PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Sterility Test by Open System	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down the procedure for Sterility Test by Open System.

2.0 SCOPE:

This SOP is applicable for Sterility Test by open System in Microbiology Laboratory of Quality Control.

3.0 RESPONSIBILITY:

Officer / Executive – Microbiology

4.0 ACCOUNTABILITY:

Head – QC

5.0 ABBREVIATIONS:

CFU	Colony Forming Unit
DNA	D Engley Neutralizing Agar
Exp.	Expiry
FTM	Fluid Thioglycollate Medium
Ltd.	Limited
LAF	Laminar Air Flow
Mfg.	Manufacturing
NLT	Not Less Then
No.	Number
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
SCM	Soyabean Casein Digest Medium

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6.0 PROCEDURE:

6.1 Prerequisite for sterility test by direct inoculation or by membrane filtration method:

S.No.	Requirements
01	Cleaning Status
02	Sterile Manifold Assembly
03	Sterile Forceps
04	Sterile Scissor
05	Sterile Filtration assembly
06	Membrane filter 0.45 µ
07	Vacuum pump
08	Filtration flask
09	Pre incubated SCM tubes
10	Pre incubated FTM tubes
11	PPW/NS
12	0.2 µ filtered 70 % IPA
13	Primary gown
14	Sterile secondary Gown
15	Sterile Primary Gloves
16	Sterile Secondary Gloves
17	Sterile Mopper
18	Tray with Silvicide solution
19	Silicon pipe
20	Silicon pipe with cork
21	Sterile Goggle
22	Marker
23	Ampoule cutter
24	SS bucket
25	EM person availability
26	Sterile micropipette
27	Micro tips
28	Membrane filter 0.2 µ
29	Empty SS tray

6.1.1 After receiving the samples for sterility test, record the details of sample in sample receiving register e.g. Date of receipt, Product Name, Batch No., in **Annexure-I**, Titled **"Sample Receipt and Analysis Record for Sterility Test"**.

6.1.2 Collect all samples to be tested for the sterility test and transfer in SS sample tray; sanitize the external surface of all samples subjected for sterility test by using sporocidal disinfectant. and

mark the SS sample tray with details of sample e.g. product name, batch number and lot number and Transfer SS sample tray through dynamic pass box in sterility room.

6.1.3 Satellite sample of primary packing material (e.g. Sterile Rubber Bung, Three piece bottle, nozzle and cap) should be sanitized by sporocidal disinfectant. If pack received in triple pack; outer most pack shall be removed when transfer to dynamic pass box of respective area, second pack shall be removed during transfer from dynamic pass box to sterility testing room and third pack shall be removed under LAF.

6.1.4 Pre incubated SCM & FTM Tubes, SCA Plates, DNA contact plates, rinsing fluid 0.1% peptone water tube, Air sampler (if required) and other required material shall be transferred to dynamic pass box of Buffer zone.

6.1.5 Before enter in the sterility area; ensure pressure differential should be within limit.

6.1.6 Enter in Sterility Area as per SOP**,** title "Entry, Exit and Gowning Procedure for Sterility Area".

6.1.7 Check the temperature & Relative Humidity, of Sterility Area as per SOP and status of cleaning and fogging of sterility area before start the sterility test. If cleaning and fogging has been done, temperature and relative humidity within limit; perform the sterility test, if not, clean and fog the area.

6.1.8 Mop the LAF platform with sporocidal disinfectant & Start the LAF as per SOP for the operation of LAF. Ensure LAF should be 'switched ON' before 30 minutes prior the test if it is in switched OFF condition.

6.1.9 After completion of sterilization cycle the sterilized articles shall be unloaded from autoclave to mobile LAF and sterilized articles contained in mobile LAF shall be transferred from cooling zone to LAF of Sterility Room.

6.1.10 In case of oils preparation and oily solutions, use media with 0.1% v/v of polysorbate 80 or other suitable emulsifying agent, in an appropriate concentration, shown not to have any antimicrobial properties under the conditions of test.

6.1.11 The external surface of all samples, sampled in presterilized bottle should be sanitize by sporocidal disinfectant and transfer through dynamic pass box of Buffer zone to sterility testing area.

6.1.12 Frequently sanitize the hand with 0.22 µ filtered 70% IPA and LAF working station with sporocidal disinfectant during sterility test.

6.1.13 Before start the Sterility test label the SCM and FTM tube with marker for sample name and batch number.

6.1.14 Before starting sterility test expose the SCA plates at specified location throughout the testing as per SOP and Personnel monitoring shall be carried out after the completion of sterility test

by contact plate method as per SOP. After personnel monitoring, sanitize the hand gloves and contact site of boiler suit with 0.22 µ filtered 70% IPA by removing it in Air lock –V.

6.2 Sterility test by direct inoculation method:

6.2.1 Quantity of sample to be examined shall be transferred as prescribed in Table 1 & Table 2 directly into the culture medium (FTM & SCM) so that the volume of the product should not be more than 10% of the volume of the medium.

6.2.2 If product is solid transfer the quantity of a dry solid or prepare a suspension of the product by adding sterile diluent to the immediate container, corresponding to not less than the quantity indicated in Table 1 & Table 2. Transfer the material so obtained to 100 ml of FTM and mix. Similarly transfer the same quantity to 100 ml of SCM and mix label the SCM and FTM tube with marker for sample name and batch number.

6.2.3 In case of sterile devices, articles should be immersed intact or disassembled to ensure that device pathways are also in contact with media, immerse the appropriate number of units per medium in a volume of medium sufficient to immerse the device completely.

6.2.4 In case of sterile gloves take one pair of gloves and one hand gloves will be transferred into the sterile 400 ml of FTM, similarly second hand gloves will be transferred into the sterile 400 ml of SCM.

6.2.5 For Negative Control SCM & FTM Tube shall be incubated for 14 days.

6.2.6 After completion of work all inoculated media and other materials shall be transferred from dynamic pass box of incubation room and exit from sterility room as per SOP for Entry/ exit and Gowning Procedure for Sterility Room.

6.2.7 The FTM, SCM tubes, and Environmental Monitored plates shall be collected from dynamic pass box of incubation room and SCM / FTM tubes / container should be labeled as per **Annexure-IV**.

6.2.8 FTM tubes shall be incubated at 32.5°C ± 2.5°C and SCM tubes shall be incubated at 22.5°C ± 2.5°C for 14 days. SCA and DNA contact plates of environmental monitoring shall be incubated at 22.5°C ± 2.5°C for NLT 72 hrs and further 32.5°C ± 2.5°C for NLT 48 hrs.

6.2.9 Daily visual observation of all tested sample tubes including negative control of FTM & SCM shall be taken for 14 days.

6.2.10 Rosazurine Ring shall be verified for Fluid Thioglycolate medium at the time of sterility release.

6.2.11 If there is a holiday on the day of release/transfer of sterility tubes, take the observation/transfer of sterility tubes on next working day.

6.2.12 If material being examined renders the medium turbid so that the presence or absence of microbial growth cannot be determined by visual examination, fill NA in observation report

for 14 days, transfer aseptically 1ml portion of the medium to the another container / tube of 100 ml FTM, SCM medium after 14th day of incubation.

6.2.13 For Negative Control SCM & FTM Tube shall be incubated for NLT 04 days.

6.2.14 Continue incubation of transferred sample tubes along with original sample tubes and observation of all tested sample tubes including negative control of FTM & SCM shall be taken for NLT 4 additional days after transfer and for a total of NLT 18 days.

6.2.15 The observations of sterility test shall be recorded in **Annexure-II**, titled **"Sterility Test Report by Direct Inoculation Method"**.

6.3 Sterility test by membrane filtration method:

6.3.1 The filtration unit shall be assembled and connect the manifold assembly with reservoir properly with silicon rubber tubing and reservoir to vacuum pump with silicon rubber tubing. Filtration flask can also be use. Put the membrane filter (nominal pore size not greater than 0.45 µm and diameter about50 mm) between the filtration cup and receptacle.

6.3.2 The membrane filter shall be selected based on the characteristics of the product if the product having antimicrobial activity use cellulose nitrate with hydrophobic edge membrane, for aqueous, oil and weakly alcohol use cellulose nitrate membrane and for strong alcoholic solutions use cellulose acetate membrane.

6.3.3 Prior the test the membrane filter shall be wetted by adding approx. 20 ml of fluid A (Sterile 0.1 % peptone water) and filters the fluid by employing vacuum. Take the quantity of the container as per Table no. 1 & Table no. 2. Aseptically cut/remove the tip of bottle/vial and ampoule with sterile SS cutter/scissor and immediately transfer the required quantity of the sample (as per Table no. 2) to filtration flask, immediately filter the solution with the help of vacuum and rinse the membrane filter with 3 x 100 ml (or Number of washing fluid as per validation study) fluid A (Sterile 0.1 % peptone water).

6.3.4 In case of dry powder injection, the prescribed quantity shall be dissolved according to the table 1 & 2 of sample into the sterile 100 ml of fluid A (Sterile 0.1 % peptone water) or. Wet the membrane filter with approx. 20 ml of fluid A (Sterile 0.1 % peptone water) and filter the solution with the help of vacuum and wash the membrane filter with 3 x 100 ml (or Number of washing fluid as per validation study) of fluid A(Sterile 0.1 % peptone water).

6.3.5 For raw material the pooled sample shall be prepared from the total number of container and the sterility test shall be performed, dissolved the 6 gm of sample into the sterile 100 ml of fluid A (Sterile 0.1 % peptone water).. Wet the membrane filter with approx. 20 ml of fluid A (Sterile 0.1 % peptone water). and filter the solution with the help of vacuum and wash the membrane filter with 3 x 100 ml (or Number of washing fluid as per validation study) of fluid A(Sterile 0.1 % peptone water).

6.3.6 For rubber bung/flip off seal/glass vials/primary packing materials of Three Piece /FFS, take 20 nos. each, transfer aseptically in to presterilized bottle and transfer suitable Qty. of fluid A sufficient to immerse the sample completely, rinse the sample, after rinsing Wet the membrane filter with approx. 20 ml of fluid A, aseptically filter the sample with sterile filtration assembly with the help of vacuum and wash the membrane filter with 3 x 100 ml fluid A(Sterile 0.1 % peptone water).

6.3.7 For sterility testing of rubber bung/flip off seal/glass vials/primary packing materials of Three Piece /FFS, Depyrogenated ampoule during process validation batches and media fill take 20 nos. each and transfer suitable Qty. of fluid A (Sterile 0.1 % peptone water) directly to presterilized bottle containing sample sufficient to immerse the sample completely, rinse the sample after rinsing Wet the membrane filter with approx. 20 ml of fluid A (Sterile 0.1 % peptone water). ,aseptically filter the sample with sterile filtration assembly with the help of vacuum and wash the membrane filter with 3 x 100 ml of fluid A (Sterile 0.1 % peptone water).

6.3.8 For sterility testing of bulk sample during process validation/hold time study batches; wet the membrane filter with approx. 20 ml of fluid A (Sterile 0.1 % peptone water).transfer aseptically 100 ml of sample, sampled in presterilized bottle to filtration flask, immediately filter the solution with the help of vacuum and rinse the membrane filter with 3 x 100 ml (or Number of washing fluid as per validation study) of fluid A (Sterile 0.1 % peptone water).

6.3.9 Oils and oily solutions of sufficiently low viscosity may be filtered without dilution through a dry membrane Viscous oils may be diluted as necessary with a suitable sterile diluent such as 0.1% v/v iso-propyl myristate shown not to have antimicrobial activity in the conditions of the test and Allow the oil to penetrate the membrane by its own weight, then filter, applying the pressure or suction gradually. Wash the membrane three times by filtering through it about 100 ml of a fluid A (Sterile 0.1 % peptone water).

6.3.10 After completion of filtration, the vacuum shall be switched OFF and lift the SS cup carefully. Aseptically cut the membrane filter into two halves with sterile SS forcep and scissor and transfer one half to SCM tube and other one half to FTM tube with Sterile Forcep.

6.3.11 Similarly perform negative control test by using another filtration assembly, first wet the membrane filter with approx. 20 ml of fluid A (Sterile 0.1 % peptone water) and filter 100 ml of sterile fluid A (Sterile 0.1 % peptone water). After filtration aseptically cut the membrane filter into two halves with sterile SS forcep and scissor and transfer one half to SCM tube and other one half to FTM tube with sterile forcep. These tubes will serve as negative control and labeled as **Annexure-IV**.

6.3.12 After completion of work all inoculated media, Environmental Monitored plates and other materials shall be transferred from dynamic pass box of incubation room and exit from sterility area as per SOP for Entry/ exit and Gowning Procedure for Sterility Room.

6.3.13 The FTM, SCM tubes and environmental monitored plates shall be collected from dynamic pass box of incubation Room and Label the SCM / FTM tubes / container as **Annexure-IV.**

6.3.14 FTM tubes shall be incubated at 32.5°C ± 2.5°C and SCM tubes shall be incubated at 22.5°C ± 2.5°C for 14 days. Incubate SCA and DNA contact plates for environmental and personal monitoring shall be incubated at 22.5°C ± 2.5°C for NLT 72 hrs. and further shall be incubated at 32.5°C ± 2.5°C for NLT 48 hrs.

6.3.15 Daily visual observation of all tested sample tubes including negative control of FTM & SCM shall be taken and recorded for 14 days.

6.3.16 Rosazurine Ring shall be verified for Fluid Thioglycolate medium at the time of sterility release.

6.3.17 If there is a holiday on the day of release/transfer of sterility tubes, take the observation/transfer of sterility tubes on next working day.

6.3.18 The observations of sterility test shall be recorded in **Annexure-III**, Titled **"Sterility Test Report by Membrane Filtration Method"**.

6.4 Sterility Test by Direct Incubation During Media Fill:

6.4.1 For sterility testing of bulk sample during media fill study. the bottle containing media shall be incubated directly at 22.5°C ± 2.5°C for 7 days after it transfer and incubate to 32.5°C ± 2.5°C for further 7 days.

6.4.2 Daily visual observation of all incubated media bottle shall be taken and recorded for 14 days.

6.4.3 If there is a holiday on the day of release/transfer of sterility tubes, take the observation/transfer of sterility tubes on next working day.

6.4.4 The observations of sterility test shall be recorded in Annexure-V, Titled "**Sterility Test Report of Media Fill by Direct incubation".**

6.5 Sterility test by Modified Membrane Filtration Method for Tobaflam Eye Drops:

6.5.1 For sterility test 10 vials shall be collected at random as per sampling SOP.

6.5.2 Pre wet the membrane with approx15-20 ml of sterile 0.1% w/v peptone water.

6.5.3 10 ml of aqueous suspensions shall be transferred from the vials of Tobaflam eye drop directly into 100 ml sterile 0.1% Peptone water and filter it through filtration unit having filter of nominal pore size not greater than 0.45 µm and diameter about 50 mm with the aid of suction pump.

6.5.4 Rinse the filter membrane three times i.e. 3x100ml with the sterile 0.1% peptone water.

6.5.5 After rinsing, filter shall be divided aseptically into two parts of approximately equal surface area and transfer one part to FTM and the other part to SCM medium.

6.5.6 For negative control Pre wet the membrane with approx15-20 ml of sterile 0.1% w/v peptone water then take 100 ml sterile 0.1% Peptone water and filter it through filtration unit having filter of nominal pore size not greater than 0.45 µm and diameter about 50 mm with the aid of suction pump.

6.5.7 Aseptically divide the filter into two parts of approximately equal surface area and transfer one part to FTM and the other part to SCM medium.

6.5.8 FTM tube shall be incubated at 30 - 35°C and SCM tube incubated at 20 -25°C for 14 days.

6.5.9 Material being examined renders the medium turbid so that the presence or absence of microbial growth cannot be determined by visual examination; fill NA in observation report for 14 days.

6.5.10 1ml portion of the medium shall be transferred aseptically to another respective tube of 100 ml FTM, SCM medium after 14th day of incubation.

6.5.11 Incubation of transferred sample tubes along with original sample tubes shall be continued for NLT 4 additional days after transfer.

6.5.12 The test tubes shall be observed daily for NLT 4 days.

6.5.13 For Negative control SCM & FTM tubes will be incubated for NLT 4 days.

6.5.14 If there is a holiday on the day of release/transfer of sterility tubes, take the observation/transfer of sterility tubes on next working day.

6.5.15 The observations of sterility test shall be recorded in Annexure-VI, Titled "**Sterility Test Report by Modified Membrane Filtration Method".**

6.6 Results /Acceptance criteria for sterility test by direct inoculation or by membrane filtration method or by modified membrane filtration method:

6.6.1 During the incubation period examine the medium for macroscopic evidence of microbial growth. If no evidence of growth is found, sample being examined complies with the test for sterility.

6.6.2 If the evidence of growth is found, sample being examined does not comply with the test for sterility, unless it can be clearly demonstrated that the test was invalid for causes unrelated to the product to be examined. The test may be considered invalid under the following conditions:

6.6.2.1 The data of the microbiological monitoring of the sterility testing facility show a fault.

6.6.2.2 Review the testing procedure used during the test in question reveals a fault.

6.6.2.3 Microbial growth is found in the negative controls.

6.6.2.4 After identification of the microorganisms isolated from the test, the growth of this species may be ascribed unequivocally to faults with respect to the material and or the technique used in conducting the sterility test.

6.6.2.5 If the test is declared to be invalid, it shall be repeated with the same number of units as in the original test. If no evidence of microbial growth is found in the repeat test, the product complies with sterility test.

6.6.2.6 If microbial growth is found in the repeat test, the product examined does not comply with the test for sterility.

Table-1

Minimum Quantity to Be Used for Each Culture Medium

Quantity in each container of Injectable preparation	Minimum quantity to be used for each culture medium
For Liquids	
Less than 1 ml	Total contents of a container
1 ml to 40 ml	Half the contents of a container but not less than 1 ml
40 ml to 100 ml	20 ml
Greater than 100 ml	10% of the contents of a container but not less than 20 ml
Antibiotic liquids	1 ml
Insoluble preparations, creams and ointments to be suspended or emulsified	Use the content of each container to provide not less than 200 mg
For Solids	
Less than 50 mg	Total contents of a container
50 mg or more but less than 300 mg	Half the contents of a container but not less than 50 mg
300 mg to 5 g	150 mg
Greater than 5 g	500 mg
Other medical devices	The whole device, cut in to pieces or disassembled

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Table-2
Minimum Number of Articles to Be Used for Each Culture Medium

Number of item in the Batch	Minimum number of articles to be used for each culture medium
Parenteral preparation	
Not more than 100 containers	10 % or 4 containers, whichever is the greater
More than 100 but not more than 500 containers	10 containers
More than 500 containers	2 % or 20 containers, whichever is less
For large volume Parenteral	2 % or 10 containers, whichever is less
Antibiotic solids	
Pharmacy bulk packages(<5g)	20 containers
Pharmacy bulk packages(≥5g)	6 containers
Bulks and Blends	6 g
Ophthalmic and other non-Injectables preparation	
Not more than 200 containers	5 % or 2 containers, whichever is the greater
More than 200 containers	10 containers
Devices	
Catgut and other surgical sutures for veterinary use	2 % or 5packages, whichever is the greater, up to a maximum total of 20 packages
Not more than 100 articles	10 % or 4 articles, whichever is the greater
More than 100 but not more than 500 articles	10 articles
Bulk solid products	
Up to 4 containers	Each container
More than 4 but not more than 50 containers	20 % or 4 containers, whichever is the greater
More than 50 containers	2 % or 10 containers, whichever is the greater

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7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT NO.
Annexure – I	Sample Receipt and Analysis Record for Sterility Test	
Annexure – II	Sterility Test Report by Direct Inoculation Method	
Annexure – III	Sterility Test Report by Membrane Filtration Method	
Annexure – IV	Label For SCM/FTM Tubes under sterility observation	
Annexure – V	Sterility Test Report of Media fill by Direct incubation	
Annexure – VI	Sterility Test Report by Modified Membrane Filtration Method	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Microbiology
- Master Copy Quality Assurance

9.0 REFERENCES:

- United State Pharmacopoeia- 41 <71> Sterility Test
- Indian Pharmacopoeia 2014
- British Pharmacopoeia 2015

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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

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ANNEXURE – I
SAMPLE RECEIPT AND ANALYSIS RECORD FOR STERILITY TEST

Sr. No.	Product/ Material Name	Batch No.	Sample Quantity	Analytical Report No.	Sampling Date	Receiving date	Analysis Sign & Date	Release Sign & Date	Checked By Sign & Date	Received By	Remarks

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ANNEXURE – II
STERILITY TEST REPORT BY DIRECT INOCULATION METHOD

Product Name		A. R. No.	
Batch No.		Mfg. Date	
Date of Sampling		Expiry Date	
Date of receiving		Sampled Quantity	
Date of Testing		Tested By	
Method Used	Direct Inoculation	Date of Release	

MEDIA CONTROL

Medium used	Fluid Thioglycollate Medium (FTM)	Soyabean Casein Digest Medium (SCM)
Autoclave Media Ref. No.	FTM/	SCM/
Incubation Temperature	32.5 ± 2.5°C	22.5 ± 2.5°C
Incubator ID No.		

OBSERVATIONS

Date	Fluid Thioglycollate Medium		Soyabean Casein Digest Medium		Observed by	Checked by
	Test Sample	Negative Control	Test Sample	Negative Control		

+ve = Growth observed –ve = No Growth observed

Remarks: Rosazurine ring in FTM verified/not verified and Sterility test complies / does not comply as per specification.

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Product Name		A. R. No.	
Medium used	Fluid Thioglycollate Medium (FTM)	Soyabean Casein Digest medium(SCM)	
Incubation Temperature	32.5 ± 2.5°C	22.5 ± 2.5°C	
Incubator ID No.			
Autoclaved Media Ref. No. after 14th day incubation	FTM/	SCM/	
Date of transfer		Transferred By.	

OBSERVATIONS AFTER 14TH DAY INCUBATION

Date	Fluid Thioglycollate Medium		Soyabean Casein Digest Medium		Observed by	Checked by
	Test Sample	Negative Control	Test Sample	Negative Control		

+ve = Growth observed –ve = No Growth observed

Remarks: Rosazurine ring in FTM verified/not verified and Sterility test complies / does not comply as per specification.

Released By:
Date:

Reviewed By:
Date:

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ANNEXURE – III
STERILITY TEST REPORT BY MEMBRANE FILTRATION METHOD

Product Name		A. R. No.	
Batch No.		Mfg. Date	
Date of Sampling		Expiry Date	
Date of receiving		Sampled Quantity	
Date of Testing		Tested By	
Method Used	Membrane Filtration	Date of Release	
Membrane Filter Details	Lot No.		
	Expiry Date		

MEDIA CONTROL

Medium used	Fluid Thioglycollate Medium (FTM)	Soyabean Casein Digest Medium (SCM)
Autoclave Media Ref. No.	FTM/	SCM/
Incubation Temperature	32.5 ± 2.5°C	22.5 ± 2.5°C
Incubator ID No.		

OBSERVATIONS

Date	Fluid Thioglycollate Medium		Soyabean Casein Digest Medium		Observed by	Checked by
	Test Sample	Negative Control	Test Sample	Negative Control		

+ve = Growth observed –ve = No Growth observed

Remarks: Rosazurine ring in FTM verified/not verified and Sterility test complies / does not comply as per specification.

Released By:
Date:

Reviewed By:
Date:

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ANNEXURE – IV

LABEL FOR SCM/FTM TUBES FOR STERILITY OBSERVATION	
Product Name	
Batch No.	
Media Reference No.	
Date of Testing	
Date of Release	
Tested By	

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ANNEXURE – V
STERILITY TEST REPORT OF MEDIA FIL BY DIRECT INCUBATION

Stage of media fill		A. R. No.	
Batch No.		Mfg. Date	
Date of Sampling		Expiry Date	
Date of receiving		Sampled Quantity	
Date of Incubation		Incubated By	
		Date of Release	

INCUBATION RECORD

Incubation Temperature	22.5 ± 2.5°C		32.5 ± 2.5°C		
Incubator ID No.					
Date of incubation		Date of transfer		Transfer By	

OBSERVATIONS

Date	Test Sample	Observed by	Checked by

+ve = Growth observed

–ve = No Growth observed

Remarks: The Sterility test complies / does not comply as per specification.

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Reviewed By:
Date:

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ANNEXURE – VI
STERILITY TEST REPORT BY MODIFIED MEMBRANE FILTRATION METHOD

Product Name		A. R. No.	
Batch No.		Mfg. Date	
Date of Sampling		Expiry Date	
Date of receiving		Sampled Quantity	
Date of Testing		Tested By	
Method Used	Membrane Filtration	Date of Release	
Membrane Filter Details	Lot No.		
	Expiry Date		

MEDIA CONTROL

Medium used	Fluid Thioglycollate Medium (FTM)	Soyabean Casein Digest Medium (SCM)
Autoclave Media Ref. No.	FTM/	SCM/
Incubation Temperature	32.5 ± 2.5°C	22.5 ± 2.5°C
Incubator ID No.		

OBSERVATIONS

Date	Fluid Thioglycollate Medium		Soyabean Casein Digest Medium		Observed by	Checked by
	Test Sample	Negative Control	Test Sample	Negative Control		

+ve = Growth observed –ve = No Growth observed

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Remarks: Rosazurine ring in FTM verified/not verified and Sterility test complies / does not comply as per specification.

Product Name		A. R. No.	
Medium used	Fluid Thioglycollate Medium (FTM)	Soyabean Casein Digest medium(SCM)	
Incubation Temperature	32.5 ± 2.5°C	22.5 ± 2.5°C	
Incubator ID No.			
Autoclaved Media Ref. No. after 14th day incubation	FTM/	SCM/	
Date of transfer		Transferred By.	

OBSERVATIONS AFTER 14TH DAY INCUBATION

Date	Fluid Thioglycollate Medium		Soyabean Casein Digest Medium		Observed by	Checked by
	Test Sample	Negative Control	Test Sample	Negative Control		

+ve = Growth observed –ve = No Growth observed

Remarks: Rosazurine ring in FTM verified/not verified and Sterility test complies / does not comply as per specification.

Released By: **Reviewed By:**
Date: **Date:**