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1.0 OBJECTIVE:

To lay down a Procedure for Cleaning Validation.

2.0 SCOPE:

This SOP is applicable to Validate Cleaning Procedure of Equipments used in manufacturing of Products at ……...

3.0 RESPONSIBILITY:

QA (Officer/ Executive): Preparation, Distribution (to Respective Department), Revision, Retrieval and Destruction of this SOP.

QA Manager: Review, Approval, Training and effective implementation of this SOP in all the applicable areas.

4.0 ACCOUNTABILITY:

Head QA: Authorization of this SOP & ensure Training and effective Implementation of SOP.

5.0 DEFINITION:

5.1 CLEANING VALIDATION:

Cleaning Validation is a Validation program to verify that the processes and procedures used to Clean Product Residue from Process Equipment and components will consistently and significantly reduce the amount of Active and/or Excipient(s) and Cleaning Agent(s) to a concentration within calculated acceptance limits.

6.0 PROCEDURE:

6.1 INSTRUCTIONS:

- Only Cleaning Procedure for Contact Parts of Equipments shall be validated.
- For similar range of Products representative range of similar Products and Processes concerned shall be considered in Validation Program by addressing the Critical Issues.

- For range of Products Cleaning Validation shall be carried out by Bracketing and considering Worst Case.
- If required Validation shall be also carried out for Individual Product.
- Cleaning Procedure for the Products and Process which are very similar, do not need to be individually validated.
- Efficacy of recovery of sampling technique shall be established.
- For Cleaning Validation, Three Consecutive Successive Validation should be performed for confirmation of Validation.

6.2 MINIMUM CLEANING VALIDATION REQUIREMENT:

If it is not possible to validate all the Equipment for all products then as a Minimum Requirement the Validation Policy should encompass conditions which represent the most appropriate challenges (Worst Case) to the procedure, as an example:

- Removal of Products which contain the products with the greatest Biological Activity.
- Removal of Products containing the Products/Intermediates/Byproducts with the Least Solubility.

6.3 WORST CASE SELECTION:

The criteria to define a worst case for evaluation of MACO (Maximum Allowable Carry Over) is on the basis of the following:

- Least daily human adult dosage of the API.
- Potent category of API.
- Least solubility of active in water
- Least MACO value of API
- Highest Strength shall be taken for the study. In case of linear formula any strength can be taken for the study.
- On addition of a new product, its MACO value is evaluated. On revision of SOP, the data will be included in respective annexure.

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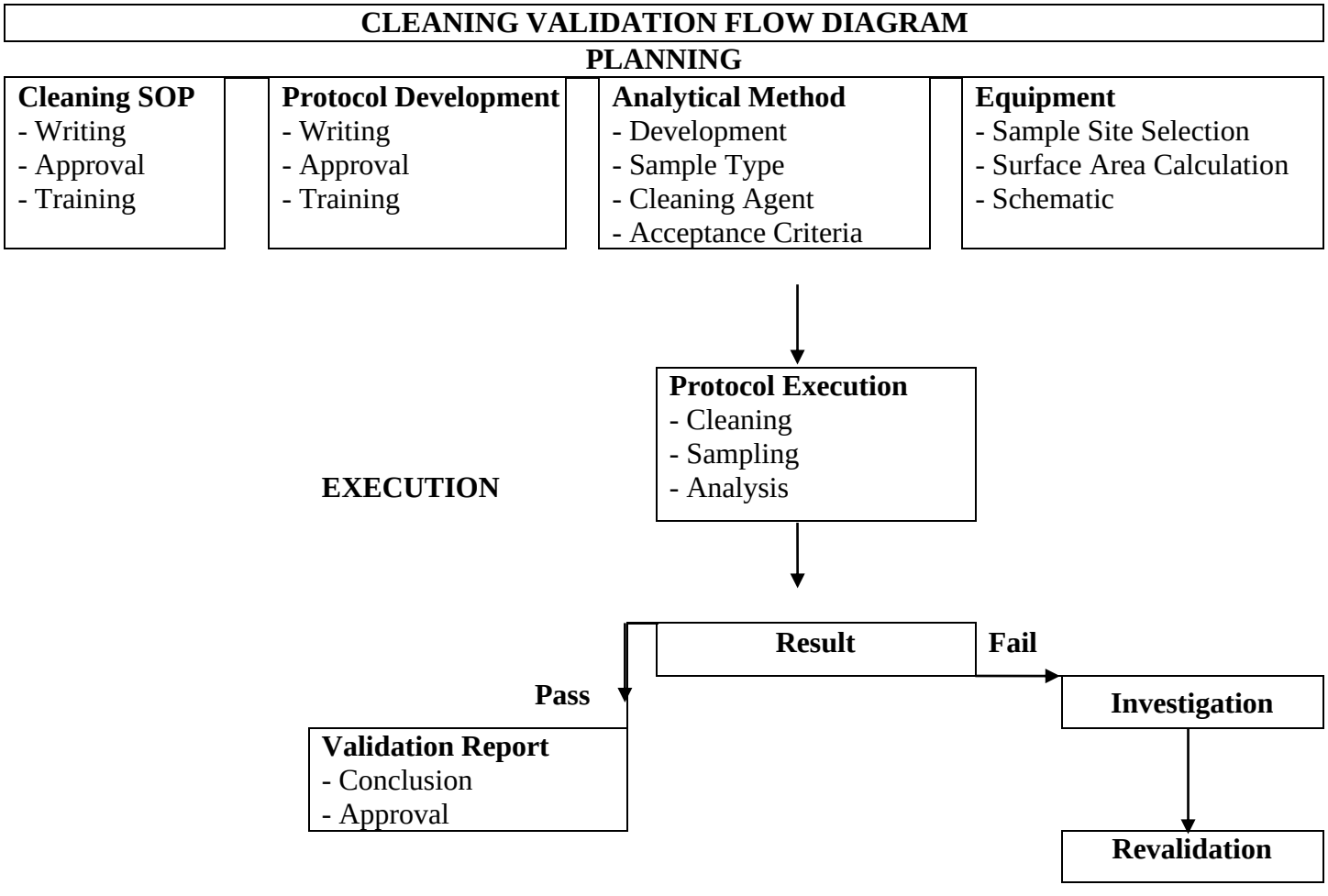
6.4 CLEANING VALIDATION METHODOLOGY:

The activity flow for Validation process is as:



6.5 CLEANING PROCESS DESCRIPTION:

All the equipment shall be clean as per their respective SOP.

6.6 MATRIXING:

6.6.1 If case of **"Multi Product"** Manufacturing Line, Product Matrixing/Grouping shall be adopted in Cleaning Validation Planning.

6.6.2 The products shall be first grouped according to formulation and dosage form, including considerations of Potency, Toxicity, and Solubility, hard to clean, adherence property, Minimum & Maximum daily dose and Batch size of next products.

6.6.3 These Product Groupings shall further be subdivided by types of Equipment used in their Manufacture.

6.6.4 Further distinctions shall be made according to cleaning method and agent. Products belonging to a single group must be similar (formulation), should share the same equipment train and same cleaning procedure should be applicable to each of them.

6.7 SAMPLING PLAN:

6.7.1 Sampling is designed to identify potential residues on Cleaned Equipment Surfaces that might be transferred to the next Manufacturing Batch.

6.7.2 Thus Sampling Plan should be such that it will be able to provide the representative information about the residues.

6.7.3 The sampling shall be based on the following considerations:

6.7.3.1 Most Difficult to Clean Locations:

- Sampling is to be planned from locations in the manufacturing equipment, which are more difficult to clean, and therefore more likely for the residues to be accumulated, if cleaning is inadequate. Selection shall be based on good scientific (by reviewing the configuration of the Equipment) judgment.

6.7.3.2 Locations that are likely to produce Non-Uniform Contamination of the Next Batch:

- There are locations in the Manufacturing Equipment wherefrom the residue may preferentially be transferred to only a limited portion of the next batch e.g. Bottom of tank. Sampling plan should cover these locations also.

6.7.3.3 Representative Functional Locations:

- At least one sample from each representative functional location should be considered e.g. Equipment Sidewall, Blade etc.

6.8 SAMPLING TECHNIQUES:

6.8.1 Sampling may either be performed by Swabbing or by Rinse.

6.8.1.1 Rinse Sampling:

- Rinse Water Sample shall be collected after rinsing the Equipment with specified quantity of Purified Water / Water for Injection as defined in individual Protocol.
- Rinse Water Sample shall be submitted to QC with Intimation Slip.

- The samples taken shall be analyzed for the content of residual active ingredient to establish that the residual levels after cleaning are below the set Acceptance Criteria.

6.8.1.2 Swab Sampling:

6.8.1.2.1 Sampling Procedure:

- Strongly preferred method, as some residues may need a mechanical or physical action to remove from the surface.
- Most of the Equipments shall be swabbed for at least 1-5 locations, depends on equipment size, accessibility and compliance.
- For Cleaning Validation Swab Sample shall be collected for Chemical / Microbiological Analysis from the locations specified as per the Sampling Locations.
- Before collection of swab sample Visual Inspection of the Equipment shall be done to check the cleanliness.
- Selection of sample position shall be based on difficult to Clean Equipment Surface Area.
- Swab Sample shall be collected from (approximate-25 sq.cm) 5x5 sq.cm.
- The recommended direction and motions used in actual swabbing of an area as shown in Figure 1.
- Recommended swab sampling procedures ensure complete residue pickup from the defined surface area. An additional step of swabbing the perimeter of the sampling area may be included if necessary.

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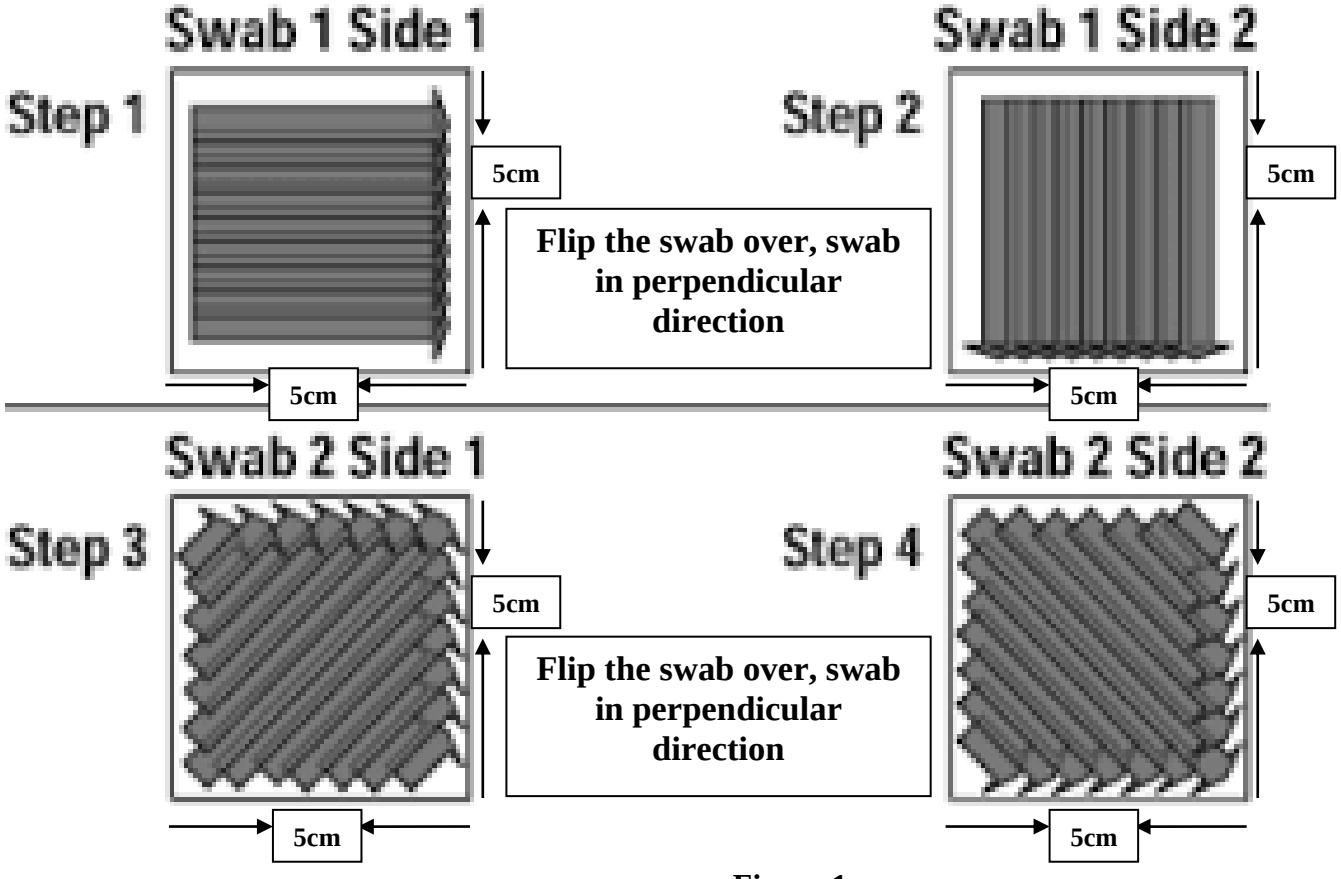

Figure 1

- **Proper swabbing procedure:**
- Define region to be tested.
- Dampen swab with diluents.
- Swab with overlapping pattern. Flip swab and repeat, passing swab in perpendicular direction. Repeat procedure with second swab at 45^0 angles.
- Swab with entire head flat against surface.
- Snap swab head at the notch along narrow edge of swab handle. Allow swab head to fall in to test tube and transfer to the Quality Control Laboratory for analysis.
- Sample for the Microbial Analysis shall be taken by Microbiologist.
- Swab Sample shall be submitted to QC with Intimation Slip.
- Technique after cleaning from the Contact Parts specified in the diagram.

- The samples taken at different stages of Cleaning Procedure shall be analyzed for the Content of Residual Active Ingredient to establish that the residual levels after cleaning are below the set Acceptance Criteria.
- The Swab Sampling Locations shall be selected on the basis of following criteria:
  - Contact Parts, which are difficult to reach.
  - Contact Parts, which are difficult to visually inspect.
  - Contact Parts contour, which may lead to build up of the residual matter.
  - Contact Surfaces, which can be sampled by Swab and likely to have contamination.

6.9 RECOVERY FACTOR:

6.9.1 Result in the analyzed sample is the acceptance limit. It should be adjusted by swab recovery factor. By including the swab recovery factor in the actual analytical calculation i.e. if RF is 0.80 (80%) and are measured 1.3 ppm in the analytical procedure then that value is adjusted by dividing the analytical results by the RF 1.3 ppm / 0.80 = 1.6 ppm

6.9.2 The other alternative is to include the recovery factor in the numerator of analyzed sample. In this case the RF 0.80 should be included in the numerator, while the numbers used shall be different; the net effect of comparing the analytical results to the calculated limit will be logically the same.

6.10 SELECTION OF ANALYTICAL METHOD:

6.10.1 The development and validation of analytical procedures for detection of product residue in Cleaning Validation Sample requires the selection of appropriate Analytical Methods.

6.10.2 A specific method must be selected carefully for detection of product residue; a non-specific analytical method may lead to false analytical results.

6.10.3 During validation of the cleaning procedure, the analytical methods used should be able to specifically quantify concentrations of all compounds of interest that may be present in samples.

6.10.4 Specific method shall be employed during cleaning validation and for subsequent cleaning verification or ongoing monitoring of cleaning, non- specific methods shall be employed.

6.11 ANALYTICAL METHOD VALIDATION:

6.11.1 Any instrumental analytical procedures used to analyze cleaning validation samples need to be specified and sufficiently sensitive to determine the low levels of residues typically found in samples.

6.11.2 The methods used to analyze samples that allow the equipment to be released for manufacture of another product shall be validated to ensure that it meets following requirements:

- Specificity
- Limit of Detection (LOD)
- Limit of Quantitation (LOQ)
- Linearity
- Precision
- Recovery of drug from spiked swabs
- Recovery of drug from spiked SS plates and other product contact materials Range
- Stability of Analytical Solution
- Robustness

Details of the Cleaning Method Validation shall be mentioned in respective Protocol.

6.12 CLEANING SOLVENT:

6.12.1 Only Water for Injection used for cleaning of equipments.

6.12.2 Cleaning techniques to be evaluated

- Manual Cleaning
- CIP and COP
- Semiautomatic
- Automatic
- Time Consideration
- Number of Cleaning Cycle

6.13 ELEMENTS OF CLEANING VALIDATION:

6.13.1 Establishment of Acceptance Criteria

6.13.1.1 Chemical Determination:

- **Limiting the level based on Toxicity Data:**

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An Acceptable Daily Intake (ADI) is calculated with suitable Safety Factors applied & this is converted to the Maximum Allowable Carryover to the Product.

The MACO can be based upon LD50 data.

Procedure

Calculate the NOEL (No Observable Effect Level) according to the following equation and use the result for the establishment of MACO

$$\text{NOEL} = \frac{\text{LD50} \times \text{BW}}{2000}$$

From the NOEL number a MACO can be calculated according to:

$$\text{MACO} = \frac{\text{NOEL previous} \times \text{MBS next} \times 1000}{\text{SF} \times \text{TDD next}}$$

$$\text{MACO (mcg/swab)} = \frac{\text{MACO} \times \text{Swab Surface Area}}{\text{Total Surface Area}}$$

Where:-

MACO Maximum Allowance Carryover: Acceptable transferred amount from the previous product into your next product (mg)

NOEL previous: No Observed Effect Level (mg/day)

LD50: Lethal Dose 50 in mg/kg animal. The identification of the animal (mouse, rat etc.) and the way of entry (IV, oral etc.) is important (mg/kg)

BW: Is the weight of an average adult (e.g. 70 kg) (kg)

2000: 2000 is an empirical constant

TDD next: Standard Therapeutic Daily Dose for the next product (mg/day)

MBS next: Minimum batch size for the next product (s) (where MACO can end up)

1000 = conversion of milligrams to micrograms

SF = Safety factor

The safety factor (SF) varies depending on the route of administration (see below).

- **Pharmacological Dose Method:**

Not Greater Then 1/1000 of the Normal Therapeutic Dose will be Present per Typical Dose of the Next Product to be run in the Equipment. The Validation Protocol should include the Calculation, which ties this Philosophy to the Acceptance Criteria for the sample to be tested.

Calculation of the maximum allowable carry over (MACO) residue of Active Ingredient based on Dose Criterion

$$\text{MACO (mcg/swab)} = \frac{\text{[SRDD (A)] x [MBS (B)] x [Swab Surface Area] x 1000}}{\text{[LRDD (B)] x [Total product contact equipment surface area (A)] x S.F.}}$$

Where A = Product to be cleaned (previous product).

B = Product to be manufactured (next / subsequent product).

S.F. = Safety Factor (for the parenterals route 10000) .

SRDD (A) = Smallest recommended Daily Dose of Product 'A' (in mg)

LRDD (B) = Largest recommended Daily Dose of Product 'B' (in mg)

MBS (B) = Minimum Batch Size of Product 'B' (in mg)

Swab Area = 25 cm2

1000 = conversion of milligrams to micrograms

Equipment surface area = in cm^2

- **Acceptance Criteria:**

Cleaning validation studies demonstrates that, residual activity of the said ingredient detected in the swab, should be within acceptable limits (NMT Maximum Allowable Carry Over).

- No absorbance found in wash water (Rinse and swab) sample should be Nil.
- If any absorbance found then carry out the determination of Assay of the sample as per method.
- pH of rinse water: 5-7.
- Conductivity of rinse water: NMT 1.3µs/cm^2

6.13.1.2 Physical Determination:

- Visual examination of the Equipment & Verification that it is Free of Visible Residues.

Acceptance Criteria:

- Should be clear & visually cleaned

6.13.1.3 Microbiological Determination:

Swab samples shall be collected from product contact surface area immediately after completion of cleaning activities and satisfactory visual inspection. The limits for the microbiological bio-burden criteria for product contact surface are given in acceptance criteria.

Acceptance Criteria:

- **Swab Samples**:
  - Total Aerobic Bacterial count : NMT 10cfu/swab
  - Total fungal count: Nil
- **Rinse Samples**:
  - Total Aerobic Bacterial count : NMT 10cfu/100 ml
  - Total fungal count: Nil
  - BET: NMT 0.25 EU/ml

6.13.1.4 Cleaning Procedures:

Written Cleaning Procedure for each piece of Equipment must be prepared that specify the Cleaning Agent, Cleaning Techniques etc.

6.13.1.4.1 Equipment Parameters to be evaluated:

- Identification of the Equipment to be cleaned
- Areas difficult to Clean
- Property of Materials
- Ease of disassembly

6.13.1.5 Safety Factor Chart:

Approach	Approach typically applicable to
1/10th to 1/100th of a Normal Daily Dose	Topical Products
1/100th to 1/1000th of a Normal Daily Dose	Oral Products
1/1000th to 1/10000th of a Normal Daily Dose	Injections, Ophthalmic Products
1/10000th to 1/100000th of a Normal Daily Dose	Research, Investigational Products

6.14 CLEANING VALIDATION PROTOCOL PREPARATION:

A Validation Protocol is defined the specific items and activities that will constitute a Cleaning Validation Study. The Cleaning Validation Protocol must be prepared prior to the initiation of the activity and must include the following:

6.14.1 Protocol pre approval

6.14.2 Objective

6.14.3 Scope

6.14.4 Responsibility

6.14.5 Execution team

6.14.6 Training record

6.14.7 Introduction of cleaning validation

6.14.8 Equipment description and cleaning process description

6.14.9 Calculation of maximum allowable carryover (maco)

6.14.10 Equipment chain matrix

6.14.11 Selection of worst case product for cleaning validation study

6.14.12 Methodology of cleaning process validation

6.14.13 Acceptance criteria

6.14.14 Sampling technique

6.14.15 Sampling plan

6.14.16 Failure investigation and corrective action

6.14.17 Documentation

6.14.18 Revalidation criteria

6.14.19 Conclusion

6.14.20 Reference

6.14.21 Abbreviations

6.14.22 Revision history

6.15 CLEANING VALIDATION REPORT PREPARATION:

The Report of Cleaning Validation Study evaluates the data generated with respect to Acceptance Criteria and provides the results and conclusions of the Study. The Report should indicate the following:

6.15.1 Report pre approval

6.15.2 Objective

6.15.3 Scope

6.15.4 Responsibility

6.15.5 Training record

6.15.6 List of instruments (calibration status)

6.15.7 Hold time study of un-cleaned & cleaned equipment

6.15.8 Observation and results

6.15.9 Deviation (if any)

6.15.10 Change control (if any)

6.15.11 Document attachment

6.15.12 Summary

6.15.13 Recommendation

6.15.14 Abbreviations

6.15.15 Revision History

6.15.16 Report post approval

Cleaning Validation Protocol & Report shall be prepared as per current version of SOP**.**

Note: Text part of Protocol shall be revised through change control procedure but Annexure of Protocol can be updated as per requirement without taking change control. A separate history sheet shall be maintained for all Annexure of Protocol.

6.16 RE-VALIDATION/RE-VERIFICATION CRITERIA:

- Change in Cleaning Procedure.
- Change in the Processing Equipment.
- Significant change in the equipment used to clean the processing equipment.
- If Introduction of New Product/Manufacturing Process which affects the Acceptance Criteria calculation.
- Significant failures of Swab sample/wash water analysis results.

6.17 Cleaning Validation Executions details shall be recorded by Quality Assurance Department as per Format shown in **Annexure-I**.

6.18 CLEANING VALIDATION MASTER PLAN:

The Cleaning Validation Master Plan is designed to provide guidelines for planning, execution and successful completion of the Cleaning Validation program. As the cleaning procedure is Automatic (CIP) & Manual, hence training of personnel shall be performed before the Cleaning Validation.

A Cleaning Validation Master Plan is defined the specific items and activities that will constitute a Cleaning Validation Study. The Cleaning Validation Master Plan must be prepared prior to the initiation of the activity and must include the following:

6.18.1 Approval
6.18.2 Introduction
6.18.3 Purpose
6.18.4 Scope
6.18.5 Responsibilities
6.18.6 Cleaning validation activity flow
6.18.7 Strategy (validation approach)
6.18.8 Acceptance criteria
6.18.9 Cleaning validation protocol
6.18.10 Analytical method development and validation
6.18.11 Revalidation criteria
6.18.12 Change Control
6.18.13 Definitions

6.18.14 Reference

6.18.15 Abbreviations

6.18.16 Revision History

7.0 ABBREVIATIONS:

API	Active Pharmaceutical Ingredient
Ltd.	Limited
MAR	Maximum Allowable Residue
No.	Number
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
STP	Standard Test Procedure
Sign	Signature
S. No.	Serial Number
ADI	Acceptable Daily Intake
etc.	Etcetera
ml	Milliliter
mg	Milligram
LOD	Limit of Detection
LOQ	Limit of Quantitation

8.0 ANNEXURES:

ANNEXURE No.	ANNEXURE TITLE	FORMAT No.
Annexure-I	Cleaning Validation Execution Record	
Annexure-II	Equipment Chain Matrix	
Annexure-III	Matrix for Selection of worst case product for cleaning validation study	
Annexure-IV	Evaluation of new product for cleaning validation	
Annexure-V	Evaluation of new equipment for cleaning validation	
Annexure-VI	Cleaning Validation Master Plan (Specimen)	

9.0 DISTRIBUTION:

- Controlled Copy No. 01 — Head Quality Assurance
- Master Copy — Quality Assurance Department

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10.0 REFERENCES:

- Validation Master Plan
- PIC Principles of Qualification and Validation in Pharmaceutical Manufacture Recommendation on Cleaning Validation. (Document PR 1/99 March 1999).
- FDA Guide to inspections of Validation of Cleaning Processes (July 1993).
- SOP**,** Titled **"Preparation, Review, Approval, Control, Execution, Compilation, Revision & Destruction of Validation/Qualification Protocols and Reports"**.

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

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ANNEXURE-I

CLEANING VALIDATION EXECUTION RECORD

Year: **Block:**

S.No.	Date	Production Line	Cleaning Validation Started On	Cleaning Validation Completed On	Cleaning Validation Details	Checked By QA (Sign & Date)	Remarks

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ANNEXURE-II

EQUIPMENT CHAIN MATRIX

S.No.	Product Name	Equipment Name	Equipment Name	Equipment Name	Equipment Name	Total surface area Sq. cm.

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ANNEXURE-III

MATRIX FOR SELECTION OF WORST CASE PRODUCT FOR CLEANING VALIDATION STUDY

S.No.	Product Name	Active Pharmaceutical Ingredient (API)	Strength (in % of API)	Max. Daily Dose (mg)	Min. Daily Dose (mg)	Max. B. Size (Kg)	Min. B. Size (Kg)	Solubility in Water	Toxicity LD 50	Total Equipment surface area (in sq. cm)	MACO Based on Toxicity (mcg/swab)	MACO Based on TDD (mcg/swab)	Category

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ANNEXURE-IV

EVALUATION OF NEW PRODUCT FOR CLEANING VALIDATION

Product Name		
Active Pharmaceutical Ingredient (API)		
Strength (in % of API)		
Max. Daily Dose (mg)		
Min. Daily Dose (mg)		
Max. B. Size (Kg)		
Min. B. Size (Kg)		
Solubility in Water		
Toxicity LD 50		
Category		
MACO		
Change in Cleaning Procedure	**Yes**	**No**

Compare the above data with the data provided in the matrix and draw the conclusion whether above product falls under the existing matrix or required cleaning verification/validation or change in acceptance criteria is required.

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ANNEXURE-V

EVALUATION OF NEW EQUIPMENT FOR CLEANING VALIDATION

Equipment Name		
Location		
Capacity		
Make		
Total surface area		
Total surface area with extra 10 %		
Equipment train	**New Introduction**	**Replacement**

Compare the above data with data provided in matrix and draw the conclusion whether above equipment falls under the existing matrix or required cleaning verification/validation or change in acceptance criteria is required.

Change in operating principles	**Yes**	**No**
Change in design		
Is surface Area of any train will be affected		
Change in cleaning procedure		
Total surface area of particular train in cm^2 (Existing)		
Total surface area of particular train in cm^2 (After considering area of new equipment)		

Conclusion:		
Validation required	**Yes**	**No**
Verification required	**Yes**	**No**
For Acceptance Criteria:		
Change in Acceptance criteria required	**Yes**	**No**
Evaluated by:	**Checked by:**	**Approved by:**

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ANNEXURE-VI

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1. **APPROVAL:**

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
EXECUTIVE/MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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