DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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

1.0 OBJECTIVE:

To lay down a procedure for performing of Equipment validation/Equipment qualification.

2.0 SCOPE:

This SOP is applicable to all the equipment used at …….

3.0 RESPONSIBILITY:

Qualification team comprising of:

Engineering department: For execution

Production department: For execution

QA department: for execution, adequacy and final approval

Head of respective department: for execution support

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 As per the requirement, the user department shall prepare "User Requirement Specification" (URS).

5.2 URS shall specify the actual operation to be performed, stage at which the equipment is used and GMP requirement

5.3 URS shall be evaluated by QA, engineering and production head.

5.4 As per the URS and in consultation with different vendors a "Design Qualification" shall be prepared which shall be checked and approved by engineering, production and Quality Assurance department.

5.5 As per the design specification, purchase order shall be generated.

5.6 Upon the supply of the equipment an "Installation Qualification" shall be done as per the recommendations of the vendor.

5.7 During Installation Qualification, the following shall be checked but not limited to:

5.8
- Identification of major components
- Identification of supporting utilities
- Identification of safety measures
- Identification of Standard Operating Procedures
- Identification of component to be calibrated
- Verification of drawing and documents
- Verification of Material of Construction

5.9 Upon approval of the Installation Qualification by QA, the equipment shall be checked for operation trials which shall be documented as "Operation Qualification"

5.10 Upon the approval of the Operation Qualification by QA, the equipment shall be checked for its performance for its operating range which shall be documented as "Performance Qualification"

5.11 Performance Qualification shall be performed as:

To ascertain the impact assessment of the critical components of the equipment on the product.

To establish, check and document the performance of the equipment in the predetermined operating ranges

5.12 A protocol shall be prepared based on the operating range and the services rendered by the equipment.

5.13 The protocol shall define the responsibility, methodology and acceptance criteria.

5.14 The final report shall be approved by Head – QA, Production and Engineering.

5.15 Re-qualification of the equipments shall be done at a periodically. Change in hardware/ major components and or software, shall trigger immediate

re -qualification.

6.0 ABBREVIATION(S):

QA : Quality Assurance

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Nil

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION