

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Microbiology	SOP No.:			
Title: Microbial Limit Test of Water, Non-Sterile Product & Material	Effective Date:			
Supersedes: Nil	Review Date:			
Issue Date:	Page No.:			

1.0 **OBJECTIVE**:

To lay down the Harmonised procedures for enumeration of Total aerobic Microbial count, total combined yeast and mould count and microbiological examination of specified microorganisms for Water, Raw material, In Process and finished product & stability sample.

2.0 SCOPE:

This procedure applies to carry out total aerobic microbial counts, total combined yeast and mould counts and microbiological examination of specified microorganisms for Water, Raw material, intermediates and finished product & stability sample.

3.0 RESPONSIBILITY:

Q.C- Microbiologist.

Head -Quality Control.

4.0 PROCEDURE:

4.1 **For Water:** Refers SOP for Microbiological Enumeration method.

For Non Sterile Product / Material: Refer GTP Test for Total Aerobic Microbial Count As per Harmonized and IP method.

- 4.2 Record the result for water in Annexure-II and For Non sterile Product / Material in Annexure-III.
- 4.3 For Microbiological Examination of Specified Microorganisms:
- 4.4 Refer GTP Test for Specified Microorganisms As per Harmonized and IP method.

Examined Sample should be free from following specified microorganisms as below:

- 1) Escherichia coli.
- 2) Salmonella spp.
- 3) Staphylococcus aureus.
- 4) Pseudomonas aeruginosa.
- 5) Shigella boydii
- 6)Bile tolerant Gram negative bacteria



MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Microbiology	SOP No.:			
Title: Microbial Limit Test of Water, Non-Sterile Product & Material	Effective Date:			
Supersedes: Nil	Review Date:			
Issue Date:	Page No.:			

7) Candida albicans

- 8) Clostridium Sporogenes
- 9) Or As per individual monographs
- 4.5 For investigation of any out of specification test result follow the SOP.

5.0 ANNEXURE (S):

Annexure –I: Sample Inward register for Microbiological Examination of Non-sterile product / material

Annexure-II: Analytical Test Report for Microbiological examination of Water

Annexure- III: Analytical Test Report for Microbiological examination of Non-Sterile Products / Material.

6.0 REFERENCE (S):

GTP: Test for Total Aerobic Microbial Count As Per Harmonized and IP Method.

GTP: Test for Specified Microorganisms As Per Harmonized and IP Method.

Pharmacopoeia: As per current version of IP, BP, USP and European Pharmacopoeia.

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

SOP: Sampling, Testing, Release & Rejection of Water.

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

7.0 ABBREVIATION (S) / DEFINITION (S):

GTP: General test procedure.

SOP: Standard Operating Procedures

Q.C.: Quality control.

QCM: Quality Control Micro.

IP: Indian Pharmacopoeia

BP: British Pharmacopoeia

USP: United States Pharmacopoeia



MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Microbiology	SOP No.:			
Title: Microbial Limit Test of Water, Non-Sterile Product & Material	Effective Date:			
Supersedes: Nil	Review Date:			
Issue Date:	Page No.:			

EP: European Pharmacopoeia

TAMC : Total Viable Aerobic Microbial Count (TAMC)

TYMC: Total Yeast and Mould Count (TYMC)

REVISION CARD

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



MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Microbiology	SOP No.:			
Title: Microbial Limit Test of Water, Non-Sterile Product & Material	Effective Date:			
Supersedes: Nil	Review Date:			
Issue Date:	Page No.:			

Annexure 1 SAMPLE INWARD REGISTER FOR MICROBIOLOGICAL EXAMINATION OF NON STERILE PRODUCT/ MATERIAL

S.No.	Name of Product/Material	Batch No.	Mfg. Date	Exp. Date	A.R.No.	Sample Received Date	Testing Date	Test Completion Date	Analyzed by	Remar ks



MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Microbiology	SOP No.:			
Title: Microbial Limit Test of Water, Non-Sterile Product & Material	Effective Date:			
Supersedes: Nil	Review Date:			
Issue Date:	Page No.:			

Annexure 2 ANALYTICAL TEST REPORT FOR MICROBIOLOGICAL EXAMINATION OF WATER

MICROBIAL LIMIT TEST REPORT								
Types of Water:	ater: A.R.				A.R. No.:			
Sample Point No:				ampled b	y:			
Date of Testing:			D	ate of Re	port :			
Specification No.:			G	TP No.:				
A)TOTAL AEROBI	IC MICROBIAL	COUNT (TAM	(C)	1				
Method used: Membrane Filtration method								
Wiceliou useu.	Pour plate metho	od						
Media used:	B.No/ Lot. No.:	Autoclave Load No.		Incuba	tor ID.		bated at perature	
Observation:	Positive control:			Negative Control:				
PLATE-1:		PLATE-2:		Average Count:				
RESULT:	Average count x	Dilution factor	=	CFU/ml				
Limit:		CFU/ml		Observed by:				
B)TOTAL YEASTS	AND MOULDS	COUNT (TYM	(C):					
Method used:								
Media used:	Lot. No.:	Autoclave Load No.		Incuba	tor ID.	Incu	bated at:	
OBSERVATION:	Positive control	•		Negative	e Control:			
PLATE-1:		PLATE-2:	•		Averag	ge Count:		
RESULT:	Average count x	Dilution factor	=		CFU/m	nl		
Limit:		CFU/ml	Ob	served by	7:			



Primary test

PHARMA DEVILS

	STANDAI	RD OPERATING	FPROCE	EDURE			
rtment: Microbiology	y			SOP No.:			
Microbial Limit Test	of Water, Non-St	erile Product & M	Iaterial	Effective Date:			
rsedes: Nil				Review Date:			
Date:				Page No.:			
C)TEST FOR SPEC	CIFIED MICRO-C	ORGANISMS:					
Enrichment for Pa							
Media used:	B.No. / Lot. No.:	Autoclave Load No.	Inc	cubator I.D	Incubated at		
	Lot. 110	Load 140.					
Positive control:		Negative Contro	.]•	Observed by	•		
Toshive control.				Observed by	•		
i)TEST FOR Esche	erichia coli						
Primary Test:							
	B.No./Lot.	Autoclave	_	1 / ID	T 1 (1		
Media used:	No.:	Load No	Inc	cubator ID.	Incubated a		
Observation:	Growth observ	red / not observed					
Positive control:	Negat	ive Control:		Observed by:			
Secondary Test:							
Media used:	B.No./Lot. No.	.: Autoclave Load No.	In	cubator ID.	Incubated a		
		Load No.					
Observation:	Cuaryth absory	ed / not observed					
Positive control:	Nega	tive Control:		Observed by:			
Confirmative Test:							
Media used:	B.No./Lot. No	Autoclave	In	cubator ID.	Incubated a		
	2.12.12.00.110	" Load No.					
Observations	Crowth shares	ad / not absorved					
Observation:		red / not observed	T a-				
Positive control:	Negative Conti	rol:	Observe	ed by:			



MICROBIOLOGY DEPARTMENT

		STANDARD	OPERA.	TING	PROCE	DURE		
Depar	rtment: Microbiology		SOP No.	:				
Title:	Microbial Limit Test	of Water, Non-Steril	e Produc	ct & Mat	terial	Effective Date:		
Super	rsedes: Nil					Review I	Pate:	
Issue	Date:					Page No.	:	
	Media used:	B.No./Lot. Autoclave Incul			oator ID.	Iı	ncubated at	
	Observation:	Growth observed	l / not ob	served				
	Positive control:	Negative Control	l :	Observ	ed by:			
	Secondary Test:							
	Media used:	B.No. / Autoclave Lot. No.: Load No.				Incubator ID. Incubated at		
	Observation:	Growth observed	/ not obs	erved				
	Positive control:	Negative Control:		Observ	ed by:			
	Confirmative Test:	D No. /	A ==4 a	clave				
	Media used:	B.No. / Lot. No.:	Incubator ID. Inc			Incubated at		
	Observation:	Growth observed	/ not obs	erved				
	Positive control:	Negative Control: Observed by:						
	iii)TEST FOR Staph	nylococcus aureus:						
	Primary test							
	Media used:	B.No./Lot. No.:	Autoc Load		Incub	ator ID.	Iı	ncubated at
	Observation:	Growth observed	l / not ob	served				

Observed by:

Negative Control:

Positive control:



MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Microbiology	SOP No.:			
Title: Microbial Limit Test of Water, Non-Sterile Product & Material	Effective Date:			
Supersedes: Nil	Review Date:			
Issue Date:	Page No.:			

Confirmative Test : Coagulase Test							
Media used:	B.No. / Lot. No.:	Autoclave Load No.		Autoclave Load No.		Incubator ID.	Incubated at
Observation:	Growth observed / not observed						
Positive control:	Negative Control: Obs			Observed by:			
	•		•				

iv)TEST FOR Pseudomonas aeruginosa:										
Primary test										
Media used:	B.No./Lot. No.:		ve Load o.	Incubator ID.	Incubated at					
Observation:	Observation: Growth observed / not observed									
Positive control:	Negative Contro	ol:	Observed by:							

Secondary Test :							
Media used:	B.No. / Lot. No.:	Autoc	elave Load No.	Incubator ID.	Incubated at		
Observation:	Growth observed / not observed						
Positive control:	Negative Control:		Observed by:				

Confirmative Test : Oxidase Test									
Media used:	B.No. / Lot. No.:	Autoc	elave Load No.	Incubator ID.	Incubated at				
Observation:	Growth observed / not observed								
Positive control:	Negative Control:		Observed by:						

Remarks: The Above water sample complies/does not comply as per Specification.



MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE							
Department: Microbiology	SOP No.:						
Title: Microbial Limit Test of Water, Non-Sterile Product & Material	Effective Date:						
Supersedes: Nil	Review Date:						
Issue Date:	Page No.:						

Annexure 3 ANALYTICAL TEST REPORT FOR MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCT / MATERIAL

STERILE PRODUCT / MATERIAL									
MICROBIAL LIMIT TEST REPORT									
Product / Material N	A.	R. No.:							
Batch No.:			Sa	mpled Da	te:				
Date of Testing:			Da	ate of Repo	ort :				
Specification No.:			G	TP No.:					
Sample Preparation: Weigh and transferg orml sample toml Soybean Casein Digest Medium (SCDM)(MEDIA Ref No. (T))Give heat treatment at 40°C - 45°C for NMT 30 Min. if necessary. For Pour Plate Take 1ml of Pretreatment SCDM (T) in duplicate plate OR For membrane filtration take 10ml of pretreated SCDM (T) followed by washing withml of Buffered Sodium Chloride Peptone Solution (BSCP) for each test									
A)TOTAL AEROBI			(C):						
Method used:	Membrane Filtra Pour plate metho								
Media used:	B.No/ Lot. No.:	Autoclave Load No.		Incubator ID.			ibated at perature		
ODCEDVATION	D '''		N.T.	4° G	4 1				
OBSERVATION:	Positive control		Neg	gative Con		<u> </u>			
PLATE-1:		PLATE-2:				e Count :			
RESULT:	Average count x		=		CFU/	ml			
Limit:		CFU/ml	· ~ `	Observe	d by:				
B)TOTAL YEASTS Method used:	AND MOULDS	COUNT (TYM	<u>(C):</u>						
Media used:	Lot. No.:	Autoclave Load No.		Incubator ID.		Incu	bated at:		
OBSERVATION:	Positive control	<u> </u>		Negative (Control:	<u> </u>			
PLATE-1:		PLATE-2:			Averag	ge Count:			
RESULT:	Average count x	Dilution factor :			CFU/m	nl			
Limit:		CFU/ml	Obs	served by :					
		·				·	·		



	STANDAR	RD OPERATING	PROCI	EDURE	
partment: Microbiology		SOP No.:			
le: Microbial Limit Test	aterial	Effective Date	:		
persedes: Nil				Review Date:	
ue Date:				Page No.:	
TEST FOR SPECI Sample Preparation Inoculate the sample C)TEST FOR SPECI Enrichment for Parameters of the sample of	n: Take	gm Sample for Sol diluents or mediu		ml Sample	for liquid.
Media used:	B.No. / Lot. No.:	Autoclave Load No.	Inc	cubator I.D	Incubated at:
Positive control:		Negative Control	:	Observed by:	
i)TEST FOR Escher	ichia coli				
Primary Test:					1
Media used:	B.No./Lot. No.:	Autoclave Load No	In	cubator ID.	Incubated at
Observation: Positive control:		ed / not observed		Observed by:	
Tositive control.	ricgati	ive control.		Observed by.	
Secondary Test:					
Media used:	B.No./Lot. No.	: Autoclave Load No.	In	cubator ID.	Incubated at
Observation:	Growth observe	ed / not observed			
Positive control:	Negat	tive Control:		Observed by:	_
Confirmative Test:					
Media used:	B.No./Lot. No.	: Autoclave : Load No.	In	cubator ID.	Incubated at
Observation:	Growth observe	ed / not observed			
Positive control:	Negative Contr	ol:	Observe	ed by:	
ii)TEST FOR Salmo	nella:				
Primary test					



Positive control:

Negative Control:

Observed by:

PHARMA DEVILS

	STANDARD	OPER	ATING	PROCE	EDURE		
partment: Microbiology	7				SOP No.:	•	
tle: Microbial Limit Test of Water, Non-Sterile Product & Material					Effective	Date:	
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ue Date:					Page No.	:	
Media used:	B.No./Lot. No.:		Autoclave Load No.			bator ID. Incubat	
Observation:	Growth observe	d / not ok	acarvad				
Positive control:	Negative Contro	ol:	Observ	ed by:			
Secondary Test: Media used:	B.No. / Lot. No.:		oclave d No.	Incubator ID. Incuba			
Observation:	Growth observed	/ not obs	erved				
Positive control:	Negative Control	:	Observ	ved by:			
Confirmative Test:							
Media used:	B.No. / Lot. No.:		oclave d No.	I	ncubator II).	Incubated at
Observation:	Growth observed	/ not obs	erved				
Positive control:	Negative Control	•	Observ	ved by:			
iii)TEST FOR Stapl	ylococcus aureus:						
Primary test							
Media used:	B.No./Lot. No.:	Autoc Load		Incub	oator ID.	I	ncubated at
Observation:	Growth observe	d / not ob	served				



MICROBIOLOGY DEPARTMENT

	STANDARD	OPERA	TING I	PROCE	DURE		
partment: Microbiology					SOP No.	:	
tle: Microbial Limit Test of Water, Non-Sterile Product & Material					Effective	Date:	
persedes: Nil					Review I	Date:	
ue Date:					Page No.	:	
Confirmative Test :	Coagulase Test						
Media used:	B.No. / Lot. No.:	Autoo Load		In	cubator ID).	Incubated at
Observation:	Growth observed	/ not obse	erved				
Positive control:	Negative Control	•	Observ	ed by:			
:v\TEST EOD Door	domonos o aureinoso						
IV)TEST FOR FSeu	domonas aeruginosa:						
Primary test							
Media used:	B.No./Lot. No.:	Autoclav No		Incub	ıbator ID. Iı		ncubated at
Observation:	Growth observe	d / not ob	served				
Positive control:	Negative Contro	ol:	Observ	ed by:			
Secondary Test:							
Media used:	B.No. / Lot. No.:	Autoc	clave Loa	d No.	Incubate	or ID.	Incubated at
Observation:	Growth observed	/ not obs	erved		•		
Positive control:	Negative Control	:	Observ	ed by:			
Confirmative Test:	Oxidase Test						
Media used:	B.No. / Lot. No.:	Autoc	clave Loa	d No.	Incubate	or ID.	Incubated at

Growth observed / not observed

Observed by:

Negative Control:

Observation:

Positive control:



		STANDARI	OPERA	TING I	PROCE	DURE			
Department	epartment: Microbiology					SOP No.:			
Title: Microl	Title: Microbial Limit Test of Water, Non-Sterile Product & Material					Effective Date:			
Supersedes:	Nil					Review D	Pate:		
Issue Date:						Page No.	:		
		obacteria (bile gram	negative	bacteria))				
Prim	ary test			T 1					
Medi	ia used:	B.No./Lot. No.:	Autoclay No		Incub	ator ID.	Iı	ncubated at	
Obse	rvation:	Growth observe	d / not ob	served					
Posit	ive control:	Negative Contro	ol:	Observe	ed by:				
Secon	ndary Test :								
1	Media used:	B.No. / Lot. No.:	Autoc	lave Loa	d No.	Incubato	or ID.	Incubated at	
Obse	rvation:	Growth observed	/ not obse	erved					
Posit	ive control:	Negative Control	:	Observ	ed by:				
Conf	irmative Test :								
ľ	Media used:	B.No. / Lot. No.:	Autoc	lave Loa	d No.	Incubate	or ID.	Incubated at	
Obse	ervation:	Growth observed	/ not obse	erved		l			
Posit	ive control:	Negative Control: Observed by:							
VI)T	EST FOR Shige	ella boydi							
Prim	ary test								
	Media used:	B.No./Lot. No.:	Autoclay No		Incub	ator ID.	Iı	ncubated at	



Observation:

PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE						
Department: Microbiology	SOP No.:					
Title: Microbial Limit Test of Water, Non-Sterile Product & Material	Effective Date:					
Supersedes: Nil	Review Date:					
Issue Date:	Page No.:					

Growth observed / not observed

Positive control:	Negative Control	:	Observed by:		
Secondary Test:					
Media used:	B.No. / Lot. No.:	Autoclave Load No.		Incubator ID.	Incubated at
Observation:	Growth observed /	not obse	erved		
Positive control:	Negative Control:		Observed by:		

Confirmative Test :							
Media used:	B.No. / Lot. No.:	Autoc	elave Load No.	Incubator ID.	Incubated at		
Observation:	Growth observed / not observed						
Positive control:	Negative Control:		Observed by:				

Remarks: The Product / Material **complies /does not comply** as per above mentioned Specification.