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Hold Time Validation Study For Sterilized Articles & Garments

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1.0 PRE-APPROVAL SIGNATURE

Name/Designation	**Signature**	**Date**
Prepared By		

Checked By		

Approved By		

2.0 OBJECTIVE:

2.1 To ensure hold time period of the articles in which are sterilized in steam sterilizer and used for routine use. The following articles and garments are studied for hold time period for the sterility level of articles.

- Sterilized Garments
- Filtration cups
- Scissors & forceps
- Gloves
- Mopping cloth
- Swabs
- Air sampler sieves.

3.0 RESPONSIBILITIES:

3.1 Validation Group consists of following members:

Head QA

Deputy Manager, QA

Head - Microbiology

Microbiologist

3.2 Specific Responsibilities

3.2.1 Microbiologist shall prepare the protocol, and also responsible for preparing the media and testing of the samples, preparation of summary report.

3.2.2 Head Microbiology & Manager QA shall check the protocol and summary for its completeness.

3.2.3 Head of the Department QA shall be responsible for the final approval of protocol and summary report.

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4.0 VALIDATION METHODOLOGY:

Before proceeding for validation following materials are required.

- Sterile forceps and Scissors
- Gloves
- Sterilized garments
- Sterilized Filtration Cups
- Sterilized Soyabean Casein Digest Medium.
- RODAC plates
- Sterilized Peptone water bottles.
- Swabs
- Air sampler sieves.

The validation study shall be performed as stated below.

4.1 Sterilized garments, Gloves, filtration cups, moping cloth shall be stored under unloading LAF of sterility testing room.

4.2 Sterilized forceps, filtration cups, swabs, Air sampler sieves can be stored in Controlled areas.

4.3 Microbiologist shall place the sterilized garments in the garment cubicle.

4.4 **For sterilized Garments:** Microbiologist shall perform the monitoring of sterile garments from any 2 different locations of sterilized garment by using RODAC plates. Incubate the RODAC plates at 30-35ºC for 48 Hrs followed by 20-25ºC for 72 Hrs.

4.5 After monitoring microbiologist shall discard the gown.

4.5.1 **For filtration cups:** Remove the wrapping pack of one filtration cup and fix it on the sterilized manifold.

4.6 With the help of a sterilized forceps place one sterilized membrane on the filter holder.

4.7 Place the top cup and clamp it.

4.8 Pour sterilized 100 ml peptone water and apply vacuum for filtration.

4.9 After filtration transfer the membrane with the help of a sterilized forceps and inoculate it in sterilized Soyabean Casein Digest medium. Incubate the tubes at 30-35ºC for 48 Hrs followed by 20-25ºC for 72 hrs.

4.10 For Forceps and Scissors: With the RODAC plates do the surface monitoring of the Forceps and Scissors. Incubate the RODAC plates at 30-35ºC for 48 Hrs followed by 20-25ºC for 72 Hrs.

4.11 For Mopping Cloth: With the RODAC plates do the surface monitoring of the mopping cloth. Incubate the RODAC plates at 30-35ºC for 48 Hrs followed by 20-25ºC for 72 Hrs.

4.12 For Gloves: With the RODAC plates do the surface monitoring of the Gloves and Incubate the RODAC plates at 30-35ºC for 48 Hrs followed by 20-25ºC for 72 Hrs.

4.13 Swabs: Incubate sterilized swabs containing SCDM at 30-35ºC for 48 Hrs followed by 20-25ºC for 72 hrs.

4.14 **Air sampler sieves:** perform the surface monitoring of air sampler sieves with the help of swabs and incubate the swabs containing SCDM at 30-35ºC for 48 Hrs followed by 20-25ºC for 72 Hrs.

4.15 Above testing sample shall be considered as the first day monitoring for garments, Forceps and scissors, Mopping cloth, Swabs, Air sampling sieves, filtration cups and Gloves.

4.16 After performing the first day monitoring, place the fresh sets of garments in the garment cubicle.

4.17 The monitoring shall be performed on all the test materials at every 24 hrs for 5 days as per the procedure mentioned above.

4.18 Record the observations and results in Annexure I.

5.0 ACCEPTANCE CRITERIA:

5.1 Sterilized stored materials should be free from microbial contamination when stored in sterility testing room and controlled area during the complete validation period.

6.0 EVALUATION OF RESULTS:

Evaluations shall be based on the basis of:

- Compliance to the acceptance criteria shall establish that the environmental storage conditions are adequate when kept under unidirectional airflow and aseptic conditions.
- Failure to meet the requirement shall require changing in storage procedure and again perform revalidation study.

7.0 REVALIDATION SCHEDULE:

Revalidation shall be carried out in case of

- When ever the storage condition changed.
- Incase of change in Sterilization parameters.

8.0 DOCUMENTATION:

Validation Report contains the following documents.

- Summary and conclusion
- Test data sheet
- Approved Validation protocol

9.0 CONCLUSION:

Summary report will contain discussion and conclusion, based on the validation study a conclusion shall be drawn.