PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation of Cleaning Validation and Hold Time/Shelf Life Study Protocol and Report	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a Procedure for Preparation of Cleaning Validation and Hold Time/Shelf Life Study Protocols and Reports.

2.0 SCOPE:

This SOP is applicable for Preparation of Cleaning Validation and Hold Time/Shelf Life Study Protocols and Reports in Quality Control department at ……...

3.0 RESPONSIBILITY:

QC (Officer/ Designee): Preparation, Revision, Retrieval and Destruction of this SOP.

4.0 ACCOUNTABILITY:

Head QC: Ensure Training and Implementation of this SOP.

5.0 DEFINITIONS

5.1 Protocol: A Protocol is a written set of instructions broader in scope than a Standard Operating Procedure (SOP).

5.2 Activity: Any monitoring or measuring or Qualification step.

5.3 Validation: Documented act of proving that any Facility/Utility/Equipment/Instrument/System actually lead to expected results.

5.4 Modification: Any significant change which may alter the validated state of Facility/Utility/ Equipment/Instrument/System.

5.5 Relocation: Change in location of any Utility, Equipment or System.

6.0 PROCEDURE:

6.1 GENERAL GUIDELINES FOR PREPARATION OF CLEANING VALIDATION AND HOLD TIME/SHELF LIFE STUDY PROTOCOL AND REPORTS:

6.1.1 Protocols and Reports shall be written in English Language by using Microsoft Word.

6.1.2 The person performing the Process or activity of QC Department shall prepare the Protocols and Reports.

6.1.3 Initiator shall have adequate knowledge, Training and experience in the related Areas of activity.

6.1.4 All the points in the Protocol/Report shall be numbered sequentially and sub paragraph of the Protocol/Report be also numbered sequentially with an incremental number derived from the heading number. Bullets may be use for sub paragraph of Protocol/Report.

6.1.5 Initiator shall check the completeness of draft Protocols and Reports and send to the Head of the Department for review.

6.1.6 Protocols and Reports shall have reference of related document such as Pharmacopoeia and Guidelines published by various Regulatory Authorities. Wherever necessary illustrations and drawing shall be indicated to provide better clarity and understanding of the Process / System.

6.1.7 The reviewer shall check the adequacy, accuracy, correctness and completeness of draft Protocols and Reports.

6.1.8 Upon receipt of the comments (if any), same shall be reviewed and incorporated in the Protocols and Reports.

6.1.9 Final copy of protocol & report shall be provided to QA.

6.1.10 All Protocols and Reports shall be prepared by Operating Officer/Executive of QC Department and Checked by QC, Head of Department/Designee.

6.1.11 Upon signature of Respective concerned persons, signed off copy of Protocol & Report shall be sent to Department Head for review by and Final approved by Head QA.

6.1.11.1 Cleaning Validation Protocol:

Cleaning Validation Protocol shall be prepared as per Annexure-I. Cleaning Validation Protocol shall contain the following Contents but not limited to:

1. Document Preparation and Approval
2. Objective
3. Scope

4. Responsibility
5. Execution Team
6. Cleaning Methodology
7. Validation Approach
8. Validation Data
9. Sampling Procedure Analysis Methodology
10. Pre-Validation Study
11. List of Materials to be used for cleaning validation
12. Establishment of Acceptance Criteria
13. Failure Investigation and Corrective Action
14. Documentation
15. Re-validation Criteria
16. Summary
17. Conclusion
18. Reference
19. Abbreviation
20. List of Annexures
21. Revision History

6.1.11.2 Hold Time Study Protocol:

Hold Time Protocol shall be prepared as per Annexure-II Hold Time Study Protocol shall contain the following Contents but not limited to:

1. Document Preparation and Approval
2. Objective
3. Scope
4. Qualification Team & Responsibilities
5. Procedure
6. Establishment of Acceptance criteria
7. Failure Investigation and Corrective Action
8. Documentation
9. Re-validation Criteria

10. Summary
11. Conclusion
12. Reference
13. Abbreviation
14. Revision History

6.1.12 PREPARATION OF VALIDATION AND HOLD TIME STUDY REPORT:

6.1.12.1 All Validation and Hold Time Study Reports shall be prepared as per format as shown in Annexure-III (Cleaning Validation) and Annexure-IV (Hold Time/Shelf Life Study). The format of Validation / Re-Validation Report shall contain the following information mention in 6.2.11.2

6.1.12.2 Cleaning Validation Report:

Cleaning Validation Report shall contain the following Contents but not limited to:

1. Objective
2. Scope
3. Qualification Team & Responsibility
4. Execution Team
5. Cleaning Methodology
6. Validation Approach
7. Sampling Procedure Analysis Methodology
8. Observations
9. Acceptance Criteria
10. Reference
11. Document Attachment
12. Deviation (If any)
13. Change Control (if any)
14. Summary
15. Conclusion
16. Approval of Report
17. Abbreviation

18. Revision History

6.1.12.3 Hold Time Study Report:

Hold Time Study Report shall contain the following Contents but not limited to:

1. Objective

2. Scope

3. Qualification Team and Responsibility

4. Execution Team

5. Procedure

6. Observations

7. Acceptance Criteria

8. Reference

9. Document Attachment

10. Deviation (If any)

11. Change Control (if any)

12. Summary

13. Conclusion

14. Approval of Report

15. Abbreviation

16. Revision History

6.1.13 Numbering System of Protocols and Reports:

6.1.13.1 All Protocols and Reports should have a unique Reference Number, which shall identify that document.

6.1.13.2 The numbering system of Cleaning Validation Protocol shall be as follows:

PD/CVP/QC/XXX, where

PD	-	…….
/	-	Slash
CVP	-	Cleaning Validation protocol
/	-	Slash
QC	-	Quality Control

/ - Slash

XXX - Unique Sequential Number for eg 001, 002, 003 etc.

6.1.13.3 The numbering system of Hold Time Study protocol shall be as follows:

PD/HTP/QC/XX/YYY, where

PD - …….

/ - Slash

HTP - Hold Time Protocol

/ - Slash

QC - Quality Control

/ - Slash

XX - Unique code for Hold Time Study

/ - Slash

YYY - Unique Sequential Number for e.g. 001, 002, 003 etc

6.1.13.4 The numbering system of Cleaning Validation Report shall be as follows:

PD/CVR/QC/XXX, where

PD - …….

/ - Slash

CVR - Cleaning Validation report

/ - Slash

QC - Quality Control

/ - Slash

XXX - Unique Sequential Number for eg 001, 002, 003 etc

6.1.13.5 The numbering system of Hold Time Study Report shall be as follows:

PD/HTR/QC/XX/YYY, where

PD - …….

/ - Slash

HTR - Hold Time Report

/	-	Slash
QC	-	Quality Control
/	-	Slash
XX	-	Unique Code for Hold time study (for e.g. Volumetric Solution as "VS")
/	-	Slash
YYY	-	Unique Sequential Number for e.g. 001, 002, 003 etc

6.1.13.6 Once a number is assigned to any Protocol and Report, the same number shall not be assigned to any other Protocols and Reports.

7.0 ABBREVIATIONS:

AHU	Air Handling Unit
API	Active Pharmaceutical Ingredients
HPLC	High Performance Liquid Chromatography
ID No.	Identification Number
Ltd.	Limited
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Cleaning Validation Protocol (Specimen)	
Annexure-II	Hold Time Study Protocol (Specimen)	
Annexure-III	Cleaning Validation Report (Specimen)	
Annexure-IV	Hold Time Study Report (Specimen)	

9.0 DISTRIBUTION:

Controlled Copy Quality Control Department

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Master Copy Quality Assurance Department

10.0 REFERENCES:

- In-House

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 PROTOCOL	**PROTOCOL No.: PD/CVP/QC/XXX**	
		REVISION No. XX	
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1.0 DOCUMENT PREPARATION AND APPROVAL

Preparation and Approval of Cleaning Validation Protocol will be joint responsibility of the following function area. Any modification in this document shall be documented and approved.

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY CONTROL)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

BODY OF PROTOCOL AS PER CONTENT DESCRIBED IN POINT NO. 6.1.11.1

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ANNEXURE-II

	HOLD TIME STUDY PROTOCOL	**PROTOCOL No.: PD/HTP/QC/XX/YYY**	
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PROTOCOL APPROVAL

Name	Designation	Signature	Date
Prepared By			
Checked By			
Reviewed By			
Approved By			

BODY OF PROTOCOL AS PER CONTENT DESCRIBED IN POINT NO. 6.1.11.2

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ANNEXURE-III

	CLEANING VALIDATION REPORT	**REPORT No.: PD/CVR/QC/XXX**	
		REVISION No. XX	
		EFFECTIVE DATE:	
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ANNEXURE-IV

	HOLD TIME STUDY REPORT	**PROTOCOL No.: PD/HTR/QC/XX/YYY**	
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DOCUMENT PREPARATION AND APPROVAL

The document is relevant to Shelf life study report held in QC Dept.

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY CONTROL)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

BODY OF REPORT AS PER CONTENT DESCRIBED IN POINT No. 6.2.11.3