Protocol for Evaluation of Effectiveness of Disinfectant & Sanitation Solution (By Mopping method)

PROTOCOL FOR EVALUATION OF EFFECTIVENESS OF DISINFECTANT & SANITATION SOLUTION (BY MOPPING METHOD)

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PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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1.0 PROTOCOL APPROVAL:

Signing of this Approval page of Validation Protocol indicates agreement with the Validation approach described in this document will be prepared and approved.

If any modification in the validation approach becomes necessary, an addendum shall be Prepared.

	NAME	SIGNATURE/DATE
Prepared By: Officer, Quality Control		
Reviewed By: Executive, Quality Control		
Reviewed By: Head, Quality Control		
Reviewed By: Head, Regulatory Affairs		
Approved By: Head, Factory		
Approved By: Head, Quality		

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2.0 **PURPOSE:** The purpose of this document to provides methodology for evaluation of effectiveness of sanitation solutions against the microorganisms by mopping method.

3.0 **SCOPE:** This protocol is applicable to all sanitation solutions used for sanitation of production area and QC microbiology lab.

4.0 PROCEDURE:

Activity	Sign
For Bacteria Streak a loopful of microorganisms on to the surface of Soyabean Casein Digest Agar Media, Lot No. _____. **Incubation:** Incubate at 30-35°C for 24 to72 hrs. Incubator No._____Date/Time In _____ Date/Time Out _____. Observe for growth.	
For Fungi Streak a loopful of microorganisms on to the surface of Sabouraud Dextrose agar Media, Lot No. _____. **Incubation:** Incubate at 20-25°C for 72 to120 hrs. Incubator No._____Date/Time In _____ Date/Time Out _____. Observe for growth.	
Harvest the growth in test tube containing of 9 ml of sterile Normal saline for Bacteria and sterile Normal saline for yeast and fungi.	
Vortex the test tubes for about 30 seconds to homogenate the contents.	
Make serial dilution up to 10^{-8} using sterile Normal saline for Bacteria and sterile Normal saline for yeast and fungi.Vortex to homogenate the contents for about 30 seconds while preparing each dilution.	

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Identify dilutions with name.

Record the details in the below table.

Name of Organism	Date of Serial Dilution /Incubation	Dilution	Volume Tested	Count /Plate			Final Inoculum Population	Observed By (Sign / Date)
				Plate 1	Plate 2	Avg.		
Bacillus subtilis								
Escherichia coli								
Staphylococcus aureus								
Candida albicans								
Aspergillus niger								
Environmental isolate								

Transfer aspectically 1 ml of 10^{-5} or any suaitable dilution of culture into empty sterile petriplates in duplicate.

Add about 15 to 20 ml of previously melted and cooled to at not more than 45°C (measure the temperature of melted media just prior to addition in to plates) and record the temperature. Soyabean casein digest agar medium for bacteria/ Sabouraud Dextrose agar Medium for yeast and fungi, mix the culture suspension with the agar and allow it to solidify at room temperature.Identify with name of microorganism and culture dilution.

Repeat above step for remaining three dilution i.e. $10^{-6,}$ 10^{-7} and 10^{-8} as well.

Repeat above procedure for remaining organisms.

Immediately store the culture suspensions in refrigerator.

Label and incubate the plates in inverted position.

For Bacteria	For Fungi
Incubate at 30-35°C for 24 to72 hrs Incubator No.: _____ Date/Time in :_____ Date/Time out: _____	Incubate at 20-25°C for 72 to120 hrs Incubator No.: _____ Date/Time in :_____ Date/Time out: _____

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Observe the plates and record number of cfu/plate.	

Preparation of sanitation solution : _____

Prepare in use concentration of sanitation solution using purified water (PW) and mixwell.Aseptically filter the sanitation solution using a 0.45 micron membrane filter under a laminar air flow (LAF) and collect the filtered sanitation solution in a sterile container.

Main procedure :

Select the surface (approx 5x5 or 10x10Cms) and make grid for the sampling in such way to prevent the repetative position and sampling.sanitized surface with approved sanitation solution _____ . Take one RODAC and label it as blank and incubate as below table.

Media Lot No. _____ Observation : _____ cfu/plate.

Add 1 ml of culture suspension having the concentration of selective dilution .spread the culture suspension on surface and allow it to air dry.

Take five samples by RODAC plates from the five different positions from surface (initial) to check the actual bioburden,label accordingly and incubate the plates.Media lot No. _____

Take sterile sponge sheet or any other,deep it into the filtered sanitation solution and mope the surface and note down time of mopping started _____.

At different time intervals of contact period, take 5 samples by RODAC plate from the different surfaces and note down the time of sampling, label accordingly and incubate.

Incubation:

For Bacteria	**For Fungi**
Incubate at 30-35°C for 24 to72 hrs Incubator No.: _____ Date/Time in :_____ Date/Time out: _____	Incubate at 20-25°C for 72 to120 hrs Incubator No.: _____ Date/Time in :_____ Date/Time out: _____

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Observe for CFU and record in the table given.

Name of Disinfectant: **Date of Test:**

Concentration: **Date of Observation:**

Name of organism	Initial Population CFU /ml	Dilution Selected	Population Taken for Test CFU /ml (X)	Observed count after contact time (Y)				Log reduction observed (X-Y)				
				0 Min	5 Min	10 Min	15 Min	0 Min	5 Min	10 Min	15 Min	Observed by (Sign /Date)
Bacillus subtilis												
Escherichia coli												
Staphylococcus aureus												
Candida albicans												
Aspergillus niger												
Environmental isolate												

ACCEPTANCE CRITERIA :

There should be at least three log reduction of initial count achieved within 15 minutes of contact time.

CONCLUSION :

The disinfectant.....is qualified as per above specification.

Done by: **Checked By:**

Sign/Date: **Sign/Date:**

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5.0 REVISION HISTORY:

S.No.	Revision No.	Reason for Revision	Effective date
1	00	First-edition – Hence Not applicable	