



PHARMA DEVILS

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
M	-	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 0.22 μ 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 0.22 μ filtered70% 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 0.22µ 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 0.22µ filtered 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/ meter³ 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 Settle Plate	Air Monitoring By 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 Quality Assurance
- Controlled Copy No. 02 Microbiology
- Master Copy 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 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time	30 – 35 ⁰ C for NLT 48 hrs.
Incubator ID No.		Incubator ID No.	

S. No.	Area	Location	Plate Code	Grade	TBC	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

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

Observed By:
Date:

Reviewed By:
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 ^o C for NLT 72 hrs.	2nd Incubation Temp & Time	30 – 35 ^o C for NLT 48 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			
5.	Granulation			D			
				D			
				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

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

Observed By:
Date:

Reviewed By:
Date:



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ANNEXURE-III

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 ⁰ C for NLT72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ C for NLT48 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.	Paste Preparation Room			D			
4.	Buffer 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

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

Observed By:

Date:

Reviewed By:

Date:



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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 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ 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			
				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

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

Observed By:
Date:

Reviewed By:
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 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ 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.	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

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

Observed By:
Date:

Reviewed By:
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/	Plate Collection Time	
1st Incubation Temp & Time	20 – 25 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time	30 – 35 ⁰ 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.	Coating			D			
				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

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

Observed By:
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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 Digest Agar	Plate Exposure Time:	
Autoclave Media Ref. No	SCA/	Plate Collection Time	
1st Incubation Temp & Time.	20 – 25 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ C for NLT 48 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

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

Observed By:
Date:

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Date:



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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 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ 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.	Capsule Sorting			D			
3.	Drying Zone			D			
4.	Encapsulation			D			
5.	Gelatin Preparation Area			D			
6.	Man Entry			D			
7.	Medicament Area			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

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

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Date:



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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 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time	30 – 35 ⁰ C for NLT 48 hrs.
Incubator ID No.		Incubator ID No.	

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

-ve control

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

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ANNEXURE-X

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	Soybean Casein Digest Agar	Plate Exposure Time:	
Autoclave Media Ref. No	SCA/	Plate Collection Time	
1st Incubation Temp & Time.	20 – 25 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ 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.	Blister			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

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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 Agar	Plate Exposure Time:	
Autoclave Media Ref. No	SCA/	Plate Collection Time	
1st Incubation Temp & Time.	20 – 25 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ 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.	Dispensing Room			D			
				D			
4.	Dispensing Booth			C			

LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

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

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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 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time	30 – 35 ⁰ 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.	Sampling Room-01			D			
				D			

LIMITS FOR SETTLE PLATE: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
C	30 cfu	40 cfu	50 cfu
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.

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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 Monitoring	Soybean Casein Digest Agar	Area	
Autoclave Media Ref. No	SCA/	Air sampling time	
1st Incubation Temp & Time	20 – 25 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time	30 – 35 ⁰ 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)

-ve control

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

Observed By:
Date:

Reviewed By:
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 Monitoring	Soyabean Casein Digest Agar	Air sampling time	
Autoclave Media Ref. No	SCA/	Air sampler ID:	
1st Incubation Temp & Time.	20 – 25 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ 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.	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	Specified Limits
D	120 cfu	160 cfu	200 cfu

-ve control

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

Observed By:
Date:

Reviewed By:
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 Monitoring	Soyabean Casein Digest Agar	Air sampling time	
Autoclave Media Ref. No	SCA/	Air Sampling ID:	
1st Incubation Temp & Time.	20 – 25 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ 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.	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

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

Observed By:
Date:

Reviewed By:
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 Agar	Air sampling time	
Autoclave Media Ref. No	SCA/	Air Sampling ID:	
1st Incubation Temp & Time.	20 – 25 ^o C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ^o 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.	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

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

Observed By:
Date:

Reviewed By:
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 Monitoring	Soyabean Casein Digest Agar	Air sampling time	
Autoclave Media Ref. No	SCA/	Air Sampler ID:	
1st Incubation Temp & Time.	20 – 25 ^o C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ^o 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.	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

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

Observed By:
Date:

Reviewed By:
Date:



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ANNEXURE-XX
ENVIRONMENT MONITORING REPORT OF COATING 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 ⁰ C for NLT72 hrs.	2nd Incubation Temp & Time	30 – 35 ⁰ 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.	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

-ve control

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

Observed By:
Date:

Reviewed By:
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 Monitoring	Soyabean Casein Digest Agar	Air sampling time	
Autoclave Media Ref. No	SCA/	Air Sampling ID:	
1st Incubation Temp & Time.	20 – 25 ^o for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ^o C for NLT 48 hrs.
Incubator ID No.	-	Incubator ID No.	-

S.No.	Area	Location	Plate Code	Grade	TB C	TFC	Total Microbial Count	Corrected Count (Feller Correction)
1.	Coating	Center of Room		D				
2.	Solution Preparation Room	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 by Active Air Sampler for above locations complies / does not comply as per prescribed limits.

Observed By:
Date:

Reviewed By:
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 Monitoring	Soyabean Casein Digest Agar	Air sampling time	
Autoclave Media Ref. No	SCA/	Air Sampling ID:	
1st Incubation Temp & Time.	20 – 25 ^o C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ^o C for NLT 48 hrs.
Incubator ID No.	-	Incubator ID No.	-

S. No.	Area	Location	Plate Code	Grade	TBC	TFC	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	Specified Limits
D	120 cfu	160 cfu	200 cfu

-ve control

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

Observed By:
Date:

Reviewed By:
Date:



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ANNEXURE-XXIII

ENVIRONMENT MONITORING REPORT OF SOFT GELATIN CAPSULE AREA BY AIR SAMPLER

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

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

Observed By:
Date:

Reviewed By:
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 Monitoring	Soybean Casein Digest Agar	Air sampling time	
Autoclave Media Ref. No	SCA/	Air Sampler ID:	
1st Incubation Temp & Time.	20 – 25 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ 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 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

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

Observed By:
Date:

Reviewed By:
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 ^o C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ^o 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

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:
Date:

Reviewed By:
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 Monitoring	Soybean Casein Digest Agar	Air sampling time	
Autoclave Media Ref. No	SCA/	Air Sampler ID:	
1st Incubation Temp & Time.	20 – 25 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time	30 – 35 ⁰ 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.	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
C	60 cfu	80 cfu	100 cfu
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:
Date:

Reviewed By:
Date:



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

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

S. No.	Area	Location	Plate Code	Grade	TBC	TF C	Total Microbial Count	Corrected Count (Feller Correction)
1.	Sampling Room	Center of Room		D				
2.	Sampling Booth	Center of Booth		C				
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

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

Observed By:
Date:

Reviewed By:
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 & Air Sampling	Soybean Casein Digest Agar	Plate Exposure Time	
		Air sampling time	
Autoclave Media Ref. No	SCA/	Air Sampler ID	
		Plate collection time	
1st Incubation Temp & Time.	20 – 25 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ C for NLT 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.	Manufacturing			D			
				D			
				D			
8.	Holding Area			D			
9.	Filling Area			D			
				D			
				D			
10.	Powder filling room			D			
				D			
Observed By							

-ve control

Remarks: The environmental monitoring result of Settle Plate for above locations complies / doesnot comply as per prescribed limits.



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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				

-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:
Date:

Reviewed By:
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 Sampling	Soyabean Casein Digest Agar	Plate Exposure Time:	
		Plate collection time	
Air sampling time		Air sampler ID	
Autoclave Media Ref. No	SCA/		
1st Incubation Temp & Time.	20 – 25 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ C for NLT 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			C			
5.	Dispensing A/L			D			
6.	Dispensing Area			D			
7.				D			
8.	Packing Material Sampling			C			
9.	Raw Material Sampling			C			

Observed By

-ve control

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



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

S. No.	Area	Location	Plate Code	Grade	TB C	T F C	Total Microbial Count	Corrected Count (Feller 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				

-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
C	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
C	60cfu	80cfu	100cfu
D	120 cfu	160 cfu	200 cfu

Observed By:
Date:

Reviewed By:
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 Monitoring	Soybean Casein Digest Agar	Air sampling time	
Autoclave Media Ref. No	SCA/	Air Sampler ID:	
1st Incubation Temp & Time.	20 – 25 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ 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.	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

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

Observed By:
Date:

Reviewed By:
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.	Coating			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

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

Observed By:
Date:

Reviewed By:
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 Monitoring	Soyabean Casein Digest Agar	Air Sampling Time	
Autoclave Media Ref. No	SCA/	Air Sampler ID:	
1st Incubation Temp & Time	20 – 25 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time	30 – 35 ⁰ 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.	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

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

Observed By:
Date:

Reviewed By:
Date:



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MICROBIOLOGY DEPARTMENT

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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	
1st Incubation Temp & Time.	20 – 25 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ 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			
				D			
3.	Airlock			D			
4.	Blister			D			
				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

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

Observed By:

Date:

Reviewed By:

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 Monitoring	Soyabean Casein Digest Agar	Air Sampling Time	
Autoclave Media Ref. No	SCA/	Air Sampler ID	
1st Incubation Temp & Time.	20 – 25 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ 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.	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:
Date:

Reviewed By:
Date:



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ANNEXURE-XXXIX

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 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ 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

Grade	Alert Level	Action Level	Specified Limits
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:
Date:

Reviewed By:
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
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 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ C for NLT 48 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

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

Observed By:
Date:

Reviewed By:
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 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ 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

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

Observed By:
Date:

Reviewed By:
Date:



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MICROBIOLOGY DEPARTMENT

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ANNEXURE-XXXXII

ENVIRONMENT MONITORING REPORT OF LIQUID LINE IN Q-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 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time	30 – 35 ⁰ 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.	Air Lock -01			D			
3.	Corridor			D			
4.	Shifting Material			D			
5.	Hold syrup			D			
6.	Sugar Melting Room			D			
7.	Mfg. Syrup			D			
9.	Air Lock -1			D			
10.	De-cartooning			D			
11.	Air Lock -2			D			
12.	Washing Room			D			
13.	Clean Equipment			C			
14.	Filling and Sealing 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
C	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 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ C for NLT 48 hrs.
Incubator ID No.	-	Incubator ID No.	-

S.No.	Area	Location	Plate Code	Grade	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		D				
		Under LAF		C				
12.	Clean Equipment	Center of Room		D				
13.	Filling and Sealing Room	Center of Room		D				
		Under LAF		C				
14.	Air Lock	Center of Room		D				
15.	Man Entry	Center of room		D				
16.	Material Day store	Center of room		D				
				D				

LIMITS FOR AIR SAMPLING: Total Aerobic Microbial count

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

-ve control

Remarks: The environmental monitoring result by Active Air Sampler method for above locations complies / does not comply as per prescribed limits.

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 Monitoring	Soybean Casein Digest Agar	Air Sampling Time	
Autoclave Media Ref. No	SCA/	Air Sampler ID	
1st Incubation Temp. & Time	20 – 25 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time	30 – 35 ⁰ 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.	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

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

Observed By:
Date:

Reviewed By:
Date:



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ANNEXURE-XXXXV

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 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ 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

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

Observed By:
Date:

Reviewed By:
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 ⁰ C for NLT 72 hrs.	2nd Incubation Temp & Time.	30 – 35 ⁰ 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.	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

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

Observed By:
Date:

Reviewed By:
Date:



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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 ± 5 days