STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Sampling of Process Validation/Equipment Qualification/Cleaning Validation /Hold Time Study Samples	**Effective Date:**
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1.0 OBJECTIVE:

To lay down a Procedure for Sampling of Process Validation/Equipment Qualification/Cleaning Validation/Hold time study samples.

2.0 SCOPE:

This SOP is applicable for Sampling of Process Validation/Equipment Qualification/Utility Qualification/Cleaning validation/Hold time study samples at ……..

3.0 RESPONSIBILITY:

Officer/Executive QA

4.0 ACCOUNTABILITY:

Head QA

5.0 DEFINITION:

5.1 Process Validation:

Process validation is establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality characteristics.

5.2 Qualification:

Action of providing and document that any premises ,system and equipment are properly installed any or work correctly and lead to the expected result qualification is often a part (the initial stage) of validation ,but the individual qualification step alone do not constitute process validation ,qualification is a part of validation.

5.3 Cleaning validation:

Cleaning validation is documented evidence that an approved cleaning procedure will provide equipment which is suitable for processing medicinal products.

5.4 Hold time study:

The maximum amount of time equipment can be left soiled before cleaning. Dirty hold time is usually defined as the time between the end of manufacturing and the beginning of the cleaning process.

6.0 PROCEDURE:

6.1 After receipt of request intimation for in process sample/finished products, Officer/Executive QA Shall check the following:

6.1.1 BMR& BPR completion up to respective stage.

6.1.2 Availability of cleaned equipment's i.e. sampling rod/spatula/Swab.

6.1.3 Personnel protective equipment's such as nose mask and hand gloves should be used properly during any activity.

6.1.4 Availability of sampling bags along with status label.

6.1.5 Processing stage i.e. in process bulk/semi finish/finished products.

6.1.6 Product details on request intimation for in process sample/finished products.

6.2 SAMPLING FOR VALIDATION/QUALIFICATION/CLEANING/HOLD TIME ACTIVITY:

6.2.1 Sampling for Validation / Qualification activity shall be performed by the trained persons only.

6.2.2 Officer / Executive QA involved in the validation / Qualification activity shall collect the samples of in process product or material at different stages as per the sampling plan mentioned in the validation / Qualification protocol.

6.2.3 Collected samples shall be packed properly in suitable container with adequate protection for light, moisture and temperature as per requirement.

6.2.4 Executive / Officer QC shall fill the intimation slip as per their respective Annexures:

For Process validation / Hold time study for product / equipment qualification in **Annexure-I.**

For Sample Intimation Slip For Qualification as per **Annexure – II.**

For Swab Intimation Slip for Cleaned / Dirty Equipment Hold Time Study as per **Annexure-III.**

For Cleaning validation Sample Intimation Slip as per **Annexure-IV.**

For Sample Intimation Slip For Qualification (Compressed Air / Nitrogen) as per **Annexure-V.**

6.2.5 Contents of intimation slip for Sterilization Process/Equipment Qualification, Cleaned/Dirty Equipment Hold Time Study and Cleaning Validation Samples may vary depending on the nature of product, equipment or process.

6.2.6 Record the sampling details as per **Annexure-V for Qualification/Validation Samples**.

In case of any deviation inform to Head QA.

7.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
gm	gram
No.	Number
Ltd.	Limited
QC	Quality Control
QA	Quality Assurance
SOP	Standard Operating Procedure

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Process Validation/Hold time study for product/Equipment qualification	
Annexure -II	Sample Intimation Slip for Qualification	
Annexure-III	Swab Intimation Slip for Cleaned/Dirty Equipment Hold Time Study	
Annexure -IV	Cleaning validation Sample Intimation Slip	
Annexure-V	Sample Intimation Slip For Qualification (Compressed Air/Nitrogen)	
Annexure-VI	Validation/Qualification Sampling Record	

ENCLOSURES: SOP Training Record

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9.0 DISTRIBUTION:

Controlled Copy No. 01	Quality Assurance Department
Controlled Copy No. 02	Production Department
Controlled Copy No. 03	Quality Control Department
Master Copy	Quality Assurance Department

10.0 REFERENCES:

Not Applicable

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
PROCESS VALIDATION/HOLD TIME STUDY FOR PRODUCT/EQUIPMENT QUALIFICATION

Intimation Ref. No.:		Date:	
Product Name:		pH	Yes/No
Product Code:		Assay	Yes/No
Batch No.:		Other tests: Yes/No	
Mfg. Date:			
Exp. Date:			
Batch Size:			
Processing stage:			
Fill volume:			
Sampling Point:			
Production chemist		**Sample Qty:**	A. R. No.:
			Release Date:

QC Remark: Above sample complies/does not complies with respect to above tests only as per Specification No.: _____

Analyst by QC	Checked By QC	Reviewed by QA

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ANNEXURE-II
SAMPLE INTIMATION SLIP FOR QUALIFICATION

Equipment Name /Instrument Name/ID No.:		
Cycle Name:		
Cycle No./Stage :		
Qualification Parameter :		
Quantity Sampled :		
Required Tests	QC Analytical Result	QC Remarks
		QC AR. No.:

Remark: Above sample complies/does not complies as per Protocol No.

Production Chemist/QA Sign & Date	Record & Sampled By (QA/Microbiologist) Sign & Date	Received by (QC) Sign & Date

Analyst by QC	Checked By QC	Reviewed by QA

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ANNEXURE-III
SWAB INTIMATION SLIP FOR CLEANED/DIRTY EQUIPMENT HOLD TIME STUDY

From: **Quality Assurance Dept.** **Date:**

To: **Quality Control (Microbiology Section)**

Sir ,

We are requesting for the swab sampling for the hold time study of cleaned equipment. The detail of the equipment is given below. So, please do the sampling in mentioned area.

Area:

Time Period **:** 0 hrs, 24 hrs, 48 hrs, 72 hrs, 96 hrs, 120 hrs, 144 hrs & 168 hrs.

Equipment Name : **Equipment ID:**

Sampling Detail:
Done on (Time):

Done By: **Verified By:**

Name & Signature **Name & Signature**

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ANNEXURE-IV

CLEANING VALIDATION SAMPLE INTIMATION SLIP

From: **Quality Assurance Dept.** **Date:**

To: **Quality Control**

Sample: Chemical Analysis/Microbiological Bio-burden Analysis

Product Name:
Product Code:
Mfg. date:
Exp. Date:
Batch Size:

S. No.	Equipment Name :	Equipment ID:	Swab Sample ID	Location
……	……..	……..	……..	……..
……	……..	……..	……..	……..
……	……..	……..	……..	……..

Sampling Details:

Done By: **Verified By:**
Name & Signature Name & Signature

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ANNEXURE-V

SAMPLE INTIMATION SLIP FOR QUALIFICATION (COMPRESSED AIR/NITROGEN)

Sample Name/ID No.:		Date:
Location:		
Sample Quantity:		
Requisition Raised: (QA)	Sampled By: (QC)	Received By: (QC)
Test to be performed:		
Remark: Above sample complies/does not complies as per Protocol No.		
Analyst by QC	Checked By QC	Reviewed by QA

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ANNEXURE-VI
VALIDATION/QUALIFICATION SAMPLING RECORD

S.No.	Date	Product Name	Product Code	Batch No.	Batch Size	Mfg. Date	Exp. Date	Processing Stage	Sample Qty.	Submitted By	Received	Ref. Intimation No.	Remark