



DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Qualification Policy	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for Qualification Policy.

2.0 SCOPE:

This SOP is applicable for Qualification or Validation of all the Equipments/Instruments/Utility, Area etc. at

3.0 RESPONSIBILITY:

Officer/Executive- QA

4.0 ACCOUNTABILITY:

Head-QA

5.0 DEFINITIONS:

Qualification is defined as an action of providing that equipment or ancillary systems are properly installed, work correctly, and actually lead to the expected results.

6.0 PROCEDURE:

6.1 PRECAUTION:

Do not use non Qualified Equipment/Instrument.

6.2 EQUIPMENTS - QUALIFICATION AND MAINTENANCE:

6.2.1 Manufacturing equipment shall be qualified for intended services and shall be assigned with a unique Tag. No. as its identity. QA Department is responsible for assigning the Tag No., maintenance of record and the list.

6.2.2 Quality Assurance, Production and Engineering Department do the Qualification for Equipment installed in the Production. Warehouse and Engineering department assigns Tag No. Independently & maintains the record and identify the Equipment “**Equipment Qualification Status**” as per **Annexure-I**.

6.2.3 Equipment has its Protocol mentioning the procedures, Frequency and Acceptance Criteria and precautions to be followed (if any specific).



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- 6.2.4** Any Qualification/Validation activity shall be carried out as per respective qualification / validation planner and should be started within the defined frequency. If qualification/ Validation activity shall not be started within the due period including permissible deviation limit, then the same shall be address through deviation. Below mentioned permissible deviation in Nos. of days shall be allowed as per set frequency:

Set Frequency	Permissible Deviation
Half Yearly	± 15 Days
Yearly	± 30 Days

- 6.2.5** Date of Qualification shall be considered as post approval date of the compiled report.
- 6.2.6** If, any Qualification done by external person/third party, then detail of the same shall be recorded in Qualification register.
- 6.2.7** A Master Qualification Plan shall be maintained for all the Equipments/Instruments as shown to **Annexure-II**, Titled “**Master Qualification Planner for Equipments/Utility**” for Periodic Qualification of Calendar year. During preparation of Master Qualification planner Planned date (PD) shall be preprinted and Executed date (ED) shall be hand written on the controlled copy of planner as per the post approval date of executed compiled report.
- 6.2.8** When any new Equipments/Instruments shall be introduced in the facility, addendum of the Master Qualification Planner for Equipments/Utility shall be prepared after qualification for the Equipment as **Annexure-III**. This addendum planner of new Equipments/Utility shall be incorporate in next year Master Qualification Planner for Equipments/Utility.
- 6.2.9** For routine servicing and maintenance, either Annual service contract or service arrangement is made with Equipment manufacturer/authorized Service agent, if required. Frequency of service shall be followed as per the contract and after completion of the servicing activity, service report shall be prepared accordingly. A history card of all critical & major equipment shall be maintained by engineering department.



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ANNEXURE-I

EQUIPMENT QUALIFICATION STATUS

Equipment Name : _____

Equipment Location : _____

Equipment ID No. : _____

Qualification Done On : _____

Qualification Due On : _____

Qualification Done By

(Sign & Date)



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ANNEXURE-II

MASTER QUALIFICATION PLANNER FOR EQUIPMENTS/UTILITY

Year:

Block:

Area:

S. No.	Name of Equipment/Utility	Identification No.	Equipment/Utility Location	Frequency	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
					PD	ED	PD	ED	PD	ED	PD	ED	PD	ED	PD	ED

(PD: Planned Date & ED: Executed Date)

Prepared By
Officer/Executive- QA
Sign & Date

Checked By
Head-Department
Sign & Date

Approved By
Head QA
Sign & Date



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ANNEXURE-III

ADDENDUM OF MASTER QUALIFICATION PLANNER FOR EQUIPMENTS/UTILITY

Year:

Block:

Area:

S. No.	Name of Equipment/ Utility	Identification No.	Equipment / Utility Location	Frequency	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
				PD												
				ED												
				PD												
				ED												
				PD												
				ED												
				PD												
				ED												

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