



DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

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

1.0 OBJECTIVE:

To lay down a Procedure for Qualification Planner.

2.0 SCOPE:

This SOP is applicable for Qualification Planner of all the Equipment/Area handled and Qualified at.....

3.0 RESPONSIBILITY:

QA (Officer/Executive)

4.0 ACCOUNTABILITY:

Head QA

5.0 DEFINITION:

Not Applicable

6.0 PROCEDURE:

PRECAUTION:

Do not use non Qualified Equipment/Area.

6.1 EQUIPMENTS/AREA - QUALIFICATION:

- 6.1.1 Manufacturing equipment shall be qualified for intended use and shall be assigned with a unique ID. No. as its identity. QA Department is responsible for assigning the ID Number independently for all equipment and utility.
- 6.1.2 Qualification team i.e. Quality Assurance, Production, Quality Control and Engineering Department along with vendor (manufacturer) (where applicable) shall qualify the equipment installed in the Production area & warehouse and identify the Equipment “**Equipment Qualification Status Label**” as **Annexure-I**.
- 6.1.3 Qualification protocol contains the procedures, Frequency and acceptance criteria and precautions and to be followed the same.
- 6.1.4 Qualification of equipment/area, done at defined frequency. However, when equipment is in operation and/or for any other reasons Qualification could not be done at due



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Period, it must be qualified under the tolerance period as mention accordingly:

Qualification	Set Frequency	Tolerance
Production Equipment	Half year ,1 & 2 Years	± One Month
Area Qualification/HVAC	Half Yearly,1 & 2 Years	± One Month
Utility	Yearly	± One Month

Due to any reason, if Qualification due date exceeds the delay in Qualification shall be approved by Head QA.

- 6.1.5** Any Qualification done by external person / agency shall be recorded and maintained with its relevant record. The Officer / Executive in qualification team shall ensures the equipment is Qualified before putting into operation.
- 6.1.6** A Master Qualification Planner shall be maintained for all the equipment's /Area as shown in **Annexure-II** for Periodic Qualification of Calendar year.
- 6.1.7** The first column of the Annexure-II i.e. "Name of Area" shall have only name of the main core area specially in case of AHU's.
- 6.1.8** The first Planner of the year shall have a revision no. as 00 and whenever there will be any changes in the planner due to addition/deletion or any reason, the revision no. shall be changed accordingly to next revision no. during the same year.
- 6.1.9** For routine Qualification, either Annual Contract or Annual Arrangement shall be made with Equipment manufacturer/Authorized Agent. Frequency of Qualification shall be followed as per the contract. A Qualification Protocol & Report shall be maintained by the Quality Assurance Department.
- 6.1.10** For routine servicing and maintenance, either Annual service contract or service arrangement shall be made with Equipment manufacturer/authorized Service agent. Frequency of servicing shall be followed as per the contract. A service report shall be maintained by the respective Department.

7.0 ABBREVIATIONS:

- SOP Standard Operating process
- QA Quality Assurance
- ID Identification
- AHU Air Handling Unit



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8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Equipment Qualification Status	
Annexure-II	Master Qualification Planner Execution Record	
Annexure-III	Under Requalification status	

9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department.
- Controlled Copy No. 01 Quality Assurance Department.
- Controlled Copy No. 02 Quality Control Department.

10.0 REFERENCES:

Validation Master Plan
WHO TRS 937

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		



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ANNEXURE-I

EQUIPMENT QUALIFICATION STATUS

EQUIPMENT QUALIFICATION STATUS

Equipment Name : -----

Equipment Location : -----

Equipment ID No. : -----

Qualification Done On : -----

Qualification Due On : -----

Qualification Done By : -----



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ANNEXURE-II

MASTER QUALIFICATION PLANNER EXECUTION RECORD

Name of Area	Name of Equipment	Equipment ID No.	Qualification Done Date	Re-Qualification Test details with due date	
				Test to be performed	Next Due Date

Prepared By
Officer/Executive-QA
Sign & Date

Checked By
Department Head
Sign & Date

Approved By
Head Quality Assurance
Sign & Date



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ANNEXURE-II

UNDER QUALIFICATION STATUS

UNDER QUALIFICATION STATUS

Equipment Name : _____

Equipment ID No. : _____

Requalification Start on : _____

Frequency : _____

(Sign & Date)