANULATION BY AIR SAMPLER

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Active Air	Soyabean Casein	Air compling time	
Monitoring	Digest Agar	Air sampling time	
Autoclave Media Ref. No	SCA/	Air sampler ID:	
1st Insulation Town & Time	$20 - 25^{\circ}$ C for NLT 72	2 <sup>nd</sup> Incubation Temp & Time.	$30 - 35^{\circ}$ C for NLT 48
1 <sup>st</sup> Incubation Temp & Time.	hrs.	2 Incubation Temp & Time.	hrs.
Incubator ID No.	-	Incubator ID No.	-

<b>S.</b> 1	No.	Area	Location	Plate	Grade	TBC	TFC	Total	Corrected
				Code				Microbial Count	Count (Feller
								Count	Correction)
	1.	Equipment Drying	Center of Room		D				
	2.	Paste Preparation Room	Center of Room		D				
	3.	Granulation	Center of Room		D				

LIMITS FOR AIR SAMPLING: Total Aerobic Microbial count

Grade	Alert Level	Action Level	<b>Specified Limits</b>
D	120 cfu	160 cfu	200 cfu

-ve control .....

Observed By:	Keviewea By:
Date:	Date:



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## ANNEXURE-XVII ENVIRONMENT MONITORING REPORT OF GRANULATION BY AIR SAMPLER

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Active Air	Soyabean Casein	Air sampling time	
Monitoring	Digest Agar		
Autoclave Media Ref. No	SCA/	Air Sampling ID:	
1st Inauhatian Tamp & Time	$20-25^{\circ}$ C for NLT	2 <sup>nd</sup> Incubation Temp & Time.	$30 - 35^{\circ}$ C for NLT 48
1 <sup>st</sup> Incubation Temp & Time.	72 hrs.	2 Incubation Temp & Time.	hrs.
Incubator ID No.	-	Incubator ID No.	-

S.No.	Area	Location	Plate	Grade	TBC	TFC	Total	Corrected
			Code				Microbial	Count
							Count	(Feller
								Correction)
1.	Paste Preparation Room	Center of Room		D				
2.	Granulation	Center of Room		D				
3.	Equipment Drying	Center of Room		D				

LIMITS FOR AIR SAMPLING: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	120 cfu	160 cfu	200 cfu

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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## ANNEXURE-XVIII ENVIRONMENT MONITORING REPORT OF GRANULATION BY AIR SAMPLER

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Air Monitoring	Soyabean Casein Digest	Air sampling time	
Wedia Osed For All Wolltoning	Agar		
Autoclave Media Ref. No	SCA/	Air Sampling ID:	
1st Incubation Temp & Time.	$20 - 25^{\circ}$ C for NLT 72	2 <sup>nd</sup> Incubation Temp &	$30 - 35^{\circ}$ C for NLT 48
1 incubation remp & rime.	hrs.	Time.	hrs.
Incubator ID No.	-	Incubator ID No.	-

I	S.No.	Area	Location	Plate	Grade	TBC	TFC	Total	Corrected
				Code				Microbial	Count (Feller
								Count	Correction)
	1.	Paste Preparation Room	Center of Room		D				
	2.	Granulation	Center of Room		D				

LIMITS FOR AIR SAMPLING: Total Aerobic Microbial Count

Grade	Alert Level	Action Level	Specified Limits
D	120 cfu	160 cfu	200 cfu

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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## ANNEXURE-XIX ENVIRONMENT MONITORING REPORT OF COMPRESSION BY AIR SAMPLER

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Active Air	Soyabean Casein Digest	Air sampling time	
Monitoring	Agar	2	
Autoclave Media Ref. No	SCA/	Air Sampler ID:	
1st Incubation Temp & Time.	$20-25^{\circ}$ C for NLT 72 hrs.	2 <sup>nd</sup> Incubation Temp & Time.	30 – 35°C for NLT 48 hrs.
Incubator ID No.	-	Incubator ID No.	-

5	S.No.	Area	Location	Plate Code	Grade	ТВС	TFC	Total Microbial Count	Corrected Count ( Feller Correction)
	1.	Compression	Center of Room		D				

LIMITS FOR AIR SAMPLING: Total Aerobic Microbial Count

Grade	Alert Level	Action Level	<b>Specified Limits</b>
D	120 cfu	160 cfu	200 cfu

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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## ANNEXURE-XX ENVIRONMENT MONITORING REPORT OF COATING BY AIR SAMPLER

	Date of Observation	
	Area Status	Static / Dynamic
Soyabean Casein Digest	Air sampling time	
Agar		
SCA/	Air Sampler ID:	
$20 - 25^{\circ}$ C for NLT72	2nd Inauhatian Tamp & Time	$30 - 35^{\circ}$ C for NLT 48
hrs.	2 incubation remp & time	hrs.
-	Incubator ID No.	-
	Agar SCA/ 20 – 25°C for NLT72	Soyabean Casein Digest Agar SCA/ Air Sampler ID:  20 – 25°C for NLT72 hrs.  Area Status Air sampling time  Air Sampler ID:  2nd Incubation Temp & Time

S.No.	Area	Location	Plate Code	Grade	ТВС	TFC	Total Microbial Count	Corrected Count ( Feller
								Correction)
1.	Coating-1	Center of Room		D				

#### LIMITS FOR AIR SAMPLING: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	120 cfu	160 cfu	200 cfu

<sup>-</sup>ve control .....

Observed By:	Reviewed By:
Date:	Date:



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## ANNEXURE-XXI ENVIRONMENT MONITORING REPORT OF COATING AREA BY AIR SAMPLER

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Active Air	Soyabean Casein Digest	Air sampling time	
Monitoring	Agar		
Autoclave Media Ref. No	SCA/	Air Sampling ID:	
1st Incubation Temp &	$20 - 25^{\circ}$ for NLT 72 hrs.	2 <sup>nd</sup> Incubation Temp & Time.	$30 - 35^{\circ}$ C for NLT 48
Time.	20 – 25 101 NL1 /2 IIIs.	2 incubation remp & time.	hrs.
Incubator ID No.	-	Incubator ID No.	-

S.No.	Area	Location	Plate	Grade	TB	TFC	Total	Corrected
			Code		C		Microbial	Count (Feller
							Count	Correction)
1.	Coating	Center of Room		D				
2	Solution Preparation	Center of		D				
2.	Room	Room		D				

#### LIMITS FOR AIR SAMPLING: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	120 cfu	160 cfu	200 cfu

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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#### **ANNEXURE-XXII**

### ENVIRONMENT MONITORING REPORT OF CAPSULE FILLING AREA AIR SAMPLER

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Active Air	Soyabean Casein	Air sampling time	
Monitoring	Digest Agar	• 0	
Autoclave Media Ref. No	SCA/	Air Sampling ID:	
1 <sup>st</sup> Incubation Temp & Time.	$20 - 25^{\circ}$ C for NLT 72	2 <sup>nd</sup> Incubation Temp & Time.	$30 - 35^{\circ}$ C for NLT 48
1 mediation temp & time.	hrs.	2 mediation remp & rime.	hrs.
Incubator ID No.	-	Incubator ID No.	-

	S. Io.	Area	Location	Plate Code	Grade	ТВС	Total Microbia l Count	Corrected Count (Feller Correction)
1		Capsule Filling	Center of Room		D			

LIMITS FOR AIR SAMPLING: Total Aerobic Microbial count

Grade	Alert Level	Action Level	<b>Specified Limits</b>
D	120 cfu	160 cfu	200 cfu

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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# ANNEXURE-XXIII ENVIRONMENT MONITORING REPORT OF SOFT GELATIN CAPSULE AREA BY AIR SAMPLER

Date of Sampling		<b>Date of Observation</b>	
Sampled By		Area Status	Static / Dynamic
Media Used For Active	Soybean Casein	Air sampling time	
Air Monitoring	Digest Agar		
Autoclave Media Ref. No	SCA/	Air Sampler ID:	
1st Incubation Temp &	$20-25^{\circ}$ C for NLT	2 <sup>nd</sup> Incubation Temp &	$30 - 35^{\circ}$ C for NLT
Time.	72 hrs.	Time.	48 hrs.
Incubator ID No.	-	Incubator ID No.	-

S. No.	Area	Location	Plate Code	Grade	ТВС	TFC	Total Microbi al Count	Corrected Count (Feller Correction)
1.	Capsule Sorting -01	Center of Room		D				
2.	Drying Zone	Center of Room		D				
3.	Encapsulation -01	Center of Room		D				
4.	Gelatin Preparation Area	Center of Room		D				
5.	Medicament Area	Center of Room		D				
6.	Drying Zone	Center of Room		D				

LIMITS FOR AIR SAMPLING: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	120 cfu	160 cfu	200 cfu
-			

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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## ANNEXURE-XXIV ENVIRONMENT MONITORING REPORT OF PACKING AREA LINE BY AIR SAMPLER

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Active Air	Soybean Casein Digest	Air sampling time	
Monitoring	Agar		
Autoclave Media Ref. No	SCA/	Air Sampler ID:	
1 <sup>st</sup> Incubation Temp & Time.	$20 - 25^{\circ}$ C for NLT 72	2 <sup>nd</sup> Incubation Temp & Time.	$30 - 35^{\circ}$ C for NLT 48
1 incubation remp & time.	hrs.	2 incubation remp & time.	hrs.
Incubator ID No.	-	Incubator ID No.	-

S.No.	Area	Location	Plate Code	Grade	ТВС	TFC	Total Microbial Count	Corrected Count (Feller Correction)
1.	Blister	Center of Room		D				
2.	Blister ALU-ALU (LOW RH)	Center of Room		D				
3.	STRIP	Center of Room		D				

LIMITS FOR AIR SAMPLING: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	120 cfu	160 cfu	200 cfu

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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## ANNEXURE-XXV ENVIRONMENT MONITORING REPORT OF PACKING AREA LINE AIR SAMPLER

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Active Air Monitoring	Soyabean Casein Digest Agar	Air sampling time	
Autoclave Media Ref. No	SCA/	Air Sampler ID:	
1st Incubation Temp & Time.	20 – 25 <sup>0</sup> C for NLT 72 hrs.	2 <sup>nd</sup> Incubation Temp & Time.	30 – 35°C for NLT 48 hrs.
Incubator ID No.	-	Incubator ID No.	-

S.No.	Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count	Corrected Count (Feller Correction)
1.	Blister	Center Room		D				
2.	Strip	Center of Room		D				
3.	Blister ALU-ALU (LOW RH)	Center of Room		D				
4.	FFS	Center of Room		D				
5.	Powder Filling	Center of Room		D				

LIMITS FOR AIR SAMPLING: Total Aerobic Microbial count

D 120 cfu 160 cfu 200 cfu	Grade	Alert Level	Action Level	Specified Limits	
	D	120 cfu	160 cfu	200 cfu	

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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### ANNEXURE-XXVI ENVIRONMENT MONITORING REPORT OF DISPENSING AREA BY AIR SAMPLER

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Active Air	Soybean Casein Digest	Air sampling time	
Monitoring	Agar	An sampling time	
Autoclave Media Ref. No	SCA/	Air Sampler ID:	
1st Incubation Temp & Time.	$20 - 25^{\circ}$ C for NLT 72	2 <sup>nd</sup> Incubation Temp & Time	$30 - 35^{\circ}$ C for NLT 48
1 incubation remp & time.	hrs.	2 incubation remp & time	hrs.
Incubator ID No.	-	Incubator ID No.	-

S. No.	Area	Location	Plate Code	Gra de	TBC	TFC	Total Microbial Count	Corrected Count ( Feller
								Correction)
1.	Dispensing Room	Center of Room		D				
2.	Dispensing Booth	Center of Booth		C				
3.	Dynamic Pass box	Center of Pass Box		D				
4.	Solvent Dispensing Room	Center of Room		D				
5.	Material Air Lock	Center of Room		D				

#### LIMITS FOR AIR SAMPLING: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
С	60 cfu	80 cfu	100 cfu
D	120 cfu	160 cfu	200 cfu

-ve control .....

Remarks:	The environmental	monitoring result	t of Active A	r Sampling fo	or above locat	tions complies /	does not comp	ıly
	as per prescribed	1 limits.						

Observed By:	Reviewed By:
Date:	Date:



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## ANNEXURE-XXVII ENVIRONMENT MONITORING REPORT OF SAMPLING AREA BY AIR SAMPLER

Date of Sampling		<b>Date of Observation</b>	
Sampled By		Area Status	Static / Dynamic
Media Used For Active Air	Soybean Casein	Air sampling time	
Monitoring	Digest Agar	An sampling time	
Autoclave Media Ref. No	SCA/	Air Sampling ID:	
1st Incubation Temp &	$20-25^{\circ}$ C for NLT	2 <sup>nd</sup> Incubation Temp &	$30 - 35^{\circ}$ C for NLT
Time.	72 hrs.	Time.	48 hrs.
Incubator ID No.	-	Incubator ID No.	-

S. No.	Area	Location	Plate Code	Gra de	TBC	TF C	Total Microbial	Corrected Count (Feller
							Count	<b>Correction</b> )
1.	Sampling Room	Center of Room		D				
2.	Sampling Booth	Center of Booth		С				
3.	Dynamic Pass Box	Center of Pass Box		D				
4.	Dynamic Pass Box	Center of Pass Box		D				
5.	Dynamic Pass Box	Center of Pass Box		D				

LIMITS FOR AIR SAMPLING: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
C	60 cfu	80 cfu	100 cfu
D	120 cfu	160 cfu	200 cfu

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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#### **ANNEXURE-XXVIII**

## ENVIRONMENTAL MONITORING REPORT OF MANUFACTURING AREA OF OINTMENT BY SETTLE PLATE AND AIR SAMPLER

Date of sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle plate	Soybean Casein	Plate Exposure Time	
&Air Sampling	Digest Agar	Air sampling time	
Autoclave Media Ref. No	SCA/	Air Sampler ID	
Autociave Media Rei. No	SCA	Plate collection time	
1 <sup>st</sup> Incubation Temp & Time.	$20 - 25^{\circ}$ C for	2 <sup>nd</sup> Incubation Temp &	$30 - 35^{\circ}$ C for NLT
1 incubation remp & time.	NLT 72 hrs.	Time.	48 hrs.
Incubator ID No.	-	Incubator ID No.	-

## MICROBIOLOGICAL ENVIRONMENTAL MONITORING OF AIR BY SETTLE PLATE METHOD

#### **OBSERVATION TABLE:**

S. No.	Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count
1.	Corridor			D			
2.	Day Store			D			
3.	Spare Parts Room			D			
4.	Tools Room			D			
5.	Clean Equipment Room			D			
6.	Janitor Room			D			
7.	7. Manufacturing			D			
				D			
				D			
8.	Holding Area			D			
9.				D			
	Filling Area			D			
				D			
10	10 5 1 611			D			
10.	Powder filling room			D			
Obs	erved By						

-ve control .....



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## MICROBIOLOGICAL ENVIRONMENTAL MONITORING OF AIR BY ACTIVE AIR SAMPLING OBSERVATION TABLE:

S. No.	Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count	Corrected Count (Feller Correction)
1.	Corridor	Center of Room		D				
2.	Manufacturing	Center of Room		D				
3.	Holding Area	Center of Room		D				
4.	Filling Area	Center of Room		D				
5.	Powder filling room	Center of Room		D				

<sup>-</sup>ve control .....

**Remarks:** The environmental monitoring result of Active Air sampling for above locations complies / does Not comply as per prescribed limits.

#### LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	60 cfu	80 cfu	100 cfu

#### LIMIT FOR AIR SAMPLING: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	120 cfu	160 cfu	200 cfu

Observed By:	Reviewed By
Date:	Date:



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# ANNEXURE-XXX ENVIRONMENTAL MONITORING REPORT OF RAW MATERIAL STORE OF OINTMENT AREA BY SETTLE PLATE AND AIR SAMPLER

Date of sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle plate, Air	Soyabean Casein Digest	Plate Exposure Time:	
Sampling	Agar	Plate collection time	
Air sampling time		Air sampler ID	
Autoclave Media Ref. No	SCA/		
1st Incubation Temp & Time.	$20 - 25^{\circ}$ C for	2 <sup>nd</sup> Incubation Temp	$30 - 35^{\circ}$ C for NLT
1 mediation temp & time.	NLT 72 hrs.	&Time.	48 hrs.
Incubator ID No.	-	Incubator ID No.	-

## MICROBIOLOGICAL ENVIRONMENTAL MONITORING OF AIR BY SETTLE PLATE METHOD

### **OBSERVATION TABLE:**

S. No.	Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count
1.	Material A/L			D			
2.	Solvent Dispensing A/L			D			
3.	Solvent Dispensing Area			D			
4.	RLAF			С			
5.	Dispensing A/L			D			
6.	Diamanaina Anas			D			
7.	Dispensing Area			D			
8.	Packing Material Sampling			С			
9.	Raw Material Sampling			С			
Obs	Observed By						

-ve control .....



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## MICROBIOLOGICAL ENVIRONMENTAL MONITORING OF AIR BY ACTIVE AIR SAMPLER OBSERVATION TABLE:

S.	Area	Location	Plate	Gra	TB	T	Total	Corrected
No.			Code	de	C	F	Microbial	
						C	Count	Correction)
1.	Solvent Dispensing Area	Center of Room		D				
2.	Reverse Laminar Air Flow			C				
3.	Dispensing Area	Center of Room		D				
4.	Dynamic Pass Box	Center of Pass Box		D				
5.	Packing Material Sampling			C				
6.	Raw Material Sampling			C	·			

<sup>-</sup>ve control .....

**Remarks:** The environmental monitoring result of Active Air sampling for above locations complies / does not comply as per prescribed limits.

### LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
С	30cfu	40cfu	50cfu
D	60 cfu	80 cfu	100 cfu

LIMITS FOR AIR SAMPLING: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
С	60cfu	80cfu	100cfu
D	120 cfu	160 cfu	200 cfu

Observed By:	Reviewed By:
Date:	Date:



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## ANNEXURE-XXXIV ENVIRONMENT MONITORING REPORT OF COMPRESSION BY AIR SAMPLER

Date of sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Active Air	Soybean Casein Digest	Air sampling time	
Monitoring	Agar		
Autoclave Media Ref. No	SCA/	Air Sampler ID:	
1st Incubation Temp & Time.	$20 - 25^{\circ}$ C for NLT 72	2 <sup>nd</sup> Incubation Temp & Time.	$30 - 35^{\circ}$ C for NLT 48
	hrs.	2 incubation remp & time.	hrs.
Incubator ID No.	-	Incubator ID No.	-

S.No.	Area	Location	Plate	Grade	TBC	TFC	Total	Corrected
			Code				Microbial	Count ( Feller
							Count	Correction)
1.	Compression	Center of Room		D				

LIMITS FOR AIR SAMPLING: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	120 cfu	160 cfu	200 cfu

<sup>-</sup>ve control .....

Observed By:	Reviewed By:
Date:	Date:



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# ANNEXURE-XXXV ENVIRONMENT MONITORING REPORT OF COATING AREA AND HOT TRAY DRAYER ROOM OF BY SETTLE PLATE

S.No.	Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count
1.	Man Entry			D			
2	Contina			D			
2.	Coating			D			

#### LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	60 cfu	80 cfu	100 cfu

-ve control .....

Observed By:	Reviewed By:
Date:	Date:'



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# ANNEXURE-XXXVI ENVIRONMENT MONITORING REPORT OF COATING AREA AND HOT TRAY DRAYER ROOM BY AIR SAMPLER

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Active Air	Soyabean Casein Digest	Air Sampling Time	
Monitoring	Agar		
Autoclave Media Ref. No	SCA/	Air Sampler ID:	
1st Incubation Temp & Time	$20 - 25^{\circ}$ C for NLT 72	2 <sup>nd</sup> Incubation Temp & Time	$30 - 35^{\circ}$ C for NLT 48
hrs.		2 Incubation Temp & Time	hrs.
Incubator ID No.	-	Incubator ID No.	-

S.No.	Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count	Corrected Count ( Feller Correction)
1.	Coating	Center of Room		D				
2.	(Hot tray drying zone)	Center of Room		D				

#### LIMITS FOR AIR SAMPLING: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	120 cfu	160 cfu	200 cfu

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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# ANNEXURE-XXXVII ENVIRONMENT MONITORING REPORT OF PACKING AREA LINE BY SETTLE PLATE

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle plate,	Soyabean Casein Digest Agar	Plate Exposure Time	
Autoclave Media Ref. No	SCA/	Plate Collection Time	
1 <sup>st</sup> Incubation Temp & Time.	20 – 25°C for NLT 72 hrs.	2 <sup>nd</sup> Incubation Temp & Time.	30 – 35°C for NLT 48 hrs.
Incubator ID No.	-	Incubator ID No.	-

S. No.	Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count
1.	Airlock			D			
2.	PL			D			
2.	ΓL			D			
3.	Airlock			D			
				D			
4.	Blister			D			
				D			

#### LIMITS FOR SETTLE PLATE: Total Aerobic Microbial Count

Grade	Alert Level	Action Level	<b>Specified Limits</b>
D	60 cfu	80 cfu	100 cfu

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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# ANNEXURE-XXXVIII ENVIRONMENT MONITORING REPORT OF PACKING AREA LINEBY AIR SAMPLER

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Active Air	Soyabean Casein Digest	Air Commline Time	
Monitoring	Agar	Air Sampling Time	
Autoclave Media Ref. No	SCA/	Air Sampler ID	
1st Insubation Town P. Time	$20 - 25^{\circ}$ C for NLT 72	2 <sup>nd</sup> Incubation Temp & Time.	$30 - 35^{\circ}$ C for NLT 48
1 <sup>st</sup> Incubation Temp & Time.	hrs.	2 Incubation Temp & Time.	hrs.
Incubator ID No.	-	Incubator ID No.	-

S. No.	Area	Location	Plate Code	Grade	ТВС	TFC	Total Microbial Count	Corrected Count (Feller Correction)
1.	PL	Center of Room		D				
2.	Blister	Center of Room		D				

#### LIMITS FOR AIR SAMPLING: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	120 cfu	160 cfu	200 cfu

-ve control .....

**Remarks:** The environmental monitoring result of Active Air Sampling for above locations complies / does not comply as per prescribed limits.

Observed By:	Reviewed By:
Date:	Date:



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# ANNEXURE-XXXIX ENVIRONMENT MONITORING REPORT OF GRANULATION BY SETTLE PLATE

Date of Sampling		<b>Date of Observation</b>	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle Plate	Soyabean Casein Digest Agar	Plate Exposure Time	
Autoclave Media Ref. No	SCA/	Plate Collection Time	
1st Incubation Temp & Time.	20 – 25 <sup>0</sup> C for NLT 72 hrs.	2 <sup>nd</sup> Incubation Temp & Time.	30 – 35°C for NLT 48 hrs.
Incubator ID No.	-	Incubator ID No.	-

S.No.	Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count
1.	Man Entry			D			
2.	Material Entry			D			
3.	Past Preparation Room			D			
4.	Granulation			D			

#### LIMITS FOR SETTLE PLATE: Total Aerobic Microbial Count

<b>D</b> 60 cfu 80 cfu 100 cfu	Grade	Alert Level	Action Level	Specified Limits
	D	60 cfu	80 cfu	100 cfu

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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## ANNEXURE-XXXX ENVIRONMENT MONITORING REPORT OF COMPRESSION BY SETTLE PLATE

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Madia Usad Fan Cattle Dlate	Soyabean Casein	Plate Exposure Time	
Media Used For Settle Plate	Digest Agar		
Autoclave Media Ref. No	SCA/	Plate Collection Time	
1 <sup>st</sup> Incubation Temp & Time.	$20 - 25^{\circ}$ C for NLT 72	2 <sup>nd</sup> Incubation Temp & Time.	$30 - 35^{\circ}$ C for NLT 48
1 incubation remp & time.	hrs.	2 incubation remp & time.	hrs.
Incubator ID No.	-	Incubator ID No.	-

Sr. No.	Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count
1.	Man Entry			D			
2.	Compression			D			

#### LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	60 cfu	80 cfu	100 cfu

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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## ANNEXURE-XXXXI ENVIRONMENT MONITORING REPORT OF COMPRESSION BY SETTLE PLATE

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle Plate	Soyabean Casein Digest Agar	Plate Exposure Time	
Autoclave Media Ref. No	SCA/	Plate Collection Time	
1st Incubation Temp & Time.	20 – 25°C for NLT 72 hrs.	2 <sup>nd</sup> Incubation Temp & Time.	30 – 35°C for NLT 48 hrs.
Incubator ID No.	-	Incubator ID No.	-

S. No.	Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count
1.	Man Entry			D			
2.	Compression			D			

#### LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	60 cfu	80 cfu	100 cfu
•			

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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# ANNEXURE-XXXXII ENVIRONMENT MONITORING REPORT OF LIQUID LINE IN Q-BLOCK BY SETTLE PLATE

Date of Sampling		<b>Date of Observation</b>	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle Plate	Soyabean Casein	Plate Exposure Time	
Wedia Osed For Settle Flate	Digest Agar		
Autoclave Media Ref. No	SCA/	<b>Plate Collection Time</b>	
1st Insubation Town 0. Time	$20 - 25^{\circ}$ C for	2 <sup>nd</sup> Incubation Temp & Time	$30 - 35^{\circ}$ C for NLT 48
1 <sup>st</sup> Incubation Temp & Time	NLT 72 hrs.	2 Incubation Temp & Time	hrs.
Incubator ID No.	-	Incubator ID No.	-

S.No.	Area	Location	Plate Code	Grade	TBC	TFC	Total Microbial Count
1.	Man Entry			D			
2.	Air Lock -01			D			
3.	Corridor			D			
				D			
4.	Shifting Material			D			
5.	Hold armin			D			
3.	Hold syrup			D			
6.	Cusan Maltina Daam			D			
0.	Sugar Melting Room			D			
7.	Mfg. Syrup			D			
7.	wiig. Syrup			D			
9.	Air Lock -1			D			
10.	De-cartooning			D			
11.	Air Lock -2			D			
10	W-1 D			D			
12.	Washing Room			С			
13.	Clean Equipment			D			
1.4	Filling and Sealing			D			
14.	Room			D			
15.	Air Lock			D			
16.	Man Entry			D			
17.	Material Day store			D		_	

#### LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
С	30cfu	40cfu	50cfu
D	60 cfu	80 cfu	100 cfu

-ve control .....

**Remarks:** The environmental monitoring result by Settle Plate method for above locations complies / does not comply as per prescribed limits.

Observed By: Reviewed By:



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# ANNEXURE-XXXXIII ENVIRONMENT MONITORING REPORT OF LIQUID LINE BY AIR SAMPLER

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle Plate	Soyabean Casein Digest Agar	Air Sampling Time	
Autoclave Media Ref. No	SCA/	Air Sampler ID	
1st Incubation Temp & Time.	20 – 25° C for NLT 72 hrs.	2 <sup>nd</sup> Incubation Temp & Time.	30 – 35°C for NLT 48 hrs.
Incubator ID No.	-	Incubator ID No.	-

S.No.	Area	Location	Plate Code	Gra de	TB C	TFC	Total Microbial Count	Corrected Count (Feller Correction)
1.	Man Entry	Center of Room		D				
2.	Air Lock -01	Center of Room		D				
3.	Corridor	Center of Corridor		D				
4.	Hold Syrup	Center of Room		D				
5.	Sugar Melting Room	Center of Room		D				
6.	Mfg. Syrup	Center of Room		D				
8.	Air Lock -1	Center of Room		D				
9.	De-cartoning	Center of Room		D				
10.	Air Lock -2	Center of Room		D				
11.	Washing Room	Center of Room Under LAF		D C				
12.	Clean Equipment	Center of Room		D				
13.	Filling and Sealing	Center of Room		D				
13.	Room	Under LAF		С				
14.	Air Lock	Center of Room		D				
15.	Man Entry	Center of room		D				
16.	Material Day store	Center of room		D				
10.	Material Day Store			D				

LIMITS FOR AIR SAMPLING: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
С	60cfu	80cfu	100cfu
D	120 cfu	160 cfu	200 cfu

-ve control .....

Observed By:	Reviewed By
Date:	Date:



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# ANNEXURE-XXXXIV ENVIRONMENT MONITORING REPORT OF COMPRESSION BY AIR SAMPLER

Date of sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Active Air	Soybean Casein Digest	Air Sampling Time	
Monitoring	Agar		
Autoclave Media Ref. No	SCA/	Air Sampler ID	
1 <sup>st</sup> Incubation Temp. &	$20 - 25^{\circ}$ C for NLT 72 hrs.	2 <sup>nd</sup> Incubation Temp &	$30 - 35^{\circ}$ C for NLT 48
Time	20 – 23 C 101 NL1 72 IIIS.	Time	hrs.
Incubator ID No.	-	Incubator ID No.	-

S.No.	Area	Location	Plate	Grade	TBC	TFC	Total	Corrected
			Code				Microbial	Count ( Feller
							Count	Correction)
1.	Compression	Center of Room		D				

LIMITS FOR AIR SAMPLING: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
D	120 cfu	160 cfu	200 cfu

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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# ANNEXURE-XXXXV ENVIRONMENT MONITORING REPORT OF COMPRESSION BY SETTLE PLATE

Date of Sampling		<b>Date of Observation</b>	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle Plate	Soyabean Casein	Plate Exposure Time	
Wiedla Osed For Settle Flate	Digest Agar		
Autoclave Media Ref. No	SCA/	<b>Plate Collection Time:</b>	
1st Incubation Temp & Time	$20 - 25^{\circ}$ C for	2 <sup>nd</sup> Incubation Temp &	$30 - 35^{\circ}$ C for NLT
1 Incubation Temp & Time	NLT 72 hrs.	Time.	48 hrs.
Incubator ID No.	-	Incubator ID No.	-

S.No.	Area	Location	Plate	Grade	TBC	TFC	Total
			Code				Microbial
							Count
1.	Man Entry			D			
2.	Compression			D			

#### LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

Grade	Alert Level	<b>Action Level</b>	Specified Limits		
D	60 cfu	80 cfu	100 cfu		

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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#### ANNEXURE-XXXXVI ENVIRONMENT MONITORING REPORT OF COMPRESSION BY AIR SAMPLER

Date of sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Active Air Monitoring	Soyabean Casein Digest Agar	Air Sampling Time	
Autoclave Media Ref. No	SCA/	Air Sampler ID	
1st Incubation Temp & Time.	20 – 25 <sup>0</sup> C for NLT 72 hrs.	2 <sup>nd</sup> Incubation Temp & Time.	30 – 35°C for NLT 48 hrs.
Incubator ID No.		Incubator ID No.	

S.No.	Area	Location	Plate Code	Grade	ТВС	TFC	Total Microbial Count	Corrected Count (Feller Correction)
1.	Compression	Center of Room		D				

LIMITS FOR AIR SAMPLING: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits		
D	120 cfu	160 cfu	200 cfu		

-ve control .....

Observed By:	Reviewed By:
Date:	Date:



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# ANNEXURE-XXXXVII ENVIRONMENT MONITORING SCHEDULE FOR SETTLE PLATES & ACTIVE AIR SAMPLING

Area	Planned Date of Settle plate in Jan.	Planned Date of active air sampling Feb.	Planned Date of Settle plate March	Planned Date of active air sampling April	Planned Date of Settle plate May	Planned Date of active air sampling June	Planned Date of Settle plate July	Planned Date of active air sampling Aug.	Planned Date of Settle plate Sept.	Planned Date of active air sampling Oct.	Planned Date of Settle plate Nov.	Planned Date of active air sampling Dec.
Compression	2	2	2	2	2	2	2	2	2	2	2	2
Compression	4	4	4	4	4	4	4	4	4	4	4	4
Compression	5	5	5	5	5	5	5	5	5	5	5	5
Compression	6	6	6	6	6	6	6	6	6	6	6	6



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Compression	7	7	7	7	7	7	7	7	7	7	7	7	
Coating area	8	8	8	8	8	8	8	8	8	8	8	8	
Coating Area	10	10	10	10	10	10	10	10	10	10	10	10	
Granulation	11	11	11	11	11	11	11	11	11	11	11	11	
Granulation	12	12	12	12	12	12	12	12	12	12	12	12	
Granulation	13	13	13	13	13	13	13	13	13	13	13	13	
Granulation	14	14	14	14	14	14	14	14	14	14	14	14	
Granulation	15	15	15	15	15	15	15	15	15	15	15	15	
Soft Gelatin capsule Area	17	17	17	17	17	17	17	17	17	17	17	17	
Capsule Filling Area	18	18	18	18	18	18	18	18	18	18	18	18	
Packing area line	19	19	19	19	19	19	19	19	19	19	19	19	
Packing area line	20	20	20	20	20	20	20	20	20	20	20	20	
Packing Area Line	21	21	21	21	21	21	21	21	21	21	21	21	
Dispensing Area	23	23	23	23	23	23	23	23	23	23	23	23	
Sampling Area	24	24	24	24	24	24	24	24	24	24	24	24	
RM store ointment & oral liquid	26	26	26	26	26	26	26	26	26	26	26	26	
Ointment mfg. Area	27	27	27	27	27	27	27	27	27	27	27	27	
Oral liquid line	28	28	28	28	28	28	28	28	28	28	28	28	

Perform the environmental monitoring  $\pm 5$  days