STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Procedure for Environmental Monitoring in Manufacturing, Packing and Stores area by Passive Air sampling and Active Air sampling method	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down the procedure for environmental monitoring in manufacturing, packing and stores area by passive air sampling and active air sampling method.

2.0 SCOPE:

This procedure is applicable for environmental monitoring of manufacturing, packing and stores area by passive air sampling and active air sampling.

3.0 RESPONSIBILITY:

Microbiologist- Quality Control

Head - Quality Control

4.0 PROCEDURE:

4.1 Passive Air Sampling by Settle Plate Method:

4.1.1 Prepare the 70% v/v IPA as per reference SOP.

4.1.2 Prepare Soyabean casein digest agar medium plates as per reference SOP.

4.1.3 **Procedure for Exposure of Plates :**

4.1.4 Mop the outer and inner surface of S. S. canister along with lid using 70 % v/v IPA.

4.1.5 Take the required quantity of Preincubated SCDA plates.

4.1.6 Mark the plates with Name of Medium, Lot No., Date of Preparation, Use before, and Sign and date. Put the petriplates in S.S. Petri dish canister and keep these canisters in S.S. sampling kit.

4.1.7 Transfer the S. S. sampling kit containing sterile SCDA plates to the material air lock of respective sampling area.

4.1.8 Mop the surface of plate exposing stands with 70% v/v IPA and transfer in respective area as per the location diagram.

4.1.9 Follow the entry/exit procedure of respective area for enter/exit in the area.

4.1.10 Arrange the plate exposing stands as per location chart of respective area given.

4.1.11 Before exposure, mark the sterile SCDA plate with Location name, No. ,date of sampling and

initial time of exposure with marker pen on the bottom of plate and put the sterile SCDA plate on S. S. plate exposure stand of respective location.

4.1.12 Expose the petri plate at designated position by open the lid of sterile SCDA plate and keep the lid on stand near SCDA plate.

4.1.13 Exposed the sterile SCDA plate for 60 minutes + 15 minutes.

4.1.14 After completion of exposure period close the lid carefully to avoid the external contamination by hand. Write down the completion time of exposure.

4.1.15 Collect the SCDA plate in to S. S. canister and transfer from material air lock of respective area to microbiology laboratory of quality control department.

4.2 Procedure for Incubation:

4.2.1 Incubate SCDA plates in inverted position along with control plate (unexposed) at 20°–25°C for 72 hrs.

4.2.2 Control plate represents the medium sterility and carrier control of plate transportation.

4.2.3 On completion of above incubation transfer all the plates at 30°–35°C for 48 hrs.

4.2.4 After the completion of incubation period, observe the SCDA plates and count the bacterial and fungal colonies. Record the result in respective Annexure.

4.3 Precautions:

4.3.1 Ensure that plates are exposed 60 minutes + 15 minutes.

4.3.2 Ensure plates are pre-incubated not less than 48-72 hours at 20°–25°C.

4.3.3 Ensure not to expose the plates immediately after cleaning & sanitization of area.

4.4 Active Air sampling :

4.4.1 Prepare 70 %v/v IPA as per reference SOP and Prepare Soyabean casein digest agar medium as per reference SOP.

4.4.2 Take the required number of pre incubated SCDA plates in S S canister, which are previously disinfected by filtered 70 %v/v IPA. Close the lid of S. S. canister.

4.4.3 Transfer the S. S. sampling kit containing sterile SCDA plates to the material air lock of

respective sampling area.

4.4.4 Disinfect the outer surface of air sampler with sterile mop, using 70%v/v IPA.

4.4.5 Sterilize the S.S. perforated lid of air sampler by autoclaving as per reference SOP, after autoclaving put it in sterile SS box and follow the same procedure as described for plate transfer to respective area where air sampling has to be performed.

4.4.6 Follow the entry/exit procedure of respective area and enter in to the room where active air sampling is to be performed.

4.4.7 Before sampling, mark the sterile SCDA plate with location and date of sampling with marker pen on the bottom of plate.

4.4.8 Open the lid of SCDA plate, place the plate in to the sampling head of the instrument and close with perforated lid. Keep the lid of plate on air sampler lid holder.

4.4.9 Operate the Air Sampler as per respective SOP.

4.4.10 Sample $1m^3$ (1000 litre) of air from each assigned location as per respective diagram and annexures.

4.4.11 Ensure that the sample quantity is displayed on the screen of the instrument after each sampling operation.

4.412 After Air sampling, open the perforated lid of Air sampler and take out the SCDA plate, close the lid and put in to the S. S. canister.

4.4.13 Disinfect the perforated lid by mopping with sterile mop using filtered 70%v/v IPA before taking another sample.

4.4.14 Collect the SCDA plate in to S. S. canister and put S. S. canister in S. S. sampling kit and transfer from material air lock of respective area to microbiology laboratory of Quality control department.

4.5 Procedure for Incubation:

4.5.1 Incubate SCDA plates in inverted position along with control plate (unexposed) at 20°–25°C in for 72 hours.

4.5.2 Control plate represents the medium sterility and carrier control of plate transportation.

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4.5.3 On completion of above incubation period transfer all the plates at 30°–35°C for 48 hours.

4.5.4 After the completion of incubation period, observe the SCDA plates and count the bacterial and fungal colonies. Record the result in respective Annexures.

4.6 Acceptance Criteria:

Grade	Active Air Sampling (Cfu/ m^3)					
	Bacteria			Fungi		
	Alert Limit	Action Limit	Specification Limit	Alert Limit	Action Limit	Specification Limit
Grade-A#	----	----	< 1	----	----	Nil
Grade-D	---	---	200	---	---	Nil

Grade	Passive Air Sampling (Cfu/ Plate)*					
	Bacteria			Fungi		
	Alert Limit	Action Limit	Specification Limit	Alert Limit	Action Limit	Specification Limit
Grade-A#	----	----	< 1	----	----	Nil
Grade-D	----	----	100	----	----	Nil

4.6.1 **#Note:** Any count observed in any location in Grade A shall trigger investigation as per reference SOP.

4.6.2 *Diameter of Plates used for environment monitoring by active air sampling and settle plate method is 90 mm.

4.6.3 Prepare the Environmental Monitoring trend for the result on quarterly basis.

Action and alert limit of Environmental Monitoring shall be assign after generating the graphical data for one year.

4.7 Frequency:

4.7.1 Passive Air Sampling (Settle plate method): Monthly.

4.7.2 Active Air Sampling: Monthly

4.7.3 All activity should be performed ±03 working days from planned schedule.

4.7.4 Environment monitoring schedule for manufacturing area.

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S.No.	Name of location	Method of monitoring Active/passive	Scheduled day for environment monitoring	Exposure time
1.	Granulation area, Packing material sampling area	Active & Passive	First monday of every month	60 minutes + 15 minutes.
2.	Raw material sampling area, dispensing area (tablet),compression area	Active & Passive	Second monday of every month	60 minutes + 15 minutes.
3.	Coating area, primary packing area	Active & Passive	Third monday of every month	60 minutes + 15 minutes.
4.	Ointment area, soft gel area	Active & Passive	Fourth monday of every month	60 minutes + 15 minutes.

5.0 ANNEXURE (S):

Annexure-I : Environmental monitoring of Raw material sampling area by passive air sampling (settle plate method).

Annexure-II : Environmental monitoring of Dispensing area (Tablet) by passive air sampling (settle plate method).

Annexure-III : Environmental monitoring of Granulation area by passive air sampling (settle plate method)

Annexure-IV : Environmental monitoring of Compression area by passive air sampling (settle plate method)

Annexure-V : Environmental monitoring of Coating area by passive air sampling (settle plate method)

Annexure-VI : Environmental monitoring of Primary Packing area by passive air sampling (settle plate method)

Annexure-VII: Environmental monitoring of Soft gel area by passive air sampling (settle plate method)

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Annexure-VIII: Environmental Monitoring Of Ointment Area By Passive Air Sampling (Settle Plate Method)

Annexure-IX: Environmental monitoring of Raw material sampling area by active ling

Annexure-X: Environmental monitoring of dispensing area By active air sampling

Annexure-XI :Environmental monitoring of granulation area (tablet) By a active air ing

Annexure-XII :Environmental monitoring of compression area (tablet) By active air sampling

Annexure-XIII :Environmental monitoring of Coating area (tablet) By active air sampling

Annexure-XIV : Environmental monitoring of Primary Packing area (Tablet) (Table ive air sampling

Annexure-XV: Environmental monitoring of soft gel area by active air Sampling

Annexure-XVI : Environmental monitoring of ointment area by active air Sampling

Annexure-XVII : Environmental monitoring location diagram of ground floor.

Annexure-XVIII : Environmental monitoring location diagram of First floor.

Annexure-XIX : Environmental monitoring location diagram of Second floor.

Annexure-XX : Environmental monitoring of Packing material sampling area by passive air sampling (settle plate method).

Annexure-XXI : Environmental monitoring of Packing material sampling area by Active Air sampling.

6.0 REFERENCE (S):

SOP: Preparation, Approval, Distribution control, revision and Destruction of Standard operating Procedure (SOP).

SOP: Preparation of Disinfectant and cleaning of Microbiology Laboratory.

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SOP: Procedure for Preparation of Media.

SOP: Investigation of out of specification of test results in microbiology.

SOP: Cleaning and operation of autoclave for media

7.0 ABBREVIATION (S) / DEFINITION (S)

S.S. : Stainless steel

SCDA : Soyabean casein digest agar

LAF : Laminar air flow

IPA : Isopropyl alcohol

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	-----	New SOP	-----