



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Microbial Monitoring of Drainage in Manufacturing Area

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 4

1.0 OBJECTIVE

To lay down procedure for microbial monitoring of drainage in manufacturing area.

2.0 SCOPE

This SOP is applicable for drainage monitoring in manufacturing area.

3.0 RESPONSIBILITY

Prepared by - Executive Microbiology

Checked by - Assistant Manager Microbiology / QC

Approved by - Head QA, QC

4.0 PROCEDURE

4.1 Monitor monthly each drain of manufacturing area for microbiological contamination.

4.2 The drains are monitored for *Escherichia coli*, *Salmonella spp.*, *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

Frequency	Acceptance Criteria
Monthly	<i>Escherichia coli</i> , <i>Salmonella</i> , <i>Staphylococcus aureus</i> and <i>Pseudomonas aeruginosa</i> should be absent

4.3 Collect approx 20 ml of drain sample in sterile container from the drainage by using a sterile pipette before the sanitization and disinfection of drain.

4.4 Label the sampling container as per Annexure - I.

4.5 Test the sample for microbial limit test as per standard test procedure and record the observation as per Annexure - II.

4.6 If any sample fails to meet the acceptance criteria follow the procedure mentioned below.

4.7 Investigate the result by reviewing the data available for test procedure, laboratory environment monitoring, sampling procedure, sample handling and storage and analyst qualification.

4.8 If any discrepancies are found, invalidate the original results and reconfirm the data by resampling.

4.9 Simultaneously inform to QA / Production/ House keeping Dept. to investigate the root cause by reviewing the data available of maintenance, cleaning and sanitisation to take appropriate corrective and preventive actions as required.

4.10 Identify the colonies present on the plate based on morphological character. If any new colonies other than routine micro flora are observed, isolate and identify the organism as per SOP.

4.11 Annually prepare a review report of all the drains.



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5.0 SAFETY & PRECAUTIONS

Not Applicable

6.0 REVISION HISTORY

Revision No.	Reason for Revision	Superseded from & date
00	First Issue	-----

7.0 REFERENCES

SOP.

8.0 ABBREVIATIONS

SOP : Standard Operating Procedure

QA : Quality Assurance

mL : Milliliter

9.0 ANNEXURES

Annexure - I : Label for sampling container

Annexure - II : Observation of microbiological monitoring of drainage



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ANNEXURE - I LABEL FOR SAMPLING CONTAINER

Label For Sampling Container

Sample: _____

Drain ID No.: _____

Date of Sampling: _____

Sampled by: _____



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ANNEXURE - II

OBSERVATION OF MICROBIOLOGICAL MONITORING OF DRAINAGE

Date of Sampling: _____ Time of Sampling: _____

Sampling Done By: _____

Date of Testing: _____ Date of Result: _____

Media	Sterilized Medium Lot No.	Media	Sterilized Medium Lot No.
Fluid Lactose Medium		Brilliant Green Agar Medium	
MacConkey Agar Medium		Xylose Lysine Deoxycholate Agar Medium	
Levine - Eosine Methylene Blue Agar Medium		Cetrimide Agar Medium	
Mannitol Salt Agar Medium		Pseudomonas Agar Medium for detection Fluorescin	
Fluid Tetrathionate Broth		Pseudomonas Agar Medium for detection Pyocyanin	
Baird Parker Agar Medium		Fluid Selenite Cystine Medium	
Fluid Soyabean Casein Digest Medium		Vogel Johnson Agar Medium	
Triple Sugar Iron Agar Medium		Bismuth Sulphite Agar Medium	

Result -

S. No.	Location	Drain No.	Pathogens			
			<i>Escherichia coli</i>	<i>Staphylococcus aureus</i>	<i>Salmonella spp.</i>	<i>Pseudomonas aeruginosa</i>
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
- ve Control						
+ ve Control						

Remarks: The above sample complies / does not complies to the laid down specification.

Tested By:

Date:

Checked By:

Date: