FACILITY QUALIFICATION			
SOP No.		**Revision No.**	
Effective Date		**Supersedes No.**	
Review Date		**Page No.**	1 of 20

1.0 PURPOSE

To define a procedure for qualification of pharmaceutical Manufacturing, Packaging, Storage and Testing facility prior to manufacturing or testing of commercial pharmaceutical products.

2.0 SCOPE

2.1 This SOP is applicable to qualify and validate all the Pharmaceutical Facility/Areas where processing, storage, packaging and microbiological testing of pharmaceutical products are carried out and supporting areas such as change rooms, corridors, airlocks, etc. at ……..

3.0 REFERENCE(S) & ATTACHMENTS

3.1 References

3.1.1 In-House

3.2 Attachments

3.2.1 Attachment-I: Format for Facility Qualification

3.2.2 Attachment-II: Format for Annexure of Facility Qualification

4.0 DEFINITION & ABBREVIATION(S)

4.1 Definitions

4.1.1 **Qualification:** Qualification is an act of planning, carrying out and recording of tests on Facility/Area which will form part of the validation process to demonstrate that it will perform as intended or designed.

Qualification consists of the following steps:

- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

4.1.2 **User Requirement Specification (URS):** It describes what the Facility/Area is intended to do and all essential requirements such as Dimension, location, surface finish, material of construction, environmental parameters etc.

4.1.3 **Design Qualification (DQ)**: Establishing documented evidence that the user requirement, which include establishment of critical operating or operational parameters or specifications before the final design is agreed, have been met. It is performed after these requirements have been incorporated in to the detailed design document.

4.1.4 **Installation Qualification (IQ)**: Establishing documented evidence that the Facility/Area is installed according to design documents.

4.1.5 **Operation Qualification (OQ)**: Establishing documented evidence that the Facility/Area performs as intended throughout all specified ranges.

4.1.6 **Performance Qualification (PQ)**: Establishing documented evidence that Facility/Area is capable of performing consistently (during multiple cycles or extended periods) to give an outcome that meets predetermined specifications.

4.1.7 **Re-Qualification**: Re-confirming that the Facility/Area are meeting the predetermined acceptance criteria after major change in the parameters.

4.1.8 **Periodic Qualification**: Re-confirming that the Facility/Area will meet the predetermined acceptance criteria after a scheduled period if there is no change.

4.1.9 **Protocol**: A written, approved plan stating how qualification/validation will be conducted. It includes design, requirements, specifications, test parameters, product characteristics, required Facility/ Area/ Equipment and procedures and relevant acceptance criteria.

4.2 Abbreviations

4.2.1 SOP: Standard operating procedure

4.2.2 EHS: Environment, Health and safety.

4.2.3 QA: Quality Assurance

4.2.4 cGMP: Current good manufacturing practices

4.2.5 No.: Number

4.2.6 NA: Not applicable

4.2.7 URS: User requirement specification.

4.2.8 DQ: Design Qualification

4.2.9 IQ: Installation qualification

4.2.10 OQ: Operation Qualification

4.2.11 PQ: Performance qualification

4.2.12 EHC: Equipment handover certificate

4.2.13 HVAC: Heating, ventilation and air conditioning

5.0 RESPONSIBILITY:

5.1 User/Validation Team:

5.1.1 To assess the qualification requirements for Facility/Area.

5.1.2 To prepare qualification documents.

5.1.3 To perform the tests documented in the qualification documents and recording of the results.

5.1.4 Ensure Facility/Area is validated as per the validation master plan.

5.1.5 To be a part of qualification team and coordinate with representatives of other departments for qualification efforts.

5.2 Engineering department:

5.2.1 To assess the qualification requirement of Facility/Area.

5.2.2 To be a part of qualification team and jointly share the efforts.

5.2.3 To execute, record and certify the tests which needs engineering measurements.

5.2.4 To provide inputs while the preparation of user requirement.

5.3 Environment, Health & Safety (EHS) department:

5.3.1 To assess the qualification requirement of Facility/Area.

5.3.2 To be a part of qualification team and jointly share the EHS aspects.

5.3.3 To execute, record and certify the safety aspects during Facility/Area qualification.

5.3.4 To provide inputs while the preparation of user requirement.

5.4 Quality Control department:

5.4.1 To assess the qualification requirement of Facility/Area.

5.4.2 To be a part of qualification team and jointly share the Quality aspects.

5.4.3 To contribute by testing and record the results during Facility/Area qualification.

5.4.4 To provide inputs while the preparation of user requirement.

5.5 Quality Assurance:

5.5.1 Issuance of number for qualification documents.

5.5.2 To assess the qualification requirement of Facility/Area

5.5.3 To be a part of qualification team and jointly share the Quality aspects.

5.5.4 To review the qualification documents and results.

5.5.5 To provide inputs while the preparation of user requirement.

5.6 Quality Assurance Head:

5.6.1 To ensure implementation of procedure as per SOP.

5.6.2 To review and approve the qualification documents.

5.7 Plant Head:

5.7.1 To ensure implementation of procedure as per SOP.

5.7.2 To review and approve the qualification documents.

6.0 Distribution:

I. Quality Assurance

II. Quality Control

III. Production

IV. Warehouse

V. Engineering

VI. Environment, Health and safety (EHS)

7.0 PROCEDURE:

7.1 General Procedures:

7.1.1 For new Facility/Area, change request shall be initiated and impact assessment (if applicable) to be performed prior to initiation of the validation procedure.

7.1.2 The approach taken towards Qualification/Validation activity shall be based on rationale/risk assessment.

7.1.3 User shall prepare the qualification document using the formats provided in this procedure.

7.1.4 Acceptance criteria shall be adequately defined to enable confirmation that they are attained.

7.1.5 During preparation of Layout or requirement of design of Area, Area code number shall be allocated as per respective SOP.

7.1.6 The documents shall be pre-approved by the Qualification team before being used for execution and also post approval will be done by the qualification team after execution.

7.1.7 The test execution during qualification shall be either carried out by or witnessed by qualification team.

7.1.8 After performance qualification, Area handover certificate shall be issued.

7.1.9 A post execution review shall be done by the Qualification team to ensure that all the tests have been carried out, all deviations (if any) has been addressed properly and the Facility/Area qualification is successfully complete.

7.2 User requirement specification (URS):

7.2.1 The User requirement specification shall be prepared by the user department in coordination with Engineering, EHS and QA department.

7.2.2 The URS shall describe the essential requirements such as dimension, location, surface finish, material of construction, environmental parameters etc. by considering regulatory cGMP requirements, safety, process and product requirements. Refer specimen format as per **Attachment-II**.

7.3 Design Qualification (DQ):

7.3.1 The Design Qualification protocol shall be prepared by the user department in coordination with Engineering, EHS and QA department. Refer specimen format as per **Attachment-III**.

7.3.2 For DQ first make the necessary diagrams or layouts if any required and write down the specification with the help of user requirement specification by considering regulatory requirements, cGMP requirements, architectural requirements, utilities requirement, accessories required, safety, process and product requirements.

7.3.3 The Design Qualification protocol shall be prepared for each Area based on user requirement.

7.3.4 Pre approvals of concerned persons mentioned in protocol shall be taken and then execute the protocol.

7.3.5 The compliance of the design with cGMP and also with the specification shall be demonstrated and documented.

7.3.6 Once design qualification is over, purchase order shall be released to vendor/contractor along with the specification.

7.4 Installation Qualification (IQ):

7.4.1 Installation qualification (IQ) shall be performed on new or modified Facility/Areas.

7.4.2 Installation of Facility/Area, piping, services and instrumentation shall be checked to current engineering drawings and specification.

7.4.3 Verify the construction and design criteria at this stage.

7.4.4 The installation qualification shall certify and demonstrate cGMP compliance and documented.

7.4.5 During Installation Qualification it shall be ensured that the Facility/Area and supporting utilities have been built & installed in compliance with their approved design specification (DQ).

7.4.6 For preparation of Installation Qualification protocol, Refer specimen format as per **Attachment-IV**.

7.7 Operational Qualification (OQ):

7.7.1 Operational Qualification (OQ) shall be performed after completion of Installation Qualification.

7.7.2 Tests that have been developed from knowledge of product, process, maximum manpower and equipment design/size/operation/cleaning/maintenance.

7.7.3 Tests to include conditions encompassing upper and lower limits of operation.

7.7.4 Development of operating and cleaning SOPs and maintenance schedule.

7.7.5 The successful operational qualification shall be well demonstrated and documented.

7.7.6 For preparation of Operation Qualification protocol, Refer specimen format as per **Attachment-V**.

7.8 Performance Qualification (PQ):

7.8.1 Performance Qualification shall be performed after successful completion of Operational Qualification.

7.8.2 Tests for environmental parameters/conditions (Physical and microbiological) and utility/services supply.

7.8.3 Tests to include a condition or set of conditions encompassing upper and lower operating limits.

7.8.4 Challenge tests if any shall be performed based on scientific rationale.

7.8.5 Performance Qualification Protocol shall be prepared as per specimen format as specified in **Attachment-VI**.

7.8.6 Perform the qualification of Facility/ Area as per approved protocol. Persons involved in performing the qualification and testing shall be trained prior to performing the qualification/tests.

7.9 Area Handover Certificate (EHC):

7.9.1 Approval for release of Area will be given by Qualification/validation team, QA Head and Plant Head for regular usage of Area after the successful and satisfactory completion of Performance qualification.

7.9.2 For preparation of Area handover certificate, refer **Attachment-X**.

7.10 Re-Qualification:

7.10.1 **Requalification is of two types:**

-Requalification after major changes in Facility/Area, change in critical attributes of HVAC andaddition or removal of major equipment resulting in civil work of Facility/Area.

-Periodic re-qualification.

7.10.2 **Re-qualification after major changes:** Shall be carried out when any major changes in Facility/Area is done, when there is change in critical attributes of HVAC, when there is addition or removal of major equipment is done resulting in civil work of Facility/Area. The extent of Re-qualification after the change shall be justified based on risk assessment/scientific rationale of the change.

7.10.3 **Periodic Re-qualification:** Shall be done at a frequency not exceeding five years if there are no changes in the Facility/Area.

7.11 A log book for issuance of numbers for qualification protocols shall be maintained by Quality Assurance department as per the format given in **Attachment-I**.

7.12 Quality Assurance shall issue the Facility qualification/ requalification protocol numbers as per below procedure in **Attachment-I**.

7.13 Numbering System for Facility Qualification Protocol:

7.13.1 For new Facility Qualification protocol, numbering shall be as: **A/FQ/XXX/B/AC**

Where,

A - Location Code
FQ - Stands for Facility Qualification
XXX - URS (stands for User requirement qualification)
- DQ (stands for Design Qualification)
- IQ (stands for Installation Qualification)
- OQ (stands for Operation Qualification)
- PQ (stands for Performance Qualification)
- AHC (stands for Facility/Area Handover Certificate)

B - B1 (stands for Hormone Block)
- B2 (stands for General Block)
- Q (stands for Quality Control/Quality Assurance)

AC - Facility/Area code Number.

7.13.2 For Re-Qualification, protocol numbering shall be as: **A/FQ/RXX/B/AC**

Where,

IA - Location Code
FQ - Facility Qualification
RXX - RDQ (stands for Re-Design Qualification)
- RIQ (stands for Re-Installation Qualification)
- ROQ (stands for Re-Operation Qualification)
- RPQ (stands for Re-Performance Qualification)

B - B1 (stands for Hormone Block)
- B2 (stands for General Block)
- Q (stands for Quality Control/Quality Assurance)

AC - Facility/Area code Number.

Note: For Re-qualification purpose use the protocol formats as specified in the Attachments of this SOP for qualification. In the protocol number put the protocol number as specified for Re-qualification protocol numbering system.

7.13.3 For Room Data Sheet (RDS), numbering shall be as: **Protocol Number/RDS**

Where,

Protocol Number: Allocated as per point no. 7.13.1 or 7.13.2.
RDS - Stands for Room Data Sheet

8.0 REVISION HISTORY

Version No.	00	**Effective Date**	
Details of revision: New SOP Prepared			

Attachment-I

FORMAT FOR FACILITY QUALIFICATION

(First Page)

	FACILITY QUALIFICATION **(_____ BLOCK)**	**PROTOCOL No.:** **Page:** **Effective Date:**

FACILITY QUALIFICATION

<Mention Company Address>

Prepared by:	**Checked by:**
Sign. & Date:	**Sign. & Date:**

(Second Page onwards)

CONTENTS

1.0 Pre-approval Protocol:

This section shall state that this document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution).

Functional Area	Name	Designation	Signature	Date

FACILITY QUALIFICATION			
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2.0 OBJECTIVE:<Mention the objective of the protocol>

3.0 SCOPE:<Mention the applicability Facility/ Areas of the protocol>

4.0 REASON FOR QUALIFICATION:

The reason for preparing this document is:

Please tick any one (or multiple) option(s) from the following (☑):

New or refurbished Facility/ Area ☐

Major change in Facility/ Area/HVAC design ☐

Change in AHU/ AHU parameters ☐

Addition or removal of major equipment resulting in civil work ☐

Equipment replacement of different capacity ☐

Periodic Re-qualification ☐

Others (Specify) ☐

5.0 RESPONSIBILITY: <Mention the details of Personnel involved in qualification activity>

Department	Name	Activity

6.0 USER REQUIREMENT SPECIFICATION (URS):

6.1 Objective: <Mention the objective of URS>

6.2 Reason for URS: <Mention the reason for preparation of URS>

6.3 Requirements: <Mention all the Facility user requirements/parameters, Facility/Area wise and mention the reference details of same in below table>

Refer Annexure No.	Area Code	Area Name

6.4 Attachments : <Mention the list of all additional attachments which are required to be attached>

S.No.	Attachment Details	Refer Attachment No.

6.5 Recommendations/ Conclusion: <Mention the conclusion and recommendations to be made after the execution and review is over>

6.6 Post approval:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution).

Functional Area	Name	Designation	Signature	Date

7.0 DESIGN QUALIFICATION (DQ):

7.1 Objective: <Mention the objective of DQ>

7.2 Reason for DQ: <Mention the reason for preparation of DQ>

7.3 Requirements: <Mention all the Facility design requirements/parameters, Facility/Area wise and mention the reference details of same in below table>

Refer Annexure No.	Area Code	Area Name

7.4 Attachments: <Mention the list of all additional attachments which are required to be attached>

Sr. No.	Attachment Details	Refer Attachment No.

7.5 Expected Documents and Drawings: <Mention the list of documents required in the below table>

Sr. No.	Document details	Required (✓ / ×)
		☐

✓: Applicable & required × : Not applicable

7.6 Recommendations/Conclusion: <Mention the conclusion and recommendations to be made after the execution and review is over>

7.7 Post approval:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution).

Functional Area	Name	Designation	Signature	Date

8.0 INSTALLATION QUALIFICATION (IQ):

8.1 Objective: <Mention the objective of IQ>

8.2 Reason for IQ: <Mention the reason for preparation of IQ>

8.3 Requirements: <Mention all the Facility installation requirements/parameters, Facility/Area wise and mention the reference details of same in below table>

Refer Annexure No.	Area Code	Area Name

8.4 Attachments: <Mention the list of all additional attachments which are required to be attached>

Sr. No.	Attachment Details	Refer Attachment No.

8.5 Expected Documents and Drawings: <Mention the list of suggestive documents required in the below table>

Sr. No.	Document details	Required (✓ / ×)
		☐

✓: Applicable & required × : Not applicable

8.6 Deviations/ Changes (if any): <Mention the deviations if any observed or any changes made or to be made>

8.7 Recommendations/ Conclusion: <Mention the conclusion and recommendations to be made after the execution and review is over>

8.8 Post approval:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution).

Functional Area	Name	Designation	Signature	Date

9.0 OPERATION QUALIFICATION (OQ):

9.1 Objective: <Mention the objective of OQ>

9.2 Reason for OQ: <Mention the reason for preparation of OQ>

9.3 Training: <Mention the Personnel details involved in qualification activity>

Sr. No.	Name	Training status	Training report availability	Checked by/ date

9.4 Verification of instruments for calibration status: <Mention the details of instruments involved during qualification activity>

Sr. No.	Instrument Name	Instrument ID	Calibration done on	Calibration due on	Checked by Sign/ Date

9.5 Reference of Standard operating procedure (SOP): <Mention the details of SOP's required for performing qualification activity>

Sr. No.	SOP Name	SOP No.	Checked by Sign/ Date

9.6 Operational Requirements: <Mention all the Facility operational requirements/parameters, Facility/Area wise and mention the reference details of same in below table>

Refer Annexure No.	Area Code	Area Name

9.7 Attachments: <Mention the list of all additional attachments which are required to be attached>

Sr. No.	Attachment Details	Refer Attachment No.

9.8 Deviations/ Incident/ Changes (if any): <Mention the deviations/ incidents if any happened or any changes made or required to be made>

9.9 Recommendations/ Conclusion: <Mention the conclusion and recommendations to be made after the execution and review is over>

9.10 Post approval:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution).

Functional Area	Name	Designation	Signature	Date

10.0 PERFORMANCE QUALIFICATION (PQ):

10.1 Objective: <Mention the objective of PQ>.

10.2 Reason for PQ: <Mention the reason for preparation of PQ>

10.3 Training: <Mention the Personnel details involved in qualification activity>

Sr. No.	Name	Training status	Training report availability	Checked by/ date

10.4 Verification of instruments for calibration status: <Mention the details of instruments involved during qualification activity>

Sr. No.	Instrument Name	Instrument ID	Calibration done on	Calibration due on	Checked by Sign/ Date

10.5 Performance Requirements: <Mention all the Facility performance requirements/parameters, Facility/ Area wise and mention the reference details of same in below table>

Refer Annexure No.	Area Code	Area Name

10.6 Attachments: <Mention the list of all additional attachments which are required to be attached>

Sr. No.	Attachment Details	Refer Attachment No.

10.7 Deviations/Incident/Changes/OOS (if any): <Mention the deviations/ incidents if any happened or any changes made or required to be made>

10.8 Recommendations/Conclusion: <Mention the conclusion and recommendations to be made after the execution and review is over>

10.9 Post approval:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution).

Functional Area	Name	Designation	Signature	Date

Format No……..

Attachment-II

(Header Part)

FORMAT FOR ANNEXURE OF FACILITY QUALIFICATION

	FACILITY _____ QUALIFICATION (_____ BLOCK)	**Annexure No.:**
		Reference Protocol No.:
		Page:

Area Name:	**Area Code:**	**Department Name:**

Pre Approval					
Prepared by: User Department	**Checked by: User Dept. Head**	**Reviewed by: EHS**	**Reviewed by: Engineering Head**	**Reviewed by: Quality Assurance**	**Approved by: QA Head**
Sign. & Date:	**Sign. & Date:**	**Sign. & Date:**	**Sign. & Date:**	**Sign. & Date:**	**Sign. & Date:**

<Mention the Contents of Annexure>

(Footer Part)

Post Approval:

Checked by: User Department	**Checked by: Engineering**	**Checked by: Health, Safety and Environment**	**Reviewed by: Quality Assurance**	**Approved by: QA Head**
Date:	**Date:**	**Date:**	**Date:**	**Date:**

Format No……