PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Collection and Testing of samples during Process Simulation	**Effective Date:**
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1.0 PURPOSE

To Lay down the stepwise procedure collection of samples during Process Stimulation in Cyto-Sterility facility and it's testing procedure.

2.0 SCOPE

This is applicable to Microbiology lab

3.0 RESPONSIBILITY

Microbiologist

4.0 PROCEDURE

4.1 Sample collection from compounding area

4.1.1 While entering the compounding area follow the procedure of entry & exit mentioned in SOP.

4.1.2 Collect the Pre filtered media in sterile-screw capped bottle perform the Bioburden according to SOP.

4.2 Sample collection from Aseptic area

4.2.1 For entry & exit in aseptic area follow the procedure mentioned in SOP.

4.2.2 Collect 200 ml sample from first filtration in sterile-screw capped bottle.

4.2.3 Perform the Growth promotion test and pH according to SOP.

4.2.4 Collect 200 ml sample from second filtration in sterile-screw capped bottle.

4.2.5 Incubate the samples at 20-25°C for 7 days followed by 30-35°C for again 7 days.

4.2.6 Collect the sample of Vials, Flip of seals and Rubber stopper in sterile screw capped bottle containing 100 ml Soybean casein digest medium at the end of the filling of that particular pack size.

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4.2.7 In case of vial bigger than 5 ml. Samples shall be collected after capping and sealing.

4.2.8 Inject Soybean casein digest medium in each vial under strict aseptic condition.

4.2.9 Incubate the samples at 20-25°C for 7 days followed by 30-35°C for 7 days.

4.2.10 Sample the compressed air through Compressed air sampler according to SOP.

4.2.11 Incubate the plate at 30-35°C for 5 days.

4.2.12 Collect first 4 filled vials for observation.

4.2.13 Collect the left out solution in sterile container and incubate the samples at 20 – 25°C for 7 days followed by 30-35°C for 7 days.

4.2.14 After completion of the media fill incubation perform the post media fill growth promotion test of the vials according to SOP.

4.2.15 Container closure integrity shall be tested whenever any new pack size is used. Perform the container closer integrity according to protocol.

4.2.16 Perform the environment monitoring such as Plate exposure, Air sampling, Surface, Finger dab, Personnel hygiene according to SOP. Record the result of passive air sampling in Annexure-I of SOP Record the result of active air sampling in Annexure-II of SOP. Record the result of swab of cRABS and filling area in Annexure-III, Record the result of cRABS gloves dabs in Annexure-IV of SOP, Record the result of personnel hygiene in Annexure-VI of SOP and Record the result of personnel finger dabs Annexure-VII of SOP.

4.3 Destruction of the media

4.3.1 Discard the contaminated vials in the terminal sterilizer and drain the media in ETP.
4.3.2 The vials, which are not contaminated, should be discarded in the ETP.

4.3.3 The empty vials should be crushed in vial crusher

Note: All the Activities should be carried out according to Media Fill protocol, All the sample should be collected according to Annexure-V and recording should be done in respective Annexure

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5.0 ABBREVIATIONS AND DEFINITIONS

SOP	Standard Operating Procedure
QCM	Quality Control Microbiology
QAD	Quality Assurance Department
Rev.	Revision
No.	Number
CSP	Cyto Sterile Production
°C	Degree Centigrade

Media fill: Method of evaluating an aseptic process using a microbial growth medium.
Air Sampler: Devices or equipment used to sample a measured amount of air in a specified time to quantitative microbiological status.

Bioburden: Population of viable microorganisms on a product.

6.0 REFERENCE DOCUMENTS

SOP	Entry and Exit in to Equipment wash area
SOP	Bioburden of Bulk preparation (Cyto Sterile preparation)
SOP	Procedure for Storage and Preparation of microbiological culture media
SOP	Procedure for Operation of Air samplers
GVD	General validation Protocol-Container closer integrity
SOP	Microbial monitoring of Cyto-Injectable manufacturing area
Annexure-I of SOP	Passive air sampling (Settle plate) Cyto sterile facility
Annexure-II of SOP	Active air sampling-Cyto sterile facility
Annexure-III of SOP	Surface Swabs-Cyto sterile facility
Annexure-IV of SOP	cRABS Gloves dab-Cyto sterile facility
Annexure-VI of SOP	Personnel gown monitoring by Contact plate method-Cyto sterile facility
Annexure-VII of SOP	Personnel finger Dabs-Cyto sterile facility
USP chapter No.<1116>	Microbiological evaluation of clean rooms and other controlled environments
USP chapter No. <61>	Microbiological examination of non sterile products.

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7.0 ANNEXURE/ATTACHMENTS

Annexure I : Form 1 - GROWTH PROMOTION TEST REPORT (PROCESS SIMULATION)
Annexure II : Form 2 - COMPRESSED AIR SAMPLING REPORT (PROCESS SIMULATION)
Annexure III : Form 3 - STERILITY TEST REPORT (PROCESS SIMULATION)
Annexure IV : Form 4 – BIOBURDEN TEST REPORT (PROCESS SIMULATION)
Annexure V : Form 5 - SAMPLING MATRIX FOR PROCESS SIMULATION

8.0 REVISION LOG

Prepared By	Checked By	Approved By
Signature/ Date	**Signature/ Date**	**Signature/ Date**