POLICY ON CLEANING VALIDATION

INTRODUCTION:

……. is committed to ensure that cleaning procedures used are effective, robust and consistent thereby ensuring products produced are of the right quality, safe and efficacious. This document provides the policy for cleaning validation.

SCOPE:

This policy is applicable to validation of procedures used for cleaning of equipment and accessories used for manufacture of finished dosage forms and active pharmaceutical ingredients at …… and associated units.

POLICY DETAILS:

Cleaning procedures that impact product quality, safety, identity or efficacy shall be validated.

Validation Master Plan

Validation Master Plan shall be in place and shall include the scope, roles and responsibilities, procedures to be validated, documentation, acceptance criteria and validation deliverables at the minimum.

General Considerations

- ✧ A written procedure shall be in place to address Cleaning Validation.
- ✧ Analytical and Microbial methods used for cleaning validation shall be validated.
- ✧ Sampling technique like Rinse and Swab or either of them shall be used for cleaning validation. Selection of technique shall be based on rationale.
- ✧ Staff involved in validation work shall have adequate training.
- ✧ Traditionally 3 consecutive exercises within the finally agreed parameters, are considered the minimum number acceptable to constitute validation of the cleaning procedure.
- ✧ Alternatively, appropriate number of exercises can be fixed based on Risk Assessment.
- ✧ Extensive testing/ monitoring shall be performed during the validation exercise in order to have thorough information of the cleaning regime.
- ✧ Deviations or failure during validation shall be investigated and documented.
- ✧ “Worst case” approach can be used for validation. There shall be documented scientific rationale for the choosing worst case.
- ✧ Acceptance criteria shall be developed case by case in a specific protocol and shall be based on a scientific rationale.
- ✧ Intervals between use and cleaning as well as cleaning and reuse shall be validated.
- ✧ All documents related to validation shall be reviewed and approved by competent personnel.

  Archival of documents related to cleaning validation shall be as per defined procedures.
- ✧ Validation activities at site where product is being transferred shall be based on local regulatory requirements and procedures set by ……..
- ✧ Cleaning Method Validation shall be completed before initiation of cleaning validation.

Validation Protocol

Validation Protocol shall specify how validation shall be conducted.

Protocol shall be approved prior to validation and shall specify critical procedure, responsibilities, sampling plans, testing methods and acceptance criteria at the minimum.

Validation Report

A Validation reports shall summarize the validation activities carried out.
The report shall include cross reference to the protocol, summary of results obtained and deviations, if any. There shall be a conclusion whether the validation is successful or not.

POLICY ON CLEANING VALIDATION

Revalidation and Changes
Revalidation shall be based on defined written procedure.
Any change to a validated procedure shall be managed through change control.

AMENDMENT AND WAIVER:
The company reserves the right to amend, alter and/or terminate this policy at any time.

DEFINITION:
Cleaning Validation:
A documented evidence that a cleaning procedure is consistent in reducing product residue and removal of cleaning agents, bio-burden, flavour, colour (if applicable) from equipment and accessories within the limits of acceptance.

ABBREVIATIONS:

API	:	Active Pharmaceutical Ingredient
CFR	:	Code of Federal Regulations
CQA	:	Corporate Quality Assurance
EU	:	European Union
ICH	:	The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
SOP	:	Standard Operating Procedure

REFERENCES:
21 CFR Parts 211
Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use. Annex 15: Qualification and Validation
Section XII: ICH Q7 “Good Manufacturing Practices Guide for API”
PDA Technical Report 29 – Points to consider for cleaning validation.
EMA’s Guideline on setting health-based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities.
ISPE guide Volume 7 “Risk-based Manufacture of Pharmaceutical Products”.
ICH Topic Q3C (R4) : Impurities: Guideline for Residual Solvents.
MINISTRY OF SOCIAL PROTECTION RESOLUTION NUMBER 3028 OF 2008 (August 13).