



STANDARD OPERATING PROCEDURE

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1.0 OBJECTIVE:

To lay down a procedure for Disinfectant preparation.

2.0 SCOPE:

This SOP is applicable to Disinfectant preparation.

3.0 RESPONSIBILITY:

Microbiologist QC

4.0 ACCOUNTABILITY:

Head QC

5.0 ABBREVIATION:

%	Percentage
IPA	Isopropyl Alcohol
No.	Number
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
WFI	Water for Injection

6.0 PROCEDURE:

6.1 PRECAUTION:

6.1.1 Use only Validated Disinfectants.

6.1.2 Discard the remaining disinfectant solution (except 70% IPA) at the end of day's operation. (i.e. after 24 hours of filtration).

6.1.3 Avoid direct contact of disinfectant with eyes and skin. In case it happens, wash the eyes and the contact parts with Purified Water/Cool Water.

6.2 ACCESSORIES REQUIRED FOR PREPARATION OF DISINFECTANTS:

6.2.1 Measuring Cylinder 5 ml, 100 ml, 1000 ml.

6.2.2 Disinfectant Preparation Vessel.

6.2.3 Disinfectant Solution Filter (0.22 μ).

6.2.4 Disinfectant Filtration vessel.

6.3 PREPARATION OF DISINFECTANT SOLUTION:

6.3.1 ACITAR (5% v/v) FOR CLEANING:

6.3.1.1 Use cleaned, Disinfectant Preparation Vessel.



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6.3.1.2 Take approximately 5 L of WFI.

6.3.1.3 Measure 500 ml of Acitar solution using measuring cylinder and pour into the disinfectant preparation vessel.

6.3.1.4 Close the Lid of the Vessel and mix.

6.3.1.5 Make up the volume up to 10 L and mix well.

6.3.1.6 Filter the prepared solution through 0.2 μ filter into the sanitized disinfectant filtration vessel and transfer the filtered solution to respective area for cleaning & sanitization.

6.3.2 VIROSIL /SILVICIDE (5% v/v) FOR CLEANING:

6.3.2.1 Use cleaned, Disinfectant Preparation Vessel.

6.3.2.2 Take approximately 5 L of WFI.

6.3.2.3 Measure 500 ml of Virosil/Silvicide solution using measuring cylinder and pour into the Disinfectant Preparation Vessel.

6.3.2.4 Close the Lid of the Vessel and mix.

6.3.2.5 Make up the volume up to 10 L and mix well.

6.3.2.6 Filter the prepared solution through 0.2 μ filter into the sanitized disinfectant filtration vessel and transfer the filtered solution to respective area for cleaning & sanitization.

6.3.3 MICROLYSE (0.2 % V/V)/ BKC (0.2 % V/V) FOR CLEANING:

6.3.3.1 Use cleaned, Disinfectant Preparation Vessel.

6.3.3.2 Collect approximately 5 L of WFI.

6.3.3.3 Measure 20 ml of Microlyse solution using measuring cylinder or 40 g of BKC solution and pour into the disinfectant preparation vessel.

6.3.3.4 Close the Lid of the Vessel and mix.

6.3.3.5 Make up the volume up to 10 L and mix well.

6.3.3.6 Filter the prepared solution through 0.2 μ filter into the sanitized disinfectant filtration vessel and transfer the filtered solution to respective area for cleaning & sanitization.

6.3.4 BACILLOCID 2.5 % V/V FOR CLEANING:

6.3.4.1 Use cleaned, Disinfectant Preparation Vessel.



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6.3.4.2 Take approximately 5 L of WFI.

6.3.4.3 Measure 250 ml of Bacillocid solution using measuring cylinder and pour into the disinfectant preparation Vessel.

6.3.4.4 Close the Lid of the Vessel and mix.

6.3.4.5 Make up the volume up to 10 L and mix well.

6.3.4.6 Filter the prepared solution through 0.2 μ filter into the sanitized disinfectant filtration vessel and transfer the filtered solution to respective area for cleaning & sanitization.

6.3.5 DETTOL 2.5 % V/V FOR CLEANING:

6.3.5.1 Use cleaned, Disinfectant Preparation Vessel.

6.3.5.2 Take approximately 5 L of WFI.

6.3.5.3 Measure 250 ml of Dettol solution using measuring cylinder and pour into the disinfectant preparation vessel.

6.3.5.4 Close the Lid of the Vessel and mix.

6.3.5.5 Make up the volume up to 10 L and mix well.

6.3.5.6 Filter the prepared solution through 0.2 μ filter into the sanitized disinfectant filtration vessel and transfer the filtered solution to respective area for cleaning & sanitization.

6.3.6 SAVLON 2.5 % V/V FOR CLEANING:

6.3.6.1 Use cleaned, Disinfectant Preparation Vessel.

6.3.6.2 Take approximately 5 L of WFI.

6.3.6.3 Measure 250 ml of Savlon solution using measuring cylinder and pour into the disinfectant preparation vessel.

6.3.6.4 Close the Lid of the Vessel and mix.

6.3.6.5 Make up the volume up to 10 L and mix well.

6.3.6.6 Filter the prepared solution through 0.2 μ filter into the sanitized disinfectant filtration vessel and transfer the filtered solution to respective area for cleaning & sanitization.

6.3.7 VIROSIL/SILVICIDE (20% V/V) FOR FOGGING:

6.3.7.1 Use cleaned, Disinfectant Preparation Vessel.

6.3.7.2 Take approximately 5 L of WFI.



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6.3.7.3 Measure 2000 ml of Virosil/Silvicide solution using measuring cylinder and pour into the disinfectant preparation vessel.

6.3.7.4 Close the Lid of the Vessel and mix.

6.3.7.5 Make up the volume up to 10 L and mix well.

6.3.8 ISO PROPYL ALCOHOL (IPA) (70%):

6.3.8.1 Use cleaned, Disinfectant Preparation Vessel.

6.3.8.2 Take approximately 3 L of WFI.

6.3.8.3 Measure 7000 ml of IPA solution using measuring cylinder and pour into the Disinfectant Preparation Vessel.

6.3.8.4 Close the Lid of the Vessel and mix.

6.3.8.5 Make up the volume up to 10 L and mix well.

6.3.8.6 Filter the prepared solution through 0.2 μ filter into the sanitized disinfectant filtration vessel.

6.4 Transfer the WFI from Injection block to Microbiology Lab in closed container.

6.5 Different percentage of Disinfectant Solution given as follows:

S.No.	Name of the Disinfectant	Concentration to be Used	Volume of Disinfectant	Volume of WFI	Total Disinfectant Volume
1.	Isopropyl Alcohol	70 % v/v	7000 ml	3000 ml	10,000 ml
2.	Dettol	2.5 % v/v	250 ml	9750 ml	10,000 ml
3.	Savlon	2.5 % v/v	250 ml	9750 ml	10,000 ml
4.	(a) Microlyse	0.2 % v/v	20 ml	9980 ml	10,000 ml
	(b) BKC	0.2 % w/v	40 g	q.s. to 10 L	10,000 ml
5.	Silviside/Virosil	5.0 % v/v	500 ml	9500 ml	10,000 ml
6.	Acitar (5.0 % v/v)	5.0% v/v	500 ml	9500 ml	10,000 ml
7.	Virosil/ Silviside	20 % v/v	2000 ml	8000 ml	10,000 ml
8.	Bacillocid 2.5 %	2.5 % v/v	250 ml	9750 ml	10,000 ml

6.6 Filtration of disinfectant solutions:

6.6.1 The Filtration process shall be carried out in the MLT -2 of Microbiology Lab as per procedure mentioned below:



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6.6.1.1 Enter the MLT and Bioassay area as per procedure mentioned on SOP, “**Entry, Exit and Gowning for MLT and Microbial Assay Area**”.

6.6.1.2 Check that the cartridge filter is assembled in housing.

6.6.1.3 Collect the disinfectant solution, IPA and WFI in controlled area in the pressure vessel.

6.6.1.4 Connect the pressure vessel outlet with the silicon pipe to the inlet of cartridge filter housing.

6.6.1.5 Connect the downstream outlet nozzle of cartridge filter to the inlet of collection vessel through tubing.

6.6.1.6 Connect the compressed air line with the stainless steel pressure vessel in the controlled area.

6.6.1.7 Close the extra inlet of collection vessel with silicon tubing.

6.6.1.8 Open the air compressed air line valve slowly and remove the air from the filter housing by opening air vents and again tighten the vents when droplets start oozing out.

6.6.1.9 Increase the air supply until the liquid start flowing through the cartridge filtration assembly Line.

6.6.1.10 Filter the disinfectant solution, Flush the cartridge filter with WFI before preceding the filtration of disinfectant sanitizing agent.

6.6.1.11 Collect the filtered disinfectant solution in the collection vessel. Then close the inlet valve of the pressure vessel.

6.6.1.12 Close the air supply valve when the filtration is over.

6.6.1.13 Check that inlet and outlet valve of all the connection vessel are closed.

6.6.1.14 Collect the filtered disinfectant solution into bottle/reservoir.

6.7 70% IPA shall be used as hand disinfectant.

6.8 Every prepared disinfectant solution must be assign preparation reference number as given below.

- DET for Dettol
- SAV for Savlon
- SIL for Silviside
- VIR for Virosil



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- BAC for Bacillocid
- ACI for Acitar
- MIC for Microlyse
- BKC for BKC

For e.g. 2.5% Dettol is prepared assign reference number

DIS/DET/01/01/01

Where

DIS : Disinfectant,

DET : Dettol,

01 : Date of preparation,

01 : Month of preparation and

01 : Serial number of preparation.

- 6.9** Disinfectant like Dettol 2.5 % v/v, Savlon 2.5 % v/v, Microlyse 0.2 % v/v , BKC 0.2 % v/v, Silviside/ Virosil 5.0 % v/v , Bacillocid 2.5 % v/v Virosil/ Silviside 20 % v/v shall be freshly prepared and used within 24 hours.
- 6.10** IPA 70% can be used up to 7 days from the day of preparation.
- 6.11** After preparation paste the label as per **Annexure-I, “Disinfectant Status Label”** and store the disinfectant solution at room temperature in MLT and Bioasay room corridor. Use daily freshly prepared disinfectant as per schedule as follows:

Disinfectant Solution	Schedule Day of Week
Silviside/Virosil	SUNDAY
Dettol/ Savlon	MONDAY
Bacillocid/Acitar	TUESDAY
Microlyse/BKC	WEDNESDAY
Silviside/Virosil	THURSDAY
Dettol/Savlon	FRIDAY
Bacillocid/Acitar	SATURDAY
Virosil/ Silviside	Daily



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6.12 Record the Preparation and reconciliation details of Disinfectant in **Annexure-II, “Disinfectant Solution Preparation and reconciliation Record”**.

6.13 In case of unavailability of any disinfectant use alternative disinfectant, which was not used on previous day and will not use in next day.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Disinfectant Status Label	
Annexure-II	Disinfectant Solution Preparation, Reconciliation and Usages Record	

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:

In-House

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

DISINFECTANT STATUS LABEL	
Name of the disinfectant	
Date of preparation	
Use before	
Prepared by	



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ANNEXURE – II DISINFECTANT SOLUTION PREPARATION, RECONCILIATION AND USAGES RECORD

Name of Disinfectant:														
Lot number of Disinfectant	Quantity received	Issued Quantity	Date of issued	Quantity balance	Date of Preparation	Volume of disinfectant taken(ml)	Volume of WFI taken	Total Volume of Disinfectant	Assign reference number	Filtered on	Used For	Used Before	Done By Sign & Date	Checked By Sign & Date