PHARMA DEVILS	
MICROBIOLOGY DEPARTMENT	

STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Monitoring of drain points by analysis of pathogens	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1. **Purpose:** The purpose of this SOP is to define the procedure for monitoring of drain points by analysis of pathogens.

2. **Scope:** This SOP is applicable to monitoring of pathogens in drain points at production, warehouse and quality control department.

3. **References, Attachments & Annexures:**
   3.1. **References:**
      3.1.1. In-house
      3.1.2. Receipt, storage, growth promotion test, use and disposal of microbiological media
   3.2. **Attachments:**
      3.2.1. Attachment-1: Drain points sampling schedule
      3.2.2. Attachment-2: Monitoring of Pathogens
   3.3. **Annexures:**
      3.3.1. Annexure-1: List of drain points

4. **Responsibilities:**
   4.1. **Microbiologist:**
      4.1.1. To perform the activity as per SOP.
      4.1.2. To maintain all the records as per SOP.
   4.2. **QC Head or designee:**
      4.2.1. To check the SOP.
      4.2.2. To give training to all concerned persons before implementation of SOP.
   4.3. **Quality Assurance:**
      4.3.1. To check the SOP.
      4.3.2. To ensure the implementation of system as per SOP.
   4.4. **Regulatory Affairs, Quality Head , Plant Head:**
      4.4.1. To review and approve the SOP.

5. **Distributions:**
   5.1. Quality Assurance
   5.2. Quality Control(Microbiology)

6. **Definitions of terms & Abbreviations:**
   6.1. **Definitions of terms:** None
   6.2. **Abbreviations:**
      6.2.1. &   : And
      6.2.2. %   : Percent
      6.2.3. A.R. No. : Analytical Report Number
      6.2.4. CAB   : Cetrimide Agar Base
      6.2.5. ID No. : Identification Number
      6.2.6. MSA   : Mannitol Salt Agar
      6.2.7. MA   :MacConkey Agar
      6.2.8. XLDA   :Xylose lyseine dextrose agar

	PHARMA DEVILS	
	MICROBIOLOGY DEPARTMENT	

STANDARD OPERATING PROCEDURE

Department: Microbiology	**SOP No.:**
Title: Monitoring of drain points by analysis of pathogens	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

      6.2.9. No.   : Number
      6.2.10. SCDM   : Soyabean Casein Digest Medium
      6.2.11. Sr. No. : Serial Number
      6.2.12. Temp.   : Temperature
      6.2.13. v/v   : Volume/volume
      6.2.14. w/v   : Weight/volume

7. **Procedure:**
    7.1. **Precautions:**
        7.1.1. Wear the hand gloves and nose mask while sampling.
    7.2. **General:**
        7.2.1. Dispense and prepare the required volume of Cetrimide agar, MacConkey agar, Xylose lyseine dextrose agar, Mannitol Salt agar and 0.9% w/v saline as per SOP of media preparation and sterilization.
        7.2.2. Arrange the sterile swabs in pre-sterilized stainless steel container or sterile polybag and cover to avoid contamination.
        7.2.3. Enter the production area, warehouse area and quality control as per respective entry procedures.
        7.2.4. Sample the swab as per drain points sampling schedule given in Attachment-1.
        7.2.5. Dip the sterile swabs in sterile 0.9% w/v saline, sample approximately 25 cm^2 area giving vertical and horizontal strokes from the drain points location given in Annexure-1.
        7.2.6. After collecting the sample from drain point, carefully keep the swab in test tube and plug the test tube with cotton plug.
        7.2.7. Each test tube shall be marked with details like Area/Location, ID No., Date of sampling & initial signature of microbiologist.
        7.2.8. Exit the production, warehouse & quality control area as per respective procedures.
        7.2.9. Streak the swab on the surface of Cetrimide agar, MacConkey agar, Xylose lyseine dextrose agar, Mannitol Salt agar.
        7.2.10. Incubate the positive and negative plates along with drain point monitoring plates at 30-35°C for 18-72 hrs.
        7.2.11. Record the result in Attachment-2 of monitoring of pathogens in drain point
        7.2.12. Refer annexure-1 for list of drain points.

        7.2.13. **Table – I: Characteristic colony morphology on selective media**

S.No.	Name of Pathogen	Name of Media	Incubation Temp. & Time
1.	*Escherichia coli*	MA	30-35°C for 18-72 hours
2.	*Salmonella*	XLDA	30-35°C for 18-72 hours
3.	*Staphylococcus aureus*	MSA	30-35°C for 18-72 hours
4.	*Pseudomonas aeruginosa*	CA	30-35°C for 18-72 hours

STANDARD OPERATING PROCEDURE

Department: Microbiology	**SOP No.:**
Title: Monitoring of drain points by analysis of pathogens	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

7.2.14. **Table – II: Characteristic colony morphology on selective media**

S.No.	Name of media	Colony morphology
1.	MacConkey Agar	Pink to red mucoid colonies
2.	Cetrimide Agar	Generally greenish colonies
4.	Xylose lyseine dextrose agar	Red colonies with or without black centers
5.	Mannitol Salt Agar	Yellow colonies with yellow zones

7.3. **Acceptance criteria:**
   7.3.1. Pathogens should be absent.

7.4. **Frequency:**
   7.4.1. Half Yearly ± 15 Days

STANDARD OPERATING PROCEDURE

Department: Microbiology	**SOP No.:**
Title: Monitoring of drain points by analysis of pathogens	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment-1
Drain points Sampling Schedule

Month: …................ **Frequency:** Half Yearly ± 15 Days

Date	Drain Point ID No.	Sampled By/Date	Remarks

Prepared by:	Checked by:	Approved by:
Date:	Date:	Date:

STANDARD OPERATING PROCEDURE		
Department: Microbiology	**SOP No.:**	
Title: Monitoring of drain points by analysis of pathogens	**Effective Date:**	
Supersedes: Nil	**Review Date:**	
Issue Date:	**Page No.:**	

Attachment-2
Monitoring of Pathogens

Sampling location		**Date of Analysis**	
Date of sampling:		**Date of Observation:**	
Pathogens	**Media Lot No.**		
E.coli			
Salmonella			
Staphylococcus aureus			
Pseudomonas aeruginosa			

Location	**Pathogens**			
	E.Coli	*Salmonella*	*S. aureus*	*P. aeruginosa*
Positive control:	**Negative control:**			

Analysed By:	**Checked By:**

STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Monitoring of drain points by analysis of pathogens	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Annexure-1
List of drain points

S. No.	Drain Point ID No.	Area/Location	S. No.	Drain Point ID No.	Area/Location

Prepared by:	Checked by:	Approved by:
Date:	Date:	Date:

8. **History:**

Version No.		Effective Date	