STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Process Validation and Equipment Qualification	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down the procedure for Equipment Qualification and Process Validation samples received in Quality control department.

2.0 SCOPE:

This SOP is applicable for Equipment Qualification and Process Validation samples received in Quality Control department.

3.0 RESPONSIBILITY:

Officer, Executive– Quality Control.

Head – Quality Control.

4.0 PROCEDURE:

4.1 For Equipment Qualification Batches:

4.1.1 Quality Assurance Department shall send the samples of different stages of different Equipments from different locations along with requisition slip as per their sampling plan of respective Protocol.

4.1.2 After receiving the samples make necessary entry in inward register as per Annexure -I

4.1.3 Generate the A.R. no. of Equipment Qualification samples as follows.

EQ-0001/22

EQ Equipment Qualification

- Dash

0001 Serial number of the sample

/ Slash

22 Last two digit of the Year (22 for year 2022)

as per SOP.

4.1.4 Write the A.R. no. on the requisition slip which is received with samples from QA Department.

4.1.5 Analyst shall analyse the samples as per respective sampling plan provided by QA

Department and submit the Report to QA Department.

4.1.6 Analyst shall analyse the Equipment Qualification samples as per Respective Specification and STP, attach the Raw data (Chromatographs, Spectrographs etc.), write the results on Analytical Raw Data Sheets (as per Annexure-II, Annexure-III and Annexure- IV respectively) issued by GLP person and submit the data to QA Department if required.

4.1.7 Make entry of status of analysis on the inward register in remarks column and give the results to Quality Assurance department through received intimation slip.

4.1.8 The Specification, STP and Raw data sheet for Equipment Qualification batches shall prepare as per SOP.

4.1.8.1 For Equipment Qualification ***Specification No.*** or ***Standard Test Procedure number*** *in* which first 9 digits are specification number or STP number and last 2 digits are revision number, represented as :

X	X	X	/	Y	Y	0	0	1	-	Z	Z

SPC or STP Specification No. / STP No. Revision No.

4.1.8.2 The first three digits (XXX) represent SPC or STP referring to specification or standard test procedures respectively.

4.1.8.3 The fourth digit is a slash "/"

4.1.8.4 The fifth to ninth digit (YY001) represents the specification / STP no. of the Equipment Qualification (Where YY represents Equipment Qualification (EQ))

4.1.8.5 The Tenth digit is a dash "-"

4.1.8.6 The eleventh and twelth digit (ZZ) represents the revision no. which shall start with "00" for the first version followed by sequential numbers for each subsequent revision.

4.2 For Process Validation Batches:

4.2.1 Quality Assurance Department shall send the samples of different stages of different Equipments from different locations along with requisition slip as per their sampling plan of respective Protocol.

4.2.2 After receiving the samples make necessary entry in inward register as per annexure -III of

SOP.

4.2.3 Generate the A.R. no. of Process validation samples as follows.

VAL-0001/22

VAL Validation Sample

- Dash

0001 Serial number of the sample

/ Slash

22 Last two digit of the Year (22 for year 2022 etc.)

as per SOP.

4.2.4 Write the A.R. no. on the requisition slip which is received with samples from QA Department.

4.2.5 Analyst shall analyse the samples as per respective sampling plan provided by QA Department and submit the Report to QA Department.

4.2.6 Analyst shall analyse the Process Validation samples as per Specification and STP of Finish Product, attach the Raw data (Chromatographs, Spectrographs etc.), write the results on Analytical Raw Data Sheets of Finish Product issued by GLP person and submit the data to QA Department if required.

4.2.7 Make entry of status of analysis on the inward register in remarks column and give the results to Quality Assurance department through received intimation slip.

5.0 ANNEXURE (S) :

Annexure – I: Equipment qualification sample inward register

Annexure – II: Template for Equipment qualification specification.

Annexure –III: Template for Equipment qualification standard test procedure.

Annexure –IV: Template for Equipment qualification analytical raw data sheet.

6.0 REFERENCE (S):

SOP: Preparation, approval, distribution control, revision and destruction of Standard Operating Procedure (SOP).

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SOP: Preparation, Approval, Distribution, Control, Revision and Destruction of Specifications, Standard Test Procedure and Analytical Raw Data Sheets.

SOP: Allocation of Analytical Reference Number.

SOP: Handling of Finished products, Semi-finished products, in process, Validation and Swab samples.

7.0 ABBREVIATION (S)/DEFINITION (S):

SOP: Standard operating procedure.

QA: Quality Assurance.

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
01	00	---	---	New SOP	---

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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ANNEXURE I
EQUIPMENT QUALIFICATION SAMPLE INWARD REGISTER

S.No.	Date	Name of product	Batch No.	Mfg. Date	Exp. Date	Batch size/ Quantity	Stage	AR No.	Date of Release	Analyzed By	Remarks

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ANNEXURE II
TEMPLATE FOR EQUIPMENT QUALIFICATION SPECIFICATION
DRUG PRODUCT SPECIFICATION

S.No.	Tests	Specification

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ANNEXURE III
TEMPLATE FOR EQUIPMENT QUALIFICATION STANDARD TEST PROCEDURE

Header part for all pages:

EQUIPMENT QUALIFICATION STANDARD TEST PROCEDURES		
STP No.		**<MATERIAL NAME>**
Supersedes		
Status		
Effective Date		
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ANNEUXRE IV
TEMPLET FOR EQUIPMENT QUALIFICATION ANALYTICAL RAW DATA SHEET

Header part for all pages:

Page X of Y

EQUIPMENT QUALIFICATION ANALYTICAL RAW DATA SHEET			
Name of Product:			
Batch No.:		**A.R. No.:**	

For first page only:

Manufacturing Date:		**STP No.:**	
Expiry Date:		**Quantity Received:**	
Date of analysis:		**Date of Release:**	

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