Report for Validation of Disinfection Efficacy of 70% Isopropyl Alcohol

Name of the Process/ Method/Study	Validation of disinfection efficacy of 70% Isopropyl Alcohol
Name of the Product	70% Isopropyl Alcohol
Validation Study Location	
Area / Department	Quality Control
Protocol Effective Date	
Validation No. *	

Prepared By:

Name	Department	Sign and Date
	Quality Control	

Reviewed By:

Name	Department	Sign and Date
	Quality Control	
	Plant Manager	

Approved By:

Name	Department	Sign and Date
	Quality Assurance	

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1. Training Record for Validation Activity.

Purpose	To train all personnel involved in the execution of this validation protocol for following topics.		
Topics	• Purpose • Description of process • Validation activity with sampling plan • SOPs • Acceptance criteria • Documentation		
Ref. Doc. No(s).			
Training by			
Name of participant	**Area of operation**	**Employee ID**	**Sign and Date**
Trainer (Sign and Date):			

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2. Verification of Appropriate Controls in place:

Ensure all the operational controls are in place. Mention the specific details to be verified and check the availability/ compliance status.

2.1 Equipment Qualification:

S.No.	Equipment Name	ID No.	Qualification Date	Due Date	Checked By

2.2 Instrument Calibration:

S.No.	Instrument Name	ID No.	Calibration Date	Due Date	Checked By

2.3 Documentation Controls:

S.No.	Document Name	Document No.	Effective Date	Checked By

	Name	Sign and Date
Reviewed By (User)		
Reviewed By (QA)		

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3. Recording of Test Data, Sample Details and Results.

Following batch of 70% Isopropyl Alcohol has been evaluated as per the protocol for disinfection efficacy.

Product name :

Lot No. :

Organisms used for evaluation:

S.No.	Name of organism
1	Escherichia coli ATCC 8739
2	Staphylococcus aureus ATCC 6538
3	Bacillus subtilis ATCC 19659
4	Candida albicans ATCC 10231
5	Aspergillus niger ATCC 16404

Evaluation of Inoculum for disinfection efficacy

Name of media :

Media lot No. :

Media sterilization :

Date of incubation :

Date of observation :

Incubator ID number:

S.No.	Name of organism	Dilution factor	CFU observed		Avg. CFU	Cfu/ mL
			Plate 1	Plate 2		
1	E. coli ATCC 8739					
2	S. aureus ATCC 6538					
3	B. subtilis ATCC 19659					

Name of media :

Media lot No. :

Media sterilization :

Date of incubation :

Date of observation :

Incubator ID number:

PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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S.No.	Name of organism	Dilution factor	CFU observed		Avg. CFU	Cfu/ mL
			Plate 1	Plate 2		
1.	C. albicans ATCC 10231					
2.	A. niger ATCC 16404					

Disinfection evaluation data:

Dilution : 70% Isopropyl Alcohol

Name of media :

Media lot No. :

Media sterilization :

Date of incubation :

Date of observation :

Incubator ID number:

Calculation of log reduction:

Log reduction = Log of challenge count – log of average CFU

S.No.	Name of Organism	Challenge count	Contact time in seconds	Observation after contact time		Avg. CFU	Log reduction
				Plate 1	Plate 2		
1.	E. coli ATCC 8739		0				
			30				
			60				
2.	S. aureus ATCC 6538		0				
			30				
			60				
3.	B. ATCC 19659		0				
			30				
			60				

Dilution : 70% Isopropyl Alcohol

Name of media :

Media lot No. :

Media sterilization :

Date of incubation :

Date of observation :

Incubator ID number:

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S.No.	Name of organism	Challenge count	Contact time in seconds	Observation after contact time		Avg. CFU	Log reduction
				Plate 1	Plate 2		
1.	C. albicans ATCC 10231		0				
			30				
			60				
2.	A. niger ATCC 16404		0				
			30				
			60				

4. Details of deviation:

Record all the deviation observed during the validation activity as per SOP and review comments with impact on validation status and/ or justification, wherever applicable.

5. Enclosures:

S.No.		Number of pages

	Name	Department	Sign and Date
Performed by			
Reviewed by			
Reviewed by			

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6. Review Comments:

	Name	Department	Sign and Date
Performed by			
Reviewed by			
Reviewed by			