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

1.0 OBJECTIVE:

To lay down a Procedure to define the Standard Operating Procedure for "Facility Qualification".

2.0 SCOPE:

2.1 This SOP is applicable for provides Guidance for Qualification & Re-qualification of Facility which may affect the Product Quality, Safety and Storage at ……..

3.0 RESPONSIBILITY :

- **QA (Officer/Executive):** SOP Preparation, Checking, Distribution, Retrieval, Approval & Training and effective implementation of this SOP in all the applicable areas.
- **Engineering**: Execution of Facility Qualification activity as per SOP.
- **Production:** Provide area as per qualification planner for Execution of Facility Qualification activity as per SOP.

4.0 ACCOUNTABILITY:

Head-Quality shall be accountable for ensuring over all compliance of this Standard Operating Procedure.

5.0 DEFINITIONS:

- **Validation / Qualification:**

  Qualification is documented evidence that a specific Equipment, Facility or System is fit/ready for intended use.

- **Performance Qualification (PQ):**

  Documented verification that the Facilities, Systems and Equipment as connected together, can perform effectively and reproducibly, to perform approved process and deliver product specification consistently.

- **System:**

Referred in this SOP means Facility System.

- **Activity:**

  Any monitoring or measuring or Qualification step.

- **Re-Qualification:**

  Planned, Periodic Qualification to prove that any Facility / Utility / Equipment / Instrument / System actually are in validated state.

- **Modification:**

  Any significant change which may alter the validated state of Facility/Utility/Equipment/ Instrument / System.

- **Relocation:**

  Change in location of any Utility, Equipment or System.

6.0 PROCEDURE:

6.1 Facility qualification shall be performed for all new creation or any major modification in facility and is governed through change management system in existing facility having any GMP impact.

6.2 During facility qualification following checks but not limited to shall be performed:

6.2.1 **Verification of layouts related to facility such as**:

6.2.1.1 Plant layout

6.2.1.2 Civil plant layout

6.2.1.3 Men material movement

6.2.1.4 Pressure zoning

6.2.1.5 HVAC zoning

6.2.1.6 Drain point location

6.2.1.7 Compressed air user point location

6.2.1.8 Microbial count location

6.2.1.9 Area classification layout

6.2.1.10 Fire Extinguisher location

6.2.2 Verification of room name and room number allocated as per drawing and designed.

6.2.3 Verification of civil works like, type of construction, floor, wall, ceiling and view panel of room or area.

6.2.4 Verification of number, movement and type of door.

6.2.5 Verification of smoothness and type of wall paint.

6.2.6 Verification of material of construction of coving location i.e. between floor and wall and between ceiling and wall.

6.2.7 Verification for the skirting of wall.

6.2.8 Verification of dimensions of room.

6.2.9 Verification of electric fitting, connection, type and number of point in room.

6.2.10 Verification of communication points.

6.2.11 Verification of potable and purified water user points.

6.2.12 Verification of compressed air user points.

6.2.13 Drain points verification.

6.2.14 Verification of type and number of HVAC air supply and return diffuser.

6.2.15 Verification of type and number of light fixture.

6.2.16 Verification of light intensity in room/area

6.2.17 Verification of equipment location with respect to room size.

6.2.18 Verification of safety system such as alarm push buttons, location of closest fire extinguisher, fire detection system and eye wash location.

6.3 All the required layouts shall be attached with report for reference purpose.

6.4 After reporting of all verification checks, summary and conclusion shall be given.

6.5 FACILITY QUALIFICATION SHOULD BE CARRIED OUT IN FOLLOWING CASES:

- Introduction of New Facility

- Replacement of Major Component
- Renovation of Facility due to any reason
- Requirement revealed through investigations

6.6 QUALIFICATION OF NEW DESIGNED FACILITY:

S.No	Parameter's	Criteria	Activity to be carried out for Number of day's
1.	Wall and Floor	Shall be verified for Surface Finish & Damages.	Once during Facility Qualification
2.	Safety Devices	Shall be verified and Identified as per design.	Once, during Facility Qualification
	Utilities		
3.	Door Interlocks	Shall be verified and identified as per design	Once during Facility Qualification
4.	Man Material Flow / Movement	Shall be as per design	Once during Facility Qualification
5.	Luminance Level	NLT 300 Lux at Working Level	Once, during Facility Qualification

6.7 REQUALIFICATION OF FACILITY QUALIFICATION:

Facility Qualification shall be performed only once and requalification of facility shall be performed after major modification on the basis of impact assessment.

6.8 PREPARATION OF PROTOCOL AND REPORT:

Protocols & Report of Facility Qualification shall be prepared by quality assurance department as per current version of QA SOP, Titled **"Preparation, of Validation/Qualification Protocols and Reports".**

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7.0 ABBREVIATION:

SOP	Standard Operating Procedure
QA	Quality Assurance
%	Percent
Mg	Milligram
MF	Manufacturing
EG	Engineering
S.No.	Serial Number
NA	Not applicable

8.0 ANNEXURES:

NA

9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department
- Controlled Copy No 01 Quality Assurance Department.
- Controlled Copy No.02 Quality Control Department.
- Controlled Copy No 03 Production Department.
- Controlled Copy No.05 Engineering Department.

10.0 REFERENCE:

- PIC's Recommendation on Guide to Good Manufacturing Practice for Medicinal Products (PE 009-9 Annexes) & GMP Annex 1 Revision 2008, Interpretation of Most important changes for the manufacture of sterile medicinal products PI-032-2).
- EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use Annex 1(Manufacture of Sterile Medicinal Products).

- ISO-14644-2 Specification for Testing & Monitoring to prove continued compliance with ISO-14644-1

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		