1. Purpose:

1.1 The purpose of this validation plan is to outline the requirements to demonstrate and document that all components, control system and functionality associated with the equipment are appropriate and according to cGMP regulated process.

2. Scope:

2.1 The scope of validation for the specific equipment includes DQ, IQ OQ and PQ which are necessary for the system to operate and is performed at the time of designing, installation, modification or relocation of equipment.

3. Responsibility:

3.1 The officer incharge alongwith the engineer of each section is responsible to raise the purchase requisition of the equipment according to the specified requirement and design qualification.

3.2 The engineer of BPD verifies the design according to the required systems and sends it to QA for authorization after getting the approval of Chief, BPD.

3.3 Engineer of the relevant production unit (where available) in collaboration with the officer incharge writes the IQ, OQ and PQ protocol of the required equipment and design data record forms accordingly. In case of production units where engineers are not part of the staff, other engineers of BPD perform this task.

3.4 The notified validation team verifies/reviews the SOPs alongwith the data record forms and send these to QA for authorization through internal auditor and approval of Chief, BPD.

3.5 Quality Assurance reviews and authorizes the protocols and data record forms accordingly.

4. Materials and Equipment:

4.1 As required for each equipment.

5. Procedure:-

5.1 Design Qualification (DQ)

5.1.1 DQ describes the equipment in sufficient detail to enable it to be built and to ensure that the equipment selected has adequate capacity to operate for the intended purpose and also synchronize with the operational requirements of the other related equipments and area where the equipment is to be installed.

5.2 Installation Qualification (IQ)

5.2.1 IQ verifies that the following are accomplished satisfactorily.

5.2.1.1 Equipment identification information.

- Manufacturer’s model.

- Serial No.
- Size.
- Dimensions.
- Capacity.
- Location in facility.

5.2.1.2 Equipment utility requirement services:-

- Water.
- Electricity.
- Gas.
- Compressed air.
- Steam.
- Drain/exhaust lines provision.
- Quality and quantity of feed utilities.
- Pipe composition and diameter.
- Filter requirement.

5.2.1.3 Equipment safety features:

- Pressure release system.
- Safety valves.
- Alarm system.
- Alarm activation settings.

5.2.2 **IQ Protocol**

5.2.2.1 An IQ protocol for each equipment/process is generated as per DOC# QAD-00-0-EV-001/02, executed and approved to provide documented evidence that the equipment is installed according to the design specification. A final report is submitted summarizing the results. Any observed deficiencies and the corrective actions are addressed in this report.

5.2.2.2 Installation Qualification (IQ) verifies that the following are accomplished satisfactorily.

- ❖ Calibration requirements.
  - Indicating parameters to be measured.
  - How they will be measured or monitored.
  - What is the acceptable range or limit.
- ❖ Pre-operational activities.
  - Cleaning and sanitization of piping systems.
  - Distribution of lines.
  - Performance of heating elements etc.
  - Door gasket integrity.
  - Soft ware checks.

5.3 **OQ Protocol**

An OQ protocol for each equipment/process is generated as per Doc # QAD-00-EV-002/01, executed and approved to provide documented evidence that the equipment operates according to the functional specification. A final report is submitted summarizing the results. Any observed deficiencies and the corrective

Actions are addressed in this report.

5.3.1 Operational qualification verifies the following:

5.3.1.1 Indicates parameters to be measured and their acceptance criteria along with range.

5.3.1.2 Monitor instrument used for measurement with date of calibration.

5.3.1.3 Control checks of servicing parameters and their result.

5.4 **Performance Qualification (PQ).**

5.4.1 Performance qualification, (PQ) verifies that a piece of equipment is properly installed and functioning with in specific operating parameters and can perform consistently reliably and reproducibly. PQ contains:

5.4.1.1 Preliminary operations including the validation of routine processing conditions during which minimum and maximum conditions for routine processing are determined.

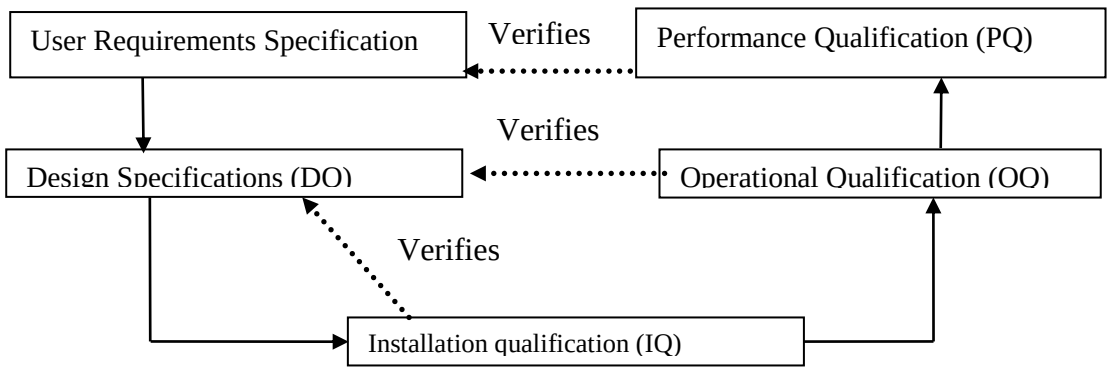
5.4.1.2 Performance qualification procedures which demonstrate that the equipment or utility system can consistently meet the operating specification and perform its intended functions during three consecutive successful cycles for various configurations.

5.4.1.3 Performance qualification acceptance criteria ensure that all processing parameters meet the specifications (cited in validation protocol) or (as per user requirement) during the number of consecutive runs and data recorded/available in result supports the claims.

5.4.2 A PQ protocol for each equipment/process is generated as per doc # QAD-00-EV-003/01, executed and approved to provide documented evidence that the equipment satisfies the user's requirements according to the specifications. A final report is submitted summarizing the results. Any observed deficiencies and the corrective actions are addressed in this report.

5.5 In validation protocol, activities, time line is the preliminary requirement, which describes the overall schedule for validation of the equipment with the indication of planned activities and timing.

5.6 Validation traceability:



6. Reporting:

6.1 Section Engineer (where available) enters record in the relevant data record Performa. In case the engineer is not available in the section, services of engineer from ESU are utilized and one of the senior technicians is trained accordingly.

6.2 O/I of the relevant section/unit alongwith the Engineer of the production division verify all the data record forms.

6.3 After verification officer incharge reviews the completed data record forms, generate report and send it to chief through IA for approval and authorization by QA.

7. Reference:

7.1 WHO guide to good manufacturing practice (GMP) requirements, Part-II validation No. WHO/VSQ/97.02,1997.

7.2 Equipment Validation –IQ. Doc# QAD-00-EV-001/02

7.3 Equipment Validation –OQ. Doc# QAD-00-EV-002/01

7.4 Equipment Validation –PQ. Doc# QAD-00-EV-003/01