

## **1 Purpose**

The purpose of this Guideline is to provide a general guideline for sterility testing. This guideline should aid in assuring that the products manufactured at the company's sites as well as by a contract manufacturers meet the appropriate regulatory and company requirements and that there is a harmonized, company-wide approach to the concept of sterility testing.

## **2 Scope and Applicability**

This Guideline applies specifically to sterility testing as at any site manufacturing sterile products as well as at third party testing labs.

In addition to the Guideline, the following items should be in place:

### **Standard Operation Procedures (SOPs).**

SOPs shall be developed to provide clear direction for the execution of the testing procedures, material preparation, data analysis, and the development of the documentation referred to in this guideline.

### **Validation Protocols**

Validation protocols shall be generated to verify and document that the methods and equipment used to perform sterility testing can reliably and consistently detect micro-organisms that may be present in units being tested. These protocols, the data generated and the associated summary reports should provide documentation of the acceptability of these methods and equipment for their intended use.

## **3 Definition**

None

## **4 Responsibilities**

- 4.1** It is the responsibility of the appropriate management to establish, issue, maintain and ensure compliance with this International Guideline for sterility testing.
- 4.2** It is the responsibility of each unit using third party testing labs to ensure that this Guideline is adhered to.

## **5 Guideline**

### **5.1 Sterility Testing**

#### **5.1.1 General Requirements**

- 5.1.1.1** Sterility testing should be carried out in a suitable clean environment that meets

- Sterility Test Methods.
- Negative Controls.
- Incubation of Sterility Test Samples.
- Cleaning and Sanitation of Sterility Test Area.
- Preparation, Testing, Approval and Storage of Sterility Test Media, Reagents and Supplies.
- Growth promotion tests.
- Maintenance of Sterility Test Area Equipment and Systems.
- Environmental Monitoring Program for the Sterility Test Area.
- Identification of Micro-organisms from Positive Sterility Test Samples.
- Preparation and Decontamination of Containers for Sterility Testing.
- Gowning (if applicable).
- Sterility Test Failure Investigation and Response.
- Decontamination and Disposal of Sterility Testing Waste.
- Interpretation of Sterility Test Results.
- Retesting.
- Trending of Sterility Test Data.
- Change Control.

### 5.1.3 Validation

**5.1.3.1** The following areas should be addressed by the validation effort to assure the reliability of the data generated by the sterility test program.

- Sterility Test Area Environment with associated instrumentation and equipment
- Sterility Test Methods
- Sanitation Procedures
- Sterilization Procedures
- Decontamination Procedures

If a barrier system/isolator is used, validation of it's associated decontamination cycles should include

Cycle efficacy / lethality studies  
Penetration studies (media and product containers)  
Environmental monitoring media for use in isolators  
Aeration / purging studies

**5.1.3.3** All proposed changes to validated systems, processes, equipment or methods shall be reviewed and approved by appropriate management prior to the change. Any changes that impact the status of a validated system process, equipment or methods may require revalidation of that system, process, equipment or method.