



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Microbiological Monitoring of Drain Traps in Injection Block	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for Microbiological Monitoring of Drain Traps.

2.0 SCOPE:

This SOP is applicable for Microbiological Monitoring of Drain Traps in Injection Block of Quality Control Area.

3.0 RESPONSIBILITY:

Officer / Executive - Microbiologist

4.0 ACCOUNTABILITY:

Head – QC

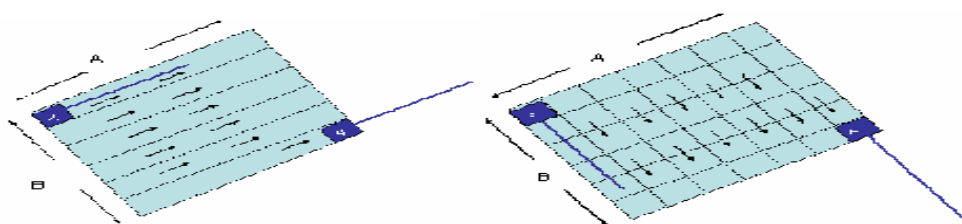
5.0 PROCEDURE:

5.1 SAMPLING:

5.1.1 Take the required quantity of swab stick and aseptically add sterile 10 ml of 0.9% saline solution, in each of individual swab tubes and kept in SS container.

5.1.2 After Cleaning & Sanitization take swab stick and rub on the Drain Traps in unidirectional to cover approx 5x5 cm area which is to be monitored. During swabbing swab should not be overlapped, it should be discontinuous. After sampling sanitize the sampled area using filtered 70% IPA.

5.1.3 Label the sample swab with drain point number, date and time and after this transfer the sample to Microbiology Laboratory for further analysis.



5.2 TEST FOR SPECIFIED MICROORGANISMS:

5.2.1 Pretreatment of Sample:

5.2.1.1 Filter 10 ml of swab sample and insert in 90ml Soyabean Casein Digest Broth Medium or soya lecithin Broth.

5.2.1.2 **Incubate** the medium at 30-35⁰C for 18-24 hrs.

5.2.2 Test for Escherichia coli:



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5.2.2.1 Shake the tube and transfer 1 ml of pretreated sample (SCM) to 100 ml of Macconkey Broth and incubate 42 to 44°C for 24 to 48 hrs.

5.2.2.2 Streak a portion from MacConkey broth on the surface of MacConkey Agar media and incubate 30 to 35°C for 18 to 72 hrs.

5.2.2.3 Upon examination, if none of the colonies confirm to the description given in Table-1, the sample meets the requirements for the absence of the E. coli.

5.2.2.4 Run Positive and Negative Control with test.

5.2.3 Test for Salmonella spp.:

5.2.3.1 Shake the tube and transfer 0.1 ml of pretreated sample to 10 ml of Rappaport Vassiliadis Salmonella Enrichment Broth and incubate at 30 to 35°C for 18 to 24 hrs.

5.2.3.2 Streak a portion from the Rappaport Vassiliadis Salmonella Enrichment Broth on surface of Xylose Lysine Deoxycholate Agar Medium and incubate 30 to 35°C for 18 to 48 hrs.

5.2.3.3 Upon examination, if none of the colonies confirm to the description given in Table-1, the sample meets the requirements for the absence of the Salmonella spp.

5.2.3.4 Run Positive and Negative Control with test.

5.2.4 Test for Pseudomonas aeruginosa:

5.2.4.1 Shake the tube and streak one loop full pretreated sample (SCM) on to the plate of Cetrinide Agar Medium and incubate 30 to 35°C for 18 to 72 hrs.

5.2.4.2 Upon examination, if none of the colonies confirm to the description given in Table-1, the sample meets the requirements for the absence of the Pseudomonas aeruginosa.

5.2.4.3 **Oxidase Test:** If growth of suspected colonies occurs, place suspected colony on the oxidase disc or paper strips or discs that previously had been impregnated with N, N-dimethyl-p-phenylenediamine dihydrochloride. If there is no development of a pink color, changing to purple color, the sample meets the requirements of the test for absence of *Pseudomonas aeruginosa*.

5.2.4.4 Run Negative Control with test.

5.2.5 Test for Staphylococcus aureus:



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5.2.5.1 Shake the tube and streak one loop full pretreated sample (SCM) on to the plate of Mannitol Salt Agar Medium and incubate at 30 to 35⁰C for 18 to 72 hrs.

5.2.5.2 Upon examination, if none of the colonies confirm to the description given in Table-1, the sample meets the requirements for the absence of the Staphylococcus aureus.

5.2.5.3 Run Negative Control with test.

5.2.6 Test for Bile-Tolerant Gram-Negative Bacteria (Enterobacteria):

5.2.6.1 **Transfer** 1 ml of sample to 100 ml Enterobacteria Enrichment Broth Mossel. Incubate the medium at 30 to 35⁰C for 24 to 48 hrs.

5.2.6.2 After Incubation, Subculture on the plate of Violet Red Bile Glucose Agar and incubate at 30 to 35⁰C for 18 to 24 hrs.

5.2.6.3 Upon examination, if none of the colonies confirm to the description given in Table-1, the sample meets the requirements for the absence of Enterobacteria.

5.2.6.4 Run Negative Control with test.

5.2.7 **Frequency of Monitoring:** Each drain point should be monitored at fortnightly basis in each month. If Monitoring of Drain is due on holiday or weekly off in such case monitoring should be performed one day before or next working day including scheduled drain point monitoring.

5.2.8 ACCEPTANCE CRITERIA:

Specified Microorganisms – *Escherichia coli*, *Salmonella spp.*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Bile-Tolerant Gram-Negative Bacteria (Enterobacteria)* should be absent.

5.2.9 Drain point sampling shall be done as per Drain Point Sampling Schedule as shown in Annexure-III, Titled “**Drain Point Sampling Schedule**”.



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TABLE-1

Specified Microorganism	Media Name	Positive Growth Characteristics	Gram Staining Characteristics
<i>E. coli</i>	MacConkey Broth	Medium colour turns to yellow.	Gram Negative Rod
	MacConkey Agar	Pink/red coloured non-mucoid colonies.	
<i>Salmonella</i>	Rappaport Vassiliadis Salmonella Enrichment Broth	Medium colour turns to reddish pink.	Gram Negative Rod
	Xylose lysine Deoxycholate Agar	Red colonies with or without black centers.	
<i>Pseudomonas aeruginosa</i>	Cetrimide Agar	Greenish yellow colonies	Gram Negative Rod
<i>Staphylococcus aureus</i>	Mannitol Salt Agar	Yellow colonies surrounded by yellow zones.	Gram Positive Cocci
<i>Bile Tolerant Gram Negative Enterobacteria</i>	Enterobacteria Enrichment Broth, Mossel	Medium colour turns to yellow.	Gram Negative
	Violet Red Bile glucose Agar	Pink/red colonies	

6.0 REFERENCES:

Drug and Cosmetic Act 1940, Schedule M

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure – I	Sample Receipt and Analysis Record for Drain Swab Sample	
Annexure – II	Drain Sample Analysis Report	
Annexure – III	Drain Point Sampling Schedule	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance Department
- Controlled Copy No. 02 Quality Control Department
- Master Copy Quality Assurance Department



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9.0 ABBREVIATIONS:

µm	Micrometer
cfu	Colony Forming Unit
CTA	Cetrimide Agar
Hrs.	Hours
IPA	Isopropyl Alcohol
LAF	Laminar Air Flow
ml	Milliliter
No.	Number
QA	Quality Assurance
QC	Quality Control
SCA	Soyabean Casein Digest Agar
SOP	Standard Operating Procedure
XLA	Xylose lysine Deoxycholate Agar

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Details of Changes	Reason for Change	Effective Date	Updated By



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ANNEXURE – II DRAIN SAMPLE ANALYSIS REPORT

Date of Sampling						
A. R. No						
Sampling Points						
Volume sampled						
Date of Testing						
Tested By						

Test : Test for Specified Microorganisms **Date of Test:** _____

Enrichment of Sample:

Test Method :

Name of media : Soyabean Casein Digest Medium or soya lecithin broth

Volume of Sample : 1 ml

Media Reference No.:

Incubator Temp. : 30-35⁰C for 18 - 24 hrs

Incubation ID No. :

Date of Incubation : **Date of Observation** :

Sampling Points							Positive control	Negative control
Observation								

Remarks:

...



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1.0 Test for *Escherichia coli*:

(I) Date :.....

Name of media : MacConkey Broth

Media Reference No.:

Incubation Temp. : 42-44⁰C for 24 -48 hrs

Incubator ID No. :

Date of Incubation :.....

Date of Observation:

Sampling Points							Positive control	Negative control
Observation								

(II) Date:

Name of Media : MacConkey Agar

Media Reference No:

Incubation Temp.: 30-35⁰C for 18 - 72 hrs

Incubator ID No. :

Date of Incubation:.....

Date of Observation. :

Sampling Points							Positive control	Negative control
Observation								

Remarks:.....

2.0 Test for *Salmonella spp*:

(I) Date.....

Name of Media: Rappaport Vassialiadis Enrichment Broth **Media Reference No.**.....

Incubation Temp. : 30-35⁰C for 18 - 24 hrs

Incubator ID No. :

Date of Incubation :.....

Date of Observation. :

Sampling Points							Positive Control	Negative Control
Observation								

(II) Date.....

Name of media: Xylose Lysine Deoxycholate Agar **Media Reference No.**.....



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Incubation Temp. : 30-35⁰C for 18 - 48 hrs.

Incubator ID No. :

Date of Incubation.....

Date of Observation.....

Sampling Points							Positive control	Negative control
Observation								

Remarks:.....

3.0 Test for *Pseudomonas aeruginosa*

Date :

Name of Media: Cetrimide Agar

Reference No:.....

Incubation Temp.: 30-35⁰C for 18 - 72 hrs

Incubator ID No. :

Date of Incubation:.....

Date of Observation:

Sampling Points							Positive control	Negative control
Observation								

Name of Test Reagent: N, N-dimethyl-p-phenyldiamine dihydrochloride (Strips / Discs)

Oxidase Test:

Date.....

Sampling Points							Positive control	Negative control
Observation								

Remarks:.....



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Remarks:.....

...

CONCLUSIONS:

Test Organism	Sampling Points					
<i>E. coli</i>						
<i>Salmonella spp.</i>						
<i>P. aeruginosa</i>						
<i>S. aureus</i>						
<i>Bile – Tolerant Gram Negative Bacteria (Enterobacteria)</i>						

Comments:.....

.....

- ve = No Growth with specified colony characteristic or specified negative response which indicate absence of specified organism (s) or Negative Test

Remarks: The above sample complies/does not comply as per IH specification.

Microbiologist:

Date:

Checked by:

Date:



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ANNEXURE – III DRAIN POINT SAMPLING SCHEDULE

Location	Sampling Point Location	Sampling Point ID No.	Frequency (Fortnightly)						
			1	2	3	4	5	6	7
			9	10	11	12	13	14	15
			16	17	18	19	20	21	22
			23	24	25	26	27	28	29
First Floor (Dry Powder)	Production Janitor		√						
	Dress Wash		√						
	Unit Preparation Room		√						
	Equipment Washing		√						
	Vial Washing		√						
	Packing Janitor Room		√						
First Floor (Three Piece)	CIP/SIP room			√					
	MFG -1			√					
	MFG-2			√					
	Unit preparation			√					
	Garment washing			√					
	Equipment washing			√					
Ground Floor (Ampoule Line)	Janitor				√				
	Ampoules washing area				√				
	Autoclave area				√				
	Equipment washing area				√				
	Garment washing area				√				
	CIP/SIP room				√				
	Manufacturing area				√				
	Terminal sterilizer				√				
	Ampoules leak test				√				

Prepared By:
Officer / Executive-QC
(Sign & Date)

Checked By:
Manager-QC
(Sign & Date)

Approved By:
Head QA
(Sign & Date)