# CLEANING VALIDATION PROTOCOL OF LYOPHILIZER

# Cleaning Validation of Lyophilizer

## TABLE OF CONTENTS

## 1.0 APPROVAL

The cleaning validation protocol is prepared by the Validation team for the project "Integrated Sterile Bulk and Formulations Facility", under the authority QA Head. Hence this document before being effective shall be approved by the QA Head.

| PREPARED BY | | |
|---|---|---|
| **NAME/ FUNCTIONAL AREA** | **DESIGNATION** | **SIGNATURE /DATE** |
| **Validation & QA** | | |

| CHECKED BY | | |
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| **Production** | | |
| **Quality Control** | | |
| **Quality Assurance** | | |

| APPROVED BY | | |
|---|---|---|
| **NAME/ FUNCTIONAL AREA** | **DESIGNATION** | **SIGNATURE /DATE** |
| **Quality Assurance – Head** | | |

## 2.0 OVERVIEW:

### 2.1 Introduction:

The purpose of this protocol is to establish that the Cleaning procedure for Lyophilizer.

### 2.2 Objective:

The objective of the cleaning validation protocol is to establish & assure with documented evidence that the cleaning procedure for Lyophilizer, remove residue of the riboflavin to levels below the established acceptance limits and verify the visually for removal of Riboflavin.

## 3.0 SCOPE AND PURPOSE:

### 3.1 Scope:

This CLV is prepared to describe the validation requirement and plan for:

- All cleaning procedures used for cleaning of lyophilizer, which are used in processing of Sterile API and lyophilized vial.

### 3.2 Purpose:

Cleaning Validation Protocol (CLV) serves to specify and to co-ordinate the validation activity required for all cleaning processes which are to be followed for lyophilizer to be used for processing of sterile API product and lyophilized vial.

CVP will serve to ensure that cleaning procedures used for lyophilizer at Integrated Sterile Bulk and Formulation Facility (which may adversely affect product quality if found to not efficiently clean the equipment as per the requirement) are validated as per cGMP requirements.

The PVP is subordinate to the Validation Master Plan (VMP) of Integrated Sterile Bulk and Formulation Facility of Rajasthan Antibiotics Limited, Bhiwadi.

## 4.0 CLEANING VALIDATION APPROACH:

This cleaning validation protocol is prepared based on project cleaning validation plan or originated based on the guidance & instruction of VMP. Lyophilizer has to be cleaned before the start of a production process. The cleaning is done to remove the traces of the product.

### 4.1 Execution Method:

Spraying the riboflavin (0.02% w/v) solution on shelf and inner surface of lyophilizer, after that kept or drying then start the cleaning procedure as per SOP and collect the sample and send to Quality control.

| S.No. | Name of Sample | Test Required | Limit |
|---|---|---|---|
| 1. | Rinse Sample | pH | 5.0 to 7.0 |
| | | Previous Product Content | NMT 10 PPM |
| | | Conductivity | NMT 1.3 µs/cm |
| | | Particulate matter | |
| | | Bioburden | 10 cfu/ 100 ml |
| | | BET | 0.25 Eu/ml |
| 2. | Check the visually for removal of riboflavin | | Not seen |

**5.0 CLEANING VALIDATION SAMPLE TEST AND LIMIT:**

**6.0 DEVIATION:** There is any deviation observed during the execution of cleaning validation of lyophilizer record as per SOP "Handling of Deviation" and attach with validation report.

**7.0 VALIDATION ACCEPTANCE CRITERIA:** All the parameters are meeting with the predefined specifications.

**8.0 REVALIDATION CRITERIA:**

Change in Manufacturing Equipments and Introduction of New Products.

**9.0 SUMMARY AND CONCLUSION:**

Summary and Conclusion concluded on the basis of three cleaning validation batches sample analysis results.

**10.0 REFERENCE DOCUMENT (IF ANY):**

| S.No. | Document Name |
|---|---|
| **1.** | Cleaning Validation Plan |
| **2.** | Validation Master Plan (VMP) |

## 11.0 LIST OF ANNEXURE:

| Annexure No. | Annexure Title |
|---|---|
| **01** | Training Record |
| **02** | Cleaning Validation – Sampling Plan |
| **03** | List of Equipment |