PROTOCOL

FOR

HOLD TIME STUDY FOR STERILIZED GARMENT

(PRODUCTION)

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HOLD TIME STUDY FOR STERILIZED GARMENTS (PRODUCTION)

1.0 PROTOCOL APPROVAL

This document is prepared by the Microbiology Department for hold time study for sterilized garments. Hence this document before being effective shall be approved by the QA Head. If any modification shall be desired it design as addendum and approved before execution.

PREPARED BY		
NAME/ FUNCTIONAL AREA	**DESIGNATION**	**SIGNATURE /DATE**
MICROBIOLOGY		

CHECKED BY		
NAME/ FUNCTIONAL AREA	**DESIGNATION**	**SIGNATURE /DATE**
MICROBIOLOGY		
PRODUCTION		

APPROVED BY		
NAME/ FUNCTIONAL AREA	**DESIGNATION**	**SIGNATURE /DATE**
QUALITY CONTROL-HEAD		
QUALITY ASSURANCE-HEAD		

HOLD TIME STUDY FOR STERILIZED GARMENTS (PRODUCTION)

2.0 OBJECTIVE

This protocol is designed to validate the documented evidence that to ensure hold time study for sterilized garments.

3.0 SCOPE

The scope of this protocol shall be limited to validate Hold Time Study for Sterilized Garments.

4.0 RESPONSIBILITY

Responsibility of different department/personnel involved in different activities related to the valuation study.

Functions	Responsibility
Microbiology	Preparation of protocol & report
Microbiology	Review of the protocol & Execution
Production	Review of the protocol & report
Quality control	Review of the protocol & report
Quality assurance	Review & Approval of protocol & report
Quality assurance	Approval of the executed protocol and report

5.0 REFERENCE DOCUMENT

Following documents are referred during preparation of the protocol:

Document Name	Document Number
Procedure for cleaning, operation and maintenance of HPHV steam sterilizer	
Procedure for cleaning and usage of Sterile Garment Cubicle	

6.0 METHODOLOGY

6.1 Pre-Requisites

6.1.1 Pre-incubated RODAC plates

6.1.2 Incubators.

6.1.3 Sterile forceps.

6.1.4 Colony counter.

6.1.5 Sterilized garments.

6.2 Validation Procedure:

6.2.1 Preparation of the media

6.2.1.1 Prepare and sterilize the media and pre-incubate as per SOP.

6.2.1.2 Place the pre-incubated media plates under LAF working zone.

6.2.1.3 Disinfect with 70% IPA to the outer surface of the medium plates and place them in the SS carrier.

6.3 **Sampling Procedure for Sterilized Garments**

6.3.1 Arrange 5 no. of sterile garment for monitoring and label them as "Garments for Hold Time Study" and stored in grade A.

6.3.2 Perform the sterile garment monitoring for all locations mentioned in Table-01.

6.3.3 Take out the sterile garment and start the monitoring using the procedure mentioned below.

6.3.4 Carefully open the RODAC plate, invert and contact the surface of agar to the surface to be monitored. Press the plate firmly to expose the whole surface of agar to the sample surface.

6.3.5 Slowly take back the plate and close the plate with lid.

6.3.6 After sampling clean the residues of media with 70 % IPA and discard the garment for washing.

6.3.7 Keep one plate as a negative control.

6.3.8 Incubate the RODAC-plates at 22.5º±2.5 ºC for 72 hrs. followed by 32.5º±2.5 ºC for next 48 hrs.

6.3.9 Repeat the whole exercise for rest of garment for 24 hrs, 48 hrs, 72 hrs. and 96 hrs.

6.3.10 Record all the observations in the respective Observation Sheet.

Table-01

S.No.	Location of Sampling Point
1.	Right Hand Finger Dab (RH)
2.	Left Hand Finger Dab (LH)
3.	Forehead (FH)
4.	Chest (CH)
5.	Left arm pit (LA)
6.	Right arm pit (RA)
7.	Right Booties (RB)
8.	Left Booties (LB)

7.0 VALIDATION PARAMETERS AND ACCEPTANCE CRITERIA

7.1 Viable particle count for garment should be <1 cfu/contact plate.

7.2 **Revalidation**

7.4.1 Revalidation shall be done whenever changes in autoclave load pattern.

8.0 SUMMARY OF VALIDATION REPORT:

The validation report shall consist of a summary document, in the narrative form, which briefly describes the work as well as conditions regarding acceptability. This validation report shall also include the raw data, which shall be completed at the time of validation activity as per annexure.

9.0 APPROVAL OF VALIDATION REPORT:

All validation parameters should comply with acceptance criteria as per protocol, reviewed and signed by Quality assurance.

10.0 ANNEXURE:

Following documents (Annexure I) are enclosed as a part of protocol and shall be pre-approved as a part of main protocol.

S.No.	Document	Title	Data sheet Number
1.	Annexure I	Observation Sheet for Sterilized Garments	

11.0 ABBREVIATIONS:

Abbreviation	Terms
SCDA	Soyabean Casein Digest Agar
RODAC	Replicating organisms detection and counting
LAF	Laminar Air Flow
CFU	Colony Forming Unit

12.0 CHANGE HISTORY DETAILS:

Version no.	Reason for revision	CRF no.	Effective date
00	First Issue	Not Applicable	

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ANNEXURE I

Media Used		Sterile Media Lot No.	
Sterilization of Garments Done On		HPHV Steam Sterilizer Cycle Number	
Incubator ID. (20-25^{0}C)		Incubator ID. (30-35^{0}C)	

Observation:

S.No.	Locations for Monitoring of Garments ↓	Total viable Aerobic Count: CFU/Contact Plate at different Days of Storage Period of Garments				
		After 0 hrs. Date _____	After 24 hrs. Date _____	After 48 hrs. Date _____	After 72 hrs. Date _____	After 96 hrs. Date _____
	Sampled by / Date →					
1.	Forehead (FH)					
2.	Chest (CH)					
3.	Left arm pit (LA)					
4.	Right arm pit (RA)					
5.	Right Booties (RB)					
6.	Left Booties (LB)					
Observed by/ Date →						

Observed by/Date: **Reviewed by/Date:**