DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Qualification of Equipment or Instrument	**Effective Date:**
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1.0 PURPOSE

To define a procedure for qualification of Equipments and Instruments.

2.0 SCOPE

2.1 This SOP is applicable to all the Equipments and Instruments (wherever applicable) used in ……..

3.0 REFERENCE(S) & ATTACHMENTS

3.1 References

3.1.1 In-House

3.2 Attachments

3.2.1 Attachment-I : Flow Chart of Equipment/ Instrument Qualification

3.2.2 Attachment-II : Equipment qualification protocol number issuance log

3.2.3 Attachment-III : Instrument qualification protocol number issuance log

3.2.4 Attachment-IV : User Requirement Specification

3.2.5 Attachment-V : Design Qualification

3.2.6 Attachment-VI : Factory Acceptance Test

3.2.7 Attachment-VII : Site Acceptance Test

3.2.8 Attachment–VIII : Installation Qualification

3.2.9 Attachment–IX : Operation Qualification

3.2.10 Attachment-X : Performance Qualification

3.2.11 Attachment-XI : Equipment/ Instrument Handover Certificate

3.2.12 Attachment-XII : Protocol issuance log for equipment qualification protocol

3.2.13 Attachment-XIII : Protocol issuance log for instrument qualification protocol

4.0 DEFINITION & ABBREVIATION(S)

4.1 Definitions

4.1.1 **Qualification:** Action of proving that any Equipment/Instrument/system/utility works correctly and actually leads to the expected results. The word validation is sometimes widened and incorporates the concept of qualification.

Qualification consists of the following steps:

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

4.1.2 **User Requirement Specification (URS):** The document describing what the Equipment/Instrument or system is intended to do and all essential requirements such as production rate, operating range, etc. It is usually developed by the user of the Equipment/Instrument/system. This document links to PQ document, which tests for each of the requirement.

4.1.3 **Design Qualification (DQ)**: Establishing documented evidence that the owner/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 **Site Acceptance Test (SAT)**: Establishing documented evidence that the item received at site confirms with the specified requirements.

4.1.5 **Functional Design Specification (FDS)**: Functional Design Specification is a document that specifies in a complete, precise, Variable manner, the required design and characteristic of an Equipment/ Instrument/ system.

4.1.6 **Factory Acceptance Test (FAT)**: Testing conducted at the supplier's factory usually involving the company (user) to determine whether or not a system satisfies its acceptance criteria and to enable the user to suggest modification and determine whether or not to accept the system.

4.1.7 **Installation Qualification (IQ)**: Establishing documented evidence that the Equipment/ Instrument / system is installed according to design documents, purchase specifications and manufacturer literature. Those parts of the systems, which are disassembled prior to shipping, shall be noted and be verified again after re-assembly at the final site.

4.1.8 **Operation Qualification (OQ)**: Establishing documented evidence that the Equipment/ Instrument or system performs as intended throughout all specified ranges.

4.1.9 **Performance Qualification (PQ)**: Establishing documented evidence that an integrated system or processing operation is capable of performing consistently (during multiple cycles or extended periods) to give an outcome that meets predetermined specifications.

4.1.10 **Re-qualification**: Qualification of an instrument/Equipment/Instrument/system which becomes necessary when a planned modification occurs which is determined to have the potential to impact the safety,

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identity, strength, quality or purity of a drug product impacted by the instrument, Equipment/ Instrument or system.

4.1.11 **Validation**: Establishing documentary evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting it's predetermined specifications and quality attributes.

4.1.12 **DQ/IQ/OQ/PQ Protocol**: A plan for DQ/IQ/OQ/PQ of a specific instrument/Equipment/Instrument /system that when executed provides documented evidence that the design intentions are met.

4.1.13 **Validation Protocol**: A written, approved plan stating how validation will be conducted. It includes test parameters, product characteristics, required Equipment/ Instrument 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 FAT: Factory acceptance test

4.2.10 SAT: Site acceptance test

4.2.11 IQ: Installation qualification

4.2.12 OQ: Operation Qualification

4.2.13 PQ: Performance qualification

4.2.14 EHC: Equipment/ Instrument handover certificate

5.0 RESPONSIBILITY:

5.1 User/ Validation Team:

5.1.1 To assess the qualification requirements for Equipment/ Instrument.

5.1.2 To prepare qualification documents.

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

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5.1.4 Ensure Equipment/ Instruments/ systems are 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 Equipment/ Instrument.

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 Equipment/ Instrument.

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 Equipment/ Instrument 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 Equipment/ Instrument.

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 Equipment/ Instrument 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 Equipment/ Instrument

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 system as per SOP.

5.7.2 To review and approve the qualification documents.

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6.0 Distribution:

I. Quality Assurance
II. Quality Control
III. Production
IV. Ware house
V. Engineering
VI. Environment, Health and safety (EHS)

7.0 PROCEDURE:

7.1 General Procedures:

7.1.1 For new Equipment/ Instrument 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.

Note:

1. If Manufacturer/Supplier are providing the Qualification documents then same shall be reviewed and check for feasibility. If found that all the required points/parameters are covered and found satisfactory then same Qualification documents can be used by validation team for execution purpose. If any point/parameter which is not covered in the Manufacturer/Supplier Qualification document then same shall be covered in the Users Qualification documents. Manufacturer/Supplier Qualification documents can only be used as an additional attachment to an approved users Qualification protocol.

2. If it is Equipment qualification then mention Equipment and if it is Instrument Qualification then mention Instrument in place of Equipment/ Instrument throughout the Qualification protocols.

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

7.1.5 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.

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

7.1.7 After performance qualification Equipment/ Instrument handover certificate shall be issued.

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7.1.8 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 Equipment/ Instrument 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 production rate, operating range, parameters required, specification of components, material of construction etc. by considering regulatory cGMP requirements, safety, process and product requirements. Refer **Attachment-IV**.

7.3 Factory acceptance test (FAT):

7.3.1 FAT shall be conducted at the supplier's factory to determine whether or not a Equipment/ Instrument/system satisfies its acceptance criteria and to enable the user to suggest modification and determine whether or not to accept the system.

7.3.2 Need to perform the FAT shall be based on the outcome of FAT assessment as per the **Attachment-VI**.

7.4 Site acceptance test (SAT):

7.4.1 SAT shall be conducted at the user's site to determine whether or not the area of installation is suitable for installing the Equipment/ Instrument/ system and also to verify whether all the required utility supplies/ services are available to support the installation and operation of the Equipment/ Instrument. Refer **Attachment-VII**.

7.5 Design Qualification (DQ):

7.5.1 The Design Qualification protocol shall be prepared by the user department in coordination with Engineering, EHS and QA department. Refer **Attachment-V**.

7.5.2 For DQ first make the necessary diagrams or layouts if any required and write down the tentative specification with the help of supplier's specification and user requirement specification by considering regulatory cGMP requirements, safety, process and product requirements.

7.5.3 The Design Qualification protocol shall be prepared for each Equipment/Instrument/system based on user requirement and technical discussions between supplier and user department.

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

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

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

7.6 Installation Qualification (IQ):

7.6.1 Installation qualification (IQ) shall be performed on new or modified Equipment/ Instruments or systems.

7.6.2 IQ shall contain, but not be limited to the following points.

7.6.3 Installation of Equipment/ Instrument, piping, services and instrumentation shall be checked to current engineering drawings and specification.

7.6.4 Collect supplier operating and working instructions (manual) and maintenance requirements, Calibration requirements, Certificates and drawings.

7.6.5 Verify the construction and design criteria at this stage.

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

7.6.7 During Installation Qualification it shall be ensured that the premises, supporting utilities and Equipment/ Instrument have been built & installed in compliance with their approved design specification (DQ).

7.6.8 For preparation of Installation Qualification protocol, refer **Attachment-VIII**.

7.7 Operational Qualification (OQ):

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

7.7.2 OQ shall contain, but not be limited to the following points.

7.7.3 Tests that have been developed from knowledge of processes, systems and Equipment/Instrument and working of subsystem.

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

7.7.5 Development of operating and cleaning SOPs maintenance schedule and Training of operators.

7.7.6 The successful operational qualification shall be well demonstrate and documented.

7.7.7 For preparation of Operation Qualification protocol, refer **Attachment-IX**.

7.8 Performance Qualification (PQ):

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

7.8.2 PQ shall include, but not be limited to the following;

7.8.3 Tests, using production materials, qualified substitutes or simulated products that have been developed from knowledge of the process and the facilities, systems or Equipment/Instrument.

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

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

7.8.6 Performance Qualification Protocol shall be prepared as per **Attachment-X**.

7.8.7 Perform the qualification of Equipment/ Instruments/systems as per approved protocol. Persons involved in performing the qualification and testing shall be trained prior to performing the qualification/tests.

7.9 Equipment/ Instrument Handover Certificate (EHC):

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

7.9.2 For preparation of Equipment/ Instrument handover certificate, refer **Attachment-XI**.

7.10 Re-Qualification:

7.10.1 **Requalification is of two types:**

- Requalification after major changes.
- Periodic re-qualification.

7.10.2 **Re-qualification after Major changes:** Shall be carried out when any major modification of Equipment/ Instrument or Change in site of Equipment/ Instrument is done. The extent of Re-qualification after the change shall be justified based on risk assessment of the change.

7.10.3 **Periodic Re-qualification:** Shall be done only for critical Equipment/ Instruments and frequency shall not exceed five years.

7.10.3.1 Periodic requalification of Quality Control equipments and instruments shall not be carried out. Qualification of Quality Control equipments and instruments shall be done after new equipment/ instrument purchase or after relocation or after major changes in the equipment/ instrument.

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-II** and **Attachment-III.**

7.12 Quality Assurance shall issue the Equipment and Instrument qualification/ requalification protocol numbers as per below procedure in **Attachment-II** and **Attachment-III respectively.**

7.13 Equipment/ Instrument code shall be allocated by Quality assurance before commencement of installation qualification activities and after receipt of Equipment/ Instrument at site.

7.14 For flow chart of Equipment/ Instrument/ system qualification steps, refer **Attachment-I**.

7.15 Numbering System for Equipment/ Instrument Qualification Protocol:

7.15.1 For new Equipment/ Instrument Qualification, protocol numbering shall be as: **IA/EQ/XX/B/NNN** (for equipment) and **IA/INQ/XX/B/NNN** (for instrument).

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Activity	First two character Code for company location identification	After first slash Abbreviated form for activity identification	After second slash Abbreviated form for qualification phase identification	After third slash Abbreviated form for Block identification	After fourth slash Serial Number	Version Number	Protocol Example
Equipment Qualification	IA	EQ	XX	B	NNN	00	
Instrument Qualification	IA	INQ	XX	B	NNN	00	

Where,

… - Location Code

EQ - Equipment Qualification

INQ - Instrument Qualification

XX - URS (stands for User requirement qualification)

- DQ (stands for Design Qualification)
- FAT (stands for Factory Acceptance test)
- SAT (stands for Site Acceptance test)
- IQ (stands for Installation Qualification)
- OQ (stands for Operation Qualification)
- PQ (stands for Performance Qualification)
- EHC (stands for Equipment Handover Certificate)
- INHC (stands for Instrument Handover Certificate)

B - B1 (stands for Block 1)

- B2 (stands for Block 2)
- U (stands for Utility/Engineering)
- Q (stands for Quality Control/ Quality Assurance)

NNN - Serial number starting from 001.

7.15.2 For Re-Qualification, protocol numbering shall be as:

……..**(For equipment)**

……..(For instrument)

Where,

IA - Location Code

EQ - Equipment Qualification

INQ - Instrument 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 Block 1)
- B2 (stands for Block 2)
- U (stands for Utility/Engineering)
- Q (stands for Quality Control/ Quality Assurance)

NNN - Serial number starting from 001.

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.

7.16 Numbering system for Addendum/Attachment for Approved Protocol:

7.16.1 Addendum/Attachment numbering shall be done as:

7.16.1.1 In case of Addendum, numbering shall be done as: **Protocol Number/AD_{NN}**

7.16.1.2 In case of Attachment, numbering shall be done as: **Protocol Number/AT_{NN}**

7.16.2 Numbering is shown in the below example:

	After first slash	Protocol Example	
Protocol or Report number as per above procedure	**AD_{NN}** (Where 'AD' stands for Abbreviated form of Addendum and 'NN' stands for serial number starting from '01' as subscript)	For Design Qualification of equipment	
		For Installation Qualification of equipment	
		For Operational Qualification of equipment	
		For Design Qualification of instrument	
		For Installation Qualification of instrument	
		For Operational Qualification of instrument	
	AT_{NN} (Where 'AT' stands for Abbreviated form of Attachment and 'NN' stands for serial number starting from '01' as subscript)	For Design Qualification of equipment	
		For Installation Qualification of equipment	
		For Operational Qualification of equipment	
		For Design Qualification of instrument	
		For Installation Qualification of instrument	
		For Operational Qualification of instrument	

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8.0 REVISION HISTORY

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

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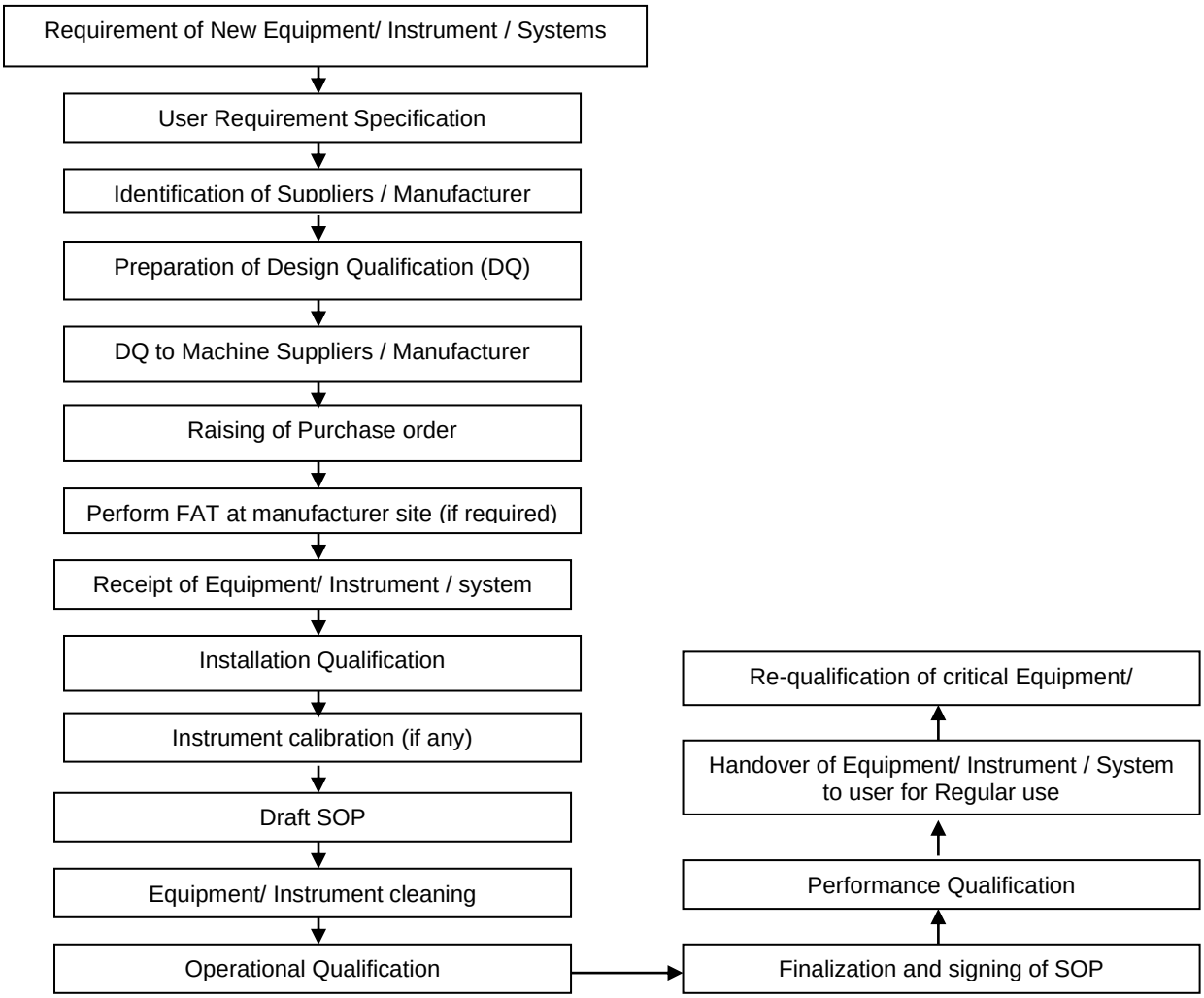
Attachment –I

Flow Chart of Equipment/Instrument Qualification



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Attachment-II

EQUIPMENT QUALIFICATION PROTOCOL NUMBER ISSUANCE LOG

Block: _____

S.No	Equipment Name	Department	EQUIPMENT QUALIFICATION PROTOCOL NUMBERS							
			URS Protocol No.	DQ Protocol No.	FAT Protocol No.	SAT Protocol No.	Equipment Code	IQ Protocol No.	OQ Protocol No.	PQ Protocol No.
	Sign & Date →									
	Sign & Date →									
	Sign & Date →									
	Sign & Date →									
	Sign & Date →									

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Attachment-III

INSTRUMENT QUALIFICATION PROTOCOL NUMBER ISSUANCE LOG

Block: _____

S.No.	Instrument Name	Department	INSTRUMENT QUALIFICATION PROTOCOL NUMBERS							
			URS	DQ	FAT	SAT	Instrument Code	IQ	OQ	PQ
			Protocol No.	Protocol No.	Protocol No.	Protocol No.		Protocol No.	Protocol No.	Protocol No.
	Sign & Date →									
	Sign & Date →									
	Sign & Date →									
	Sign & Date →									
	Sign & Date →									

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Attachment-IV

	EQUIPMENT/INSTRUMENT QUALIFICATION	Document No.	
	USER REQUIREMENT SPECIFICATION	Revision No.	
Equipment/ Instrument Name		PAGE No.	
Equipment/ Instrument Capacity			

USER REQUIREMENT SPECIFICATIONS

Equipment/Instrument Name

Site Address

Document Reference: _____
Issue Date: _____

Contents:

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17.0 Material of Construction:
18.0 Surface Finish:
19.0 Electrical and Control Equipment/ Instrument Philosophy:
20.0 cGxP Considerations:
21.0 Expected Documents and Drawings:
22.0 Available Utilities:
23.0 Maintenance Requirements:
24.0 Delivery, Installation and Commissioning Requirements:
25.0 Other Specific Requirements:
26.0 Reference Documents:
27.0 Abbreviations:
28.0 Attachments:

Prepared by: Validation QA	Reviewed by: User Department Head
Sign. & Date:	**Sign. & Date:**

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Attachment-V

	EQUIPMENT/INSTRUMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	
Equipment/ Instrument Name		PAGE No.	
Equipment/ Instrument Capacity			

DESIGN QUALIFICATION

Equipment/Instrument Name

Site Address

Document Reference: _____
Issue Date: _____

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13.6 Capacity / Speed:
13.7 Automation and Safety Features:
13.8 System Boundaries:
13.9 Material of Construction:
13.10 Surface Finish:
13.11 Electrical and Control Equipment/ Instrument Philosophy:
13.12 cGxP Considerations:
14.0 Expected Documents and Drawings:
15.0 Available Utilities:
16.0 Maintenance Requirements:
17.0 Delivery, Installation and Commissioning Requirements:
18.0 Other Specific Requirements:
19.0 Reference Documents:
20.0 Abbreviations:
21.0 Attachments:
22.0 Recommendations/ Conclusion:
23.0 Post Approval:

Functional area	Name	Designation	Signature	Date

Prepared by: Validation QA	Reviewed by: User Department Head
Sign. & Date:	**Sign. & Date:**

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Attachment-VI

	EQUIPMENT/INSTRUMENT QUALIFICATION	Document No.	
	FACTORY ACCEPTANCE TEST	Revision No.	
Equipment/ Instrument Name		PAGE No.	
Equipment/ Instrument Capacity			

Purpose:

Fill the following details and evaluate whether FAT shall be conducted or not.

a. Approved URS No./Date of approval:_____
b. Name of the vendor and address:_____
c. Name of the client and address:_____
d. Sr. No. (as applicable) of the Equipment/ Instrument/instrument/system:_____
e. Model of the Equipment/ Instrument/instrument/system:_____

S.No.	Description of situations	YES/NO
		YES □ NO □

Decision making:

S.No.	Inferences	FAT is Mandatory/Optional

Refer attached Manufacturer/Supplier FAT No. (if applicable):

Refer attached FAT No.:_____.

Summary and Conclusion:

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Review and Approval:

Functional area	Name	Designation	Signature	Date

Prepared by: Validation QA	Reviewed by: User Department Head
Sign. & Date:	**Sign. & Date:**

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Attachment-VII

	EQUIPMENT/INSTRUMENT QUALIFICATION	Document No.	
	SITE ACCEPTANCE TEST	Revision No.	
Equipment/ Instrument Name		PAGE No.	
Equipment/ Instrument Capacity			

SITE ACCEPTANCE TEST

Equipment/ Instrument Name

Site Address

Document Reference: _____

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Content:

Functional area	Name	Designation	Signature	Date

Prepared by: Validation QA	Reviewed by: User Department Head
Sign. & Date:	**Sign. & Date:**

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Attachment-VIII

	EQUIPMENT/ INSTRUMENT QUALIFICATION	Document No.	
	INSTALLATION QUALIFICATION	Revision No.	
Equipment/ Instrument Name		PAGE No.	
Equipment/ Instrument Capacity			

INSTALLATION QUALIFICATION

Equipment/ Instrument Name

Site Address

Document Reference: _____

Issue Date: _____

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Content:

Functional area	Name	Designation	Signature	Date

Prepared by: Validation QA	Reviewed by: User Department Head
Sign. & Date:	**Sign. & Date:**

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Attachment-IX

	EQUIPMENT/ INSTRUMENT QUALIFICATION	Document No.	
	OPERATIONAL QUALIFICATION	Revision No.	
Equipment/ Instrument Name		PAGE No.	
Equipment/ Instrument Capacity			

OPERATIONAL QUALIFICATION

Equipment/ Instrument Name

Site Address

Document Reference: _____

Issue Date: _____

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Content:

Functional area	Name	Designation	Signature	Date

Prepared by: Validation QA	Reviewed by: User Department Head
Sign. & Date:	**Sign. & Date:**

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Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment-X

	EQUIPMENT/ INSTRUMENT QUALIFICATION	Document No.	
	PERFORMANCE QUALIFICATION	Revision No.	
Equipment/ Instrument Name		PAGE No.	
Equipment/ Instrument Capacity			

PERFORMANCE QUALIFICATION

Equipment/ Instrument Name

Site Address

Document Reference: _____

Issue Date: _____

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Qualification of Equipment or Instrument	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Content:

Functional area	Name	Designation	Signature	Date

Prepared by: Validation QA	Reviewed by: User Department Head
Sign. & Date:	**Sign. & Date:**

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Qualification of Equipment or Instrument	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment-XI

	EQUIPMENT/INSTRUMENT QUALIFICATION	Document No.	
	EQUIPMENT/INSTRUMENT HANDOVER CERTIFICATE	Revision No.	
Equipment/Instrument Name		PAGE No.	
Equipment/Instrument Capacity			

EQUIPMENT/INSTRUMENT HANDOVER CERTIFICATE

This is to certify that the _____ having Equipment/ Instrument code no. _____ installed at _____ has been qualified and is being finally handed over to user department for _____

Certificate Approval:

Functional area	Name	Designation	Signature	Date

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Qualification of Equipment or Instrument	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment-XII

PROTOCOL ISSUANCE LOG FOR EQUIPMENT QUALIFICATION PROTOCOL

S.No.	Date	Protocol No.	Title	Equipment Name	Equipment Code No.	Protocol Issued By Sign/Date	Protocol Received By Sign/Date	Remark

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Qualification of Equipment or Instrument	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment-XIII

Protocol issuance log for Instrument qualification protocol

S.No.	Date	Protocol No.	Title	Instrument Name	Instrument Code No.	Protocol Issued By/Date	Protocol Received By/date	Remark