



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Preparation, Filtration, Storage, Usage, Distribution and Destruction of Disinfectant Solution

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
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1.0 OBJECTIVE:

To lay down a Procedure for Preparation, Filtration, Storage, Usage, Distribution and Destruction of Disinfectant Solution.

2.0 SCOPE:

This SOP is applicable for Preparation, Filtration, Storage, Usage, Distribution and Destruction of Disinfectant Solution for Production department.

3.0 RESPONSIBILITY:

Officer / Executive Production/ Warehouse

4.0 ACCOUNTABILITY:

Head Production/ Warehouse

5.0 ABBREVIATIONS:

%	Percentage / Percent
μ	Micron
L	Liter
LAF	Laminar Air Flow
Ltd	Limited
No.	Number
Pvt.	Private
QA	Quality Assurance
SOP	Standard Operating Procedure
WFI	Water for Injection
MAL	Material Air Lock
PAL	Personnel Air Lock
MSDS	Material Safety Data Sheet

6.0 PROCEDURE:

6.1 PRECAUTION AND INSTRUCTION:

- 6.1.1** Use only Validated Disinfectants and Employees carrying out sanitation of aseptic areas shall be trained specifically for this purpose.
- 6.1.2** Different sanitizing agents shall be used in rotation and the concentrations of the same shall be as per the recommendations of the manufacturer.
- 6.1.3** All disinfectant solution except IPA shall receive by production personnel and shall store in designated place with status label.



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- 6.1.4** IPA shall receive by warehouse (Whenever required) in suitable & cleaned container.
- 6.1.5** Ensure and verify the manufacturing date and Shelf-life of the particular disinfectant at the time of receipt. The disinfectant shall be used within its Shelf-life period, mentioned on container label as Annexure- IV Titled as “Disinfectant status label”.
- 6.1.6** After opening the sealed container of any particular disinfectant use the solution within 10 days in case of Virosil / Silvicide and within 3 months for remaining all disinfectant solutions.
- 6.1.7** After cleaning/sanitization leave the area at least for 10 minutes to achieve the maximum effectiveness of used disinfectant solution.
- 6.1.8** The prepared disinfectant solution shall be used till one day of preparation and discard the remaining disinfectant solution at the end of day’s operation (i.e after 24 hours of preparation)
- 6.1.9** Avoid direct contact of disinfectant with eyes and skin. In case it happens, wash the eyes and the contact parts with Purified Water / Cold Water OR refer respective MSDS.
- 6.1.10** Disinfectant Solution should be prepared in Cool WFI at room temperature.

6.2 ACCESSORIES REQUIRED FOR PREPARATION OF DISINFECTANTS:

- 6.2.1** Measuring Cylinder 1000 ml, 100 ml.
- 6.2.2** Disinfectant Preparation Vessel.
- 6.2.3** Disinfectant Solution Filter (0.2 μ).
- 6.2.4** Disinfectant Solution Filter assembly.
- 6.2.5** Disinfectant Filtration vessel.

6.3 A. LIST OF DISINFECTANTS, COMPOSITION AND CONCENTRATION (Routine):

S. No.	Name of Disinfectant	Composition	Purpose	Concentration Used	Category/ Functional Role
1.	Microlyse	Benzalkonium Chloride Solution IP – 4.0% Tetrazine and Alizarine cyanine Green F.	Area , Floor & Wall Sanitization	0.2 % v/v	Bactericidal, Fungicidal, Germicidal
2.	Bacillocid Or	-1.6 Dihydroxy 2, 5-Dioxahexan (Chemically bound formaldehyde) 11.2 g \equiv 0.23% w/v -Gluteraldehyde 5.0 g (0.1% w/v) Benzalkonium Chloride 5.0 g (0.1% w/v) -Alkyl Urea Derivatives 3.0 g. (0.06% w/v)	Area , Floor & Wall Sanitization	2.5% v/v	Bactericidal, Fungicidal, Sporicidal
	Acitar	Gluteraldehyde – 2.0 % w/v	Area, Floor &	5.0 % v/v	Bactericidal,



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S. No.	Name of Disinfectant	Composition	Purpose	Concentration Used	Category/ Functional Role
		Benzalkonium Chloride Solution IP – 5.0 % w/v	Wall Sanitization		Fungicidal, Virucidal, Sporocidal
3.	Virosil / Silvicide	Hydrogen Peroxide Solution IP- 10.0% w/v Silver Nitrate Solution IP - 0.01% w/v	Area , Floor & Wall Sanitization	5.0% v/v	Batericidal, Fungicidal, Sporocidal
4.	Virosil/ Silvicide	Hydrogen Peroxide Solution IP - 10.0% w/v Silver Nitrate Solution IP - 0.01% w/v	Fogging	20 % v/v	Batericidal, Fungicidal, Sporocidal
5.	Iso Propyl Alcohol (IPA)	Iso Propyl Alcohol - 70% v/v	Hand Sanitization and Surface Sanitization.	70%	Batericidal, Sporocidal
6.	®Vesta Syde SQ	Didecyldimethyl ammonium chloride 10.5 %	Area , Floor & Wall Sanitization	1.6 % v/v	Fungicidal, Virucidal
7.	®Virex II 256	-Didecyl Ammonium chloride 8.7 % -n-alkyl dimethyl benzyl ammonium chloride 8.19%	Area, Floor & Wall Sanitization	0.4 %	Batericidal, Fungicidal, Sporocidal

- Note:** 1. In case of non-availability of any above mentioned scheduled disinfectant, alternate equivalent disinfectants of any other brand having similar composition or Activity/action may be used.
2. Virex II 256 & Vesta Syde SQ which are already qualified disinfectants kept as standby and may be used alternatively, only in case non availability of any scheduled disinfectant or any emergency scenario / observed excursion.
3. In case of non-availability of any schedule disinfectant, alternate schedule next disinfectant shall be used for sanitization.

B. LIST OF DISINFECTANTS, COMPOSITION AND CONCENTRATION (Non-Routine):

- **Double concentrations of the Schedule disinfectants shall be used in the Month of JULY, AUGUST and SEPTEMBER for every year in case of Excursion, any recommendation or Whenever required.**

S. No.	Name of Disinfectant	Composition	Purpose	Concentration Used	Category/ Functional Role
1.	Microlyse	Benzalkonium Chloride Solution IP – 4.0% Tetrazine and Alizarine cyanine Green F.	Area , Floor & Wall Sanitization	0.4 % v/v	Batericidal, Fungicidal, Germicidal



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S. No.	Name of Disinfectant	Composition	Purpose	Concentration Used	Category/ Functional Role
2.	Baciloid	1.6 Dihydroxy 2, 5-Dioxahexan (Chemically bound formaldehyde) 11.2 g \equiv 0.23% w/v Gluteraldehyde 5.0 g (0.1% w/v) Benzalkonium Chloride 5.0 g (0.1% w/v) Alkyl Urea Derivatives 3.0 g. (0.06% w/v)	Area , Floor & Wall Sanitization	5.0% v/v	Batericidal, Fungicidal, Sporicial
	Or	Acitar	Gluteraldehyde – 2.0 % w/v Benzalkonium Chloride Solution IP – 5.0 % w/v	Area, Floor & Wall Sanitization	10.0 % v/v
3.	Virosil / Silvicide	Hydrogen Peroxide Solution IP - 10.0% w/v Silver Nitrate Solution IP - 0.01% w/v	Area, Floor & Wall Sanitization	10.0% v/v	Batericidal, Fungicidal, Sporicial
4.	Virosil/ Silvicide	Hydrogen Peroxide Solution IP - 10.0% w/v Silver Nitrate Solution IP - 0.01% w/v	Fogging	20 % v/v	Batericidal, Fungicidal, Sporicial
5.	Iso Propyl Alcohol (IPA)	Iso Propyl Alcohol - 70% v/v	Hand Sanitization and Surface Sanitization.	70%	Batericidal, Sporicial
6.	[®] Vesta Syde SQ	Didecyldimethyl ammonium chloride 10.5 %	Area , Floor & Wall Sanitization	3.2 % v/v	Fungicidal, Virucidal
7.	[®] Virex II 256	Didecyl Ammonium chloride 8.7 % n-alkyl dimethyl benzyl ammonium chloride 8.19%	Area , Floor & Wall Sanitization	0.8 %	Batericidal, Fungicidal, Sporicial

6.4 PREPARATION OF DISINFECTANT SOLUTIONS (ROUTINE):

6.4.1 All disinfectant solutions shall be prepared in Unit Preparation or Disinfectant preparation area.

6.4.2 Below mentioned quantity of disinfectant solution is as example. Actual quantity of disinfectant solution shall be prepared as per requirement.

6.4.3 Microlyse 0.2 % v/v (For Sanitization):

6.4.3.1 Use cleaned, Disinfectant Preparation Vessel and Collect approximately 20 L of WFI.

6.4.3.2 Measure 100 ml of Microlyse / Benzalkonium Chloride using measuring cylinder and pour into the Disinfectant Preparation Vessel and close the Lid of the Vessel for mixing.

6.4.3.3 Make up the volume up to 50 L and mix well by Spatula/filtered Compressed Air/Nitrogen.



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6.4.3.4 Above solution shall be filter & transfer into sterilized vessel, as procedure mentioned in **clause no. 6.5** for further use in sanitization.

6.4.4 Acitar /Bacilocid 5% v/v (For Sanitization):

6.4.4.1 Use cleaned, Disinfectant Preparation Vessel and take approximately 20 L of WFI.

6.4.4.2 Measure 2500 ml of Acitor solution using measuring cylinder and pour into the Disinfectant Preparation Vessel and close the Lid of the Vessel for mixing.

6.4.4.3 Make up the volume up to 50 L and mix well by Spatula/ filtered Compressed Air/Nitrogen.

6.4.4.4 Above solution shall be filter & transfer in sterilized vessel, as procedure mentioned in **clause no. 6.5** for further use for in sanitization.

6.4.5 Bacilocid 2.5% v/v (For Sanitization):

6.4.5.1 Use cleaned, Disinfectant Preparation Vessel and take approximately 20 L of WFI.

6.4.5.2 Measure 1250 ml of Bacilocid solution using measuring cylinder and pour into the Disinfectant Preparation Vessel and close the Lid of the Vessel for mixing.

6.4.5.3 Make up the volume up to 50 L and mix well by Spatula / Filtered Compressed Air/Nitrogen.

6.4.5.4 Above solution shall be filter & transfer in sterilized vessel, as procedure mentioned in **clause no. 6.5** for further use in sanitization.

6.4.6 Virosil /Silvicide 5% v/v (For Sanitization):

6.4.6.1 Use cleaned, Disinfectant Preparation Vessel and take approximately 20 L of WFI.

6.4.6.2 Measure 2500 ml of Virosil solution using measuring cylinder and pour into the Disinfectant Preparation Vessel and Lid of the Vessel shall be mixed for mixing.

6.4.6.3 Make up the volume up to 50 L and mix well by Spatula / Filtered Compressed Air/Nitrogen.

6.4.6.4 Above solution shall be filter & transfer in sterilized vessel, as procedure mentioned in **clause no. 6.5** for further use in sanitization.

6.4.7 Virosil/Silvicide 20% v/v (For Fogging):

6.4.7.1 Use cleaned, Disinfectant Preparation Vessel and take approximately 10 L of WFI.

6.4.7.2 Measure 4 L of Virosil solution using measuring cylinder and pour into the Disinfectant Preparation Vessel and close the Lid of the Vessel for mixing.

6.4.7.3 Make up the volume up to 20 L and mix well by purging of filtered Compressed Air/Nitrogen.



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6.4.7.4 Above solution shall be filter & transfer in sterilized vessel, as procedure mentioned in **clause no. 6.5** for further use in sanitization.

6.4.7.5 Virosil/Silvicide 20 % solution shall be used for fogging only.

6.4.8 Iso Propyl Alcohol (IPA) 70% (For Hand Sanitization):

6.4.8.1 Use cleaned, Disinfectant Preparation Vessel & take approximately 10 L of WFI.

6.4.8.2 Measure 35 L of IPA solution using measuring cylinder and pour into the Disinfectant Preparation Vessel and close the Lid of the Vessel for mixing.

6.4.8.3 Make up the volume up to 50 L and mix well by Spatula / filtered Compressed Air/Nitrogen.

6.4.8.4 Above solution shall be filter & transfer in sterilized vessel, as procedure mentioned in **clause no. 6.5** for further use in sanitization.

6.4.9 Vesta Syde SQ 1.6% v/v (For Sanitization):

6.4.9.1 Use cleaned, Disinfectant Preparation Vessel and take approximately 20 L of WFI.

6.4.9.2 Measure 800 ml of Vesta Syde SQ solution using measuring cylinder and pour into the Disinfectant Preparation Vessel and close the Lid of the Vessel for mixing.

6.4.9.3 Make up the volume up to 50 L and mix well by Spatula / filtered Compressed Air/Nitrogen.

6.4.9.4 Above solution shall be filter & transfer in sterilized vessel, as procedure mentioned in **clause no. 6.5** for further use in sanitization.

6.4.10 Virex II 256, 0.4 % v/v (For Sanitization):

6.4.10.1 Use cleaned, Disinfectant Preparation Vessel and approximately 20 L of WFI.

6.4.10.2 Measure 200 ml of Virex II 256 solution using measuring cylinder and pour into the Disinfectant Preparation Vessel and close the Lid of the Vessel for mixing.

6.4.10.3 Make up the volume up to 50 L and mix well by Spatula / filtered Compressed Air/Nitrogen.

6.4.10.4 Above solution shall be filter & transfer in sterilized vessel, as procedure mentioned in **clause no. 6.5** for further use in sanitization.

Note:-In Above preparations concentration of disinfectant as per table A as routine and related disinfectant concentration shall be double as per table B as non-routine.



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6.5 FILTRATION:

- 6.5.1 Filter the disinfectant solution through filtration assembly under LAF in disinfectant filtration room.
- 6.5.2 Check and ensure that Pre - Integrity of the filter is performed and is pass.
- 6.5.3 Place the Sterilized Filter assembly under LAF.
- 6.5.4 Connect the outlet of Disinfectant Filter to the inlet of Disinfectant Holding Vessel (Filtration Vessel).
- 6.5.5 Connect inlet of Disinfectant Preparation Vessel to Compressed Air/Nitrogen supply line.
- 6.5.6 Open and regulate the Compressed Air/Nitrogen pressure through pressure regulator gradually to achieve a pressure of $0.5 \text{ Kg/cm}^2 - 1.0 \text{ Kg/cm}^2$.
- 6.5.7 Allow the solution to pass through the 0.2μ and collect solution in Sterilized Filtration Vessel/SS container.
- 6.5.8 After complete solution has been filtered, close Compressed Air supply and disconnect the Compressed Air supply.
- 6.5.9 Store the filtered disinfectant solution in sterilized Holding Vessel under LAF.
- 6.5.10 Disconnect all silicon tubes and transfer them to Unit Preparation Area for cleaning.
- 6.5.11 Perform the post-Integrity of the filter after the filtration.

6.6 STORAGE

- 6.6.1 The disinfectant shall be stored in dedicated place before & after preparation with proper status label as **Annexure- IV**, titled as "**Disinfectant Status Label**" along with its Shelf-life.

6.7 USAGE IN MANUFACTURING & PACKING AREA'S:

- 6.7.1 For use in Aseptic Areas, prepare only required quantity of Disinfectant Solution and store in Sterilized Container and keep under LAF.
- 6.7.2 Destroy the unused quantity at the end of the day by pouring it in drain point.
- 6.7.3 For packing area prepare daily required quantity of disinfectant solution and do not filter it.

6.8 DISINFECTANT ISSUANCE TO WAREHOUSE:

- 6.8.1 For use in Warehouse Areas, disinfectant solution shall be prepared in production area.



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6.8.2 Transfer the filtered disinfectant in closed sterilized container.

6.8.3 Record the disinfectant preparation, filtration and issuance to warehouse in **Annexure-I**, titled as “**Disinfectant Issuance, Usage and Destruction Record**”.

6.8.4 Destroy the unused quantity at the end of the day.

6.8.5 Record the disinfectant issuance, usage, and destruction of disinfectant for warehouse in **Annexure- II** titled as “**Disinfectant Issuance, Usage and Destruction Record for Warehouse Area**”

6.9 SCHEDULE FOR PREPARATION AND USE OF DISINFECTANT SOLUTION:

6.9.1 Disinfectant solution for Sanitization shall be prepared as per schedule mentioned in **Annexure No-III** Titled as “**Disinfectants Preparation Schedule For Sanitization**”

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT NO.
Annexure-I	Disinfectant Issuance, Usage And Destruction Record	
Annexure-II	Disinfectant Issuance, Usage and Destruction Record for Warehouse Area	
Annexure-III	Disinfectants Preparation Schedule For Sanitization	
Annexure-IV	Disinfectant Status Label	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

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

9.0 REFERENCES:

Schedule M

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-III DISINFECTANTS PREPARATION SCHEDULE FOR SANITIZATION

S.No.	Name of Disinfectant	Purpose	Recommended Hold contact time after cleaning	Scheduled Day
1.	Microlyse (0.2% v/v)	Area, Floor & Wall Sanitization	10 min	Sunday
2.	Acitar (5.0 %v/v) / Bacilocid (2.5% v/v)	Area, Floor & Wall Sanitization	10 min	Monday
3.	Silvicide/Virosil (5.0%v/v)	Area, Floor & Wall Sanitization	10 min	Tuesday
4.	Microlyse (0.2%v/v)	Area, Floor & Wall Sanitization	10 min	Wednesday
5.	Acitar (5.0 %v/v) / Bacilocid (2.5% v/v)	Area, Floor & Wall Sanitization	10 min	Thursday
6.	Silvicide/Virosil (5.0%v/v)	Area, Floor & Wall Sanitization	10 min	Friday
7.	Acitar (5.0 %v/v) / Bacilocid (2.5% v/v)	Area, Floor & Wall Sanitization	10 min	Saturday
8.	Iso Propyl Alcohol (70% v/v)	Foot ,Hand and Surface Sanitization.	20-30 second.	Daily

Note:

- 1) In case of non-availability of any above mentioned scheduled disinfectant, alternate equivalent disinfectants of any other brand having similar composition or Activity/action may be used.
- 2) Virex II 256 & Vesta Syde SQ which are already qualified disinfectants kept as standby and may be used alternatively, only in case non-availability of any scheduled disinfectant or any emergency scenario / observed excursion.
- 3) In case of non-availability of any schedule disinfectant, alternate schedule next disinfectant shall be used for sanitization.



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ANNEXURE-IV DISINFECTANT STATUS LABEL

DISINFECTANT STATUS LABEL	
Detail	Checked By Sign/Date
Date of receipt	
Use before date (Before Opening)	
Date of Opening	
Use before date (After Opening)	