# DOCUMENT APPROVAL

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| --- | --- | --- | --- |
| **Department** | **Name** | **Designation** | **Signature / Date** |
| **PREPARED BY** | | | |
| Anticancer Area (Block D) Production |  |  |  |
| **REVIEWED BY** | | | |
| Anticancer Area (Block D) Production |  |  |  |
| EHS |  |  |  |
| Engineering |  |  |  |
| Quality Engineering / Validation |  |  |  |
| Quality Assurance |  |  |  |
| **APPROVED BY** | | | |
| Head- Anticancer Area (Block D) Production |  |  |  |
| Head-Engineering |  |  |  |
| Head-Q.E. / Validation |  |  |  |
| Head-Quality Assurance |  |  |  |
| **NOTIFIED TO** | | | |
| Factory Head |  |  |  |

# LIST OF ATTACHMENTS

|  |  |  |
| --- | --- | --- |
| **Sr. No** | Topics | **Number of Pages** |
| **Attachment of Document** | | |
|  | Attachment 1 - Check list for requisite feature of 21 CFR Part 11 compliance for process control system | **\_\_** |
| Total Pages of Document | | **\_\_** |

# REFERENCES

* Equipment Qualification Master Plan
* Validation Master Plan
* Change control number PR# \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# REVISION HISTORY

|  |  |
| --- | --- |
| **Revision No.:** 00 | **Effective Date:** |
| **Reason for Revision:**   * -NA- | |

# LIST OF ABBREVIATION

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| --- | --- | --- | --- |
| **Abbreviation** | **Description** | **Abbreviation** | **Description** |
| SOP | Standard Operating Procedure | FAT | Factory Acceptance Test |
| ANA | Antineoplastic Area  (Block D) | LPH | Liter Per Hour |
| QA | Quality Assurance | QE | Quality Engineering |
| DQ | Design qualification | OQ | Operational Qualification |
| IQ | Installation Qualification | URS | User requirement specification |
| GMP | Good Manufacturing Practice | P&ID | Piping and instrumentation diagram |
| MOC | Material of construction | PSI | Pounds per Square Inch |

# EQUIPMENT

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| Pump extrusion system |

# REQUIREMENT

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|  | **Equipment Overview:**  The extrusion system shall be used as part of [Liposome](http://www.genizer.com/) manufacturing setup to generate homogeneous populations of anti-cancel drugs liposomal vesicles by forcing aqueous suspensions of lipid through stacked polycarbonate filters with defined pore size.  Extrusion is a technique where the [liposome suspension](http://www.genizer.com/) is passed through a stack of membrane filters of defined pore size.  An [extruder](http://www.genizer.com/) is equipped with a piston pump which pushes fluid through the membranes and by adjusting various parameters such as applied pressure, number of cycles, temperature and pore size; liposomes of suitable size distribution are produced. The design and operation of the system shall meet GMP and cleanroom requirements.  Current scope of extrusion system shall include the required in feed and out feed connectors which shall ensure easy integration with the [liposome](http://www.genizer.com/) manufacturing skid.  A centralized control system consisting of Industrial PC (IPC) based control shall be provided to monitor, control and record the detection operation.  All the required utilities shall be in LIPOSOME PHARMA scope of supply. All the utility specifications shall be given by vendor for the respective utility. |
|  | **Capacity of Equipment:** |
| Capable of producing an outflow between 0.0 to 6.0 L /min @ operating pressure upto 1500 PSI/100bar. |
|  | **Quantity:** |
| 01 no extrusion system comprising of a piston pump and 4 to 8 jacketed filter holders. |
|  | **Area of Installation** |
| Machines to be installed in ANA Block-D of Liposome Pharma facility. |

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|  | **Size / Dimension of Equipment:** |
| Approximate dimension of the equipment should not be more than (L\_2500mm\_XW\_1400mm\_\_XH\_2000mm\_\_)  **Note:** Equipment dimensions to be finalized after technical discussion with supplier. |
|  | **Size / Dimension of Installation Room:** |
| (L6000mm XW6000mm XH3500mm)  **Note:** Based on the finalized equipment dimensions, installation space requirement to be finalized. |
|  | **Intended Use / Purpose:** |
| * The extrusion system shall be capable of reproducibly generate uniformly sized liposomal vesicles and shall be suitable for a batch size of 50—80 L. * The system shall comprise of a sanitary grade GMP compliant piston sanitary pump with good metering accuracy and capable of delivering flow rate of up to 6LPM at high pressures ranging up to 1500PSI with minimal 5% pulsation. * The pump shall be connected through temperature controlled manifold to jacketed filter holders housing polycarbonate filters wherein flow can be maintained through the filters either individually or in combination of two. * The whole system shall be compact and be easily integrated with Liposome Pharma [liposome manufacturing system](http://www.genizer.com/). |
|  | **GMP Requirements:**  The machine shall be developed in accordance with   * Current Good Manufacturing Practices (cGMP) * Good Automated Manufacturing Practice (GAMP5) * Good Engineering Practice (GEP) * 21 CFR Part 11 * Food & Drug Authority (FDA) |

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|  | **Other specific requirement:**   * The extrusion system shall be capable of achieving homogenous and reproducible liposome suspension. * System shall be provided with inlet and outlet end connections of suitable dimensions as approved by Liposome Pharma. * System shall be compatible for sanitization with 70% IPA solution. Product non - Contact Parts shall be of SS 304 / SS316L / FDA Compliant material with surface finish of Ra ≤ 0.80 µm. * Machine shall be easy to clean. * Product contact parts shall be made of SS316 / 316L * It shall have an operating pressure range of 0—1500 psig(0-100bar) * System shall be capable of operating in a temperature range of 10 - 80℃. * System shall have a piston pump giving out precision metering with minimal pulsation at high flow rates. * All product contact parts shall be electro polished to a minimum finish of 15Ra µinches (0.38µm). * System shall be designed for CIP (Clean in place) and SIP (Sterilization in place) * System shall have eight jacketed filter holder assembly which shall be able to house stack of multiple membrane filters having 142mm/293mm diameter and the filter holders shall be provided with support mesh made of stainless steel and drain disc of suitable MOC to prevent membrane rupture. The top casing of filter holders shall be provided with lifting lugs. * The system shall be able to operate both in auto (process control) and manual mode (operator control). * The system shall have programmable flow control to limit the extrusion pressure at the process set point (pressure shall be settable between 0-1500PSI).The operator control mode shall enable the operator to adjust and maintain flow manually as per process requirement. * System shall have provision for purging the process line and filter holder pathways with inert gas like nitrogen to reduce the holdup volume. * Machine shall be designed for Electric Power Supply of 380 V AC-440 V AC / 50/60 Hz / 3 Phase * Machine control system shall have provision for connection with UPS (UPS shall be in the scope of Liposome Pharma). * Instrument Power Supply of machine shall be 24 V DC & shall be intrinsically safe. | |
|  | **Key Features** | **Description** |
| Working Height | Elevated platform to be provided by Liposome Pharma |
| Operating pressure range | 0-1500 psig (0-100Bar) |
| Operating temperature range | Process temperature 10 – 80℃ (50 – 176℉)  System shall withstand SIP pressure and temperature |
| Pump type | GMP compliant piston pump with good metering accuracy and capable of delivering flow rate of up to 6LPM at high pressure ranging up to 1500PSI with minimal 5% pulsation |
| Operating modes | **Maintenance mode with Limited/ Restricted access:** For calibration of transmitters, setting alarm set points, CIP/SIP processes, batch parameters  **Batch production mode with Operator access:** Shall have defined tests and sequences for regular production run. |
| Process control mode | The system shall have provision to switch between Auto and Manual mode.  **Auto process control mode:** System shall be programmed to control the pump flow rate such that the process set point is not exceeded.  **Manual control mode:** Operator shall be able to control process flow rate thereby maintaining the desired extrusion pressure. |
| Temperature control | Filter holders, pump head and process piping shall be jacketed to provide temperature regulation to the system.  Hot water shall be used for heating of filter holders, pump head and process piping which shall be in the scope of LIPOSOME PHARMA.  Cleanroom compatible insulation shall be provided with all hot surfaces and exposed surfaces shall be marked with proper labeling.  Inlet and outlet connectors of hot water jacket shall be supplied with Staubli RBE plug and socket connections with zero drip arrangement to avoid spillage of hot water when opened. |
| Valve types | 2 way and 3 way diverting 0.5 inch OD TC ball valve |
| Process piping | 0.5-inch ASME-BPE-stainless steel tubing with tri-clamp end connectors. |
| Gaskets and Clamps | All gaskets, O-rings and clamps shall be of sanitary type |
| Process monitoring | **Temperature monitoring:**  The system shall include process temperature transmitters with temperature range (-50 to 200℃) installed at the outlet of each head and in the main process (inlet) line just prior to the filter holder lines.  The transmitters shall be of reputed make and have accuracy of ±0.15℃ over the range.  **Pressure monitoring:**  There shall be a pressure transmitter of reputed make installed just before the filter holder process lines are split from the main process lines.  The dual temperature and pressure transmitter shall have a range of 0 - 3000 PSI with an accuracy of ±0.5% of the span. This transmitter shall provide the pressure measurement that the process control modes controls against.  All process values shall be displayed on the HMI, paperless chart recorder and local display head of the respective transmitter.  Programmable alarm set points shall be available to set process warning and fault conditions which shall stop the system if it is running or prevent the system from starting if fault is present. |
| Utility monitoring | Temperature and pressure transmitters of reputed make shall be installed in the feed and return connections of the heating loop and each filter holder to monitor the heating fluid temperature and pressure through the system. Programmable alarm set points for process warning and faults shall be available for all the temperature and pressure transmitters.  Under fault condition the system shall stop if running or prevent the system to start if fault is present.  Temperature transmitter range: -50 to 200℃  Pressure transmitter range: 0 to 3000PSI (0-200bar)  Purging circuit shall have a pressure transmitter with a range of 0 to 3000PSI (0 to 200bar) and an accuracy of 0.5% of the span to monitor pressure within the purging circuit. Programmable process faults and warnings shall be available so that the purging is stopped under fault conditions |
| 21 CFR part 11 compliance | Yes |

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|  | **Industrial PC (IPC) Based Control Station:**  The control station shall be constructed from a SS NEMA4X rated control console   * + A single Industrial panel PC shall be considered.   + The touchscreen (glass display) shall be capacitive touch offering a high level of protection from scratches and damages.   + It shall have a single-touch capability and shall be operative with gloves.   + It shall be suitable for wall mounting / desktop stand / floor stand. The same will be defined during the DQ phase.   + IPC shall include interfaces with the operator, supervisors and the user’s control system to ensure safe, reliable, continuous, automatic operation and easy, safe, reliable configuration. Provision for multi-level access for application login (User, Maintenance, Supervisor, Application, Admin and OEM)   + The IPC shall be suitable for operator control and monitoring as well as data collection, communication and printing.   + It shall possess modular structure and service-friendly design. It shall be maintenance free.   + The IPC shall be designed to grant the complete automation of the machine.   + The control system shall comply to:   + cGMP   + FDA   + FDA 21 CFR Part 11   + The process / machine data shall be displayed during the operation on all the GUIs of the system and optionally sent to the local printer. Printer to be provided by Vendor and make/model of printer to be defined by Liposome Pharma.   + Batch report format shall be approved by [Liposome](http://www.genizer.com/) Pharma.   + It shall be possible to retrieve all archived process reports for re-printing if required.   + There shall be digital display of temperature and pressure conditions and provision for unique batch number entry, report generation and data logging.   + All process data shall have compliance with 21 CFR part 11 requirements as per Attachment – 01.   + Usernames and passwords shall be unique to the equipment with unlimited number of users   + User tracking for operator access shall be there   + The system shall be able to integrate and communicate with plant system based on Mitsubishi, Allen Bradley or Siemens communication protocol.   + In case of power outage, UPS shall be provided to PLC control circuit. | | |
| **Technical Specifications of IPC:** | | |
| a | Design | Panel PC built-in unit with protective enclosure |
| b | Front | TFT Capacitive Glass Display |
| c | Operation | Single-touch |
| d | Size | 7” |
| e | Processor | Suitable / Equipment Compliant |
| f | Main Memory | Suitable / Equipment Compliant |
| g | Operating System | None defined |
| h | Storage | As Per Liposome Pharma Requirements |
| i | Interfaces | 1. Ethernet Port 2. USB 2.0 3. Serial Port |
| j | Degree of Protection | IP 66 at front, IP 65 at rear, IP 66 in protective enclosure |
|  | **Salient Features:**   * The machine design shall be cGMP compliant and suitable for operation and cleaning in accordance with pharmaceutical specifications led down by the national / international regulatory authorities. * The machine construction shall be as per GEP standards: no hollow areas, special lubricants, superior surface quality etc. * The machine shall be fully built on a stainless steel frame, to ensure the maximum hygiene and sanitation levels. The design shall prevent dirt trap areas and also provides easy access to the drive components for maintenance. * The machine shall be mounted on the anti-vibration pads. * The machine drive mechanisms shall be easily accessible for inspection, lubrication, adjustments and changeover. * All welds (if any) shall be grounded smooth, flush and free of weld splatter or occlusions. An integrated safety concept at all accesses shall be followed. * The qualification and validation documentation shall be in accordance with cGMP. GAMP5, ISO and FDA. * The change over and cleaning procedure shall be easy and all parts of the machine shall be easily accessible for efficient cleaning. The change formats shall be designed as per quick format change in the control system. Specific torque spanner to be included in scope of supply by vendor if required. * Electrical cables, control cables, process piping and tubing shall not be routed through structural tubing. Any holes in the structural tubing for fasteners or other necessary items shall be suitably sealed. * An integrated electrical cabinet shall be provided with the machine. The same will be defined during the DQ phase | | |

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# EQUIPMENT / SYSTEM SPECIFICATIONS

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| **8.1** | **Equipment / System mounting** |
| The machine shall be mounted on the floor of the installation room with the help of heavy duty self-levelling, SS legs and shall be able to withstand any kind of vibration during its operation. The height of the machine base frame shall be ± 180 mm from the top of the finished floor level. |
| **8.2** | **Machine Packaging:**  The machine shall be properly packed before dispatch to avoid damage during transport, storage and handling, and the total gross weight should be less than 500.0kg. A sign to indicate the upright position of the machine / ancillary / auxiliary / Tip & Tell / Shock Indicators to be placed during transport and storage shall be clearly marked. Also required arrangement shall be provided to handle the equipment for loading/unloading of equipment. |
| **8.3** | **Operating range** |
| System shall be designed for clean room application having operating pressure range of 0 to 100 bar and operating temperature range of 10 to 80℃. System shall be compatible with standard CIP and SIP procedures and withstand sterilization temperature hold. |
| **8.4** | **Requirement of controlling valves / pneumatic valves**  As per machine supplier model availability. |
| **8.5** | **Expected utility consumption:**  All the utilities shall be in LIPOSOME PHARMA scope of supply. All the utility specifications shall be given by vendor for the respective utility. |
| **8.6** | Spares list to be supplied at the time of installation. Operational spares shall be supplied for two years usage. |
| **8.7** | Calibration certificates required at the time of installation. |
| **8.8** | Onsite training of workers and Officers to be given at the time of qualification. |
| **8.9** | All the electrical wiring should be covered with guards. |
| **8.10** | Electrical diagram of I/O card drawings. Data sheet for critical components and assemblies. All the electrical wiring should be covered with guards. |

# FUNCTIONAL REQUIREMENT SPECIFICATION

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| **9.1** | **Operational facility**  Machine shall be suitable for operation in Manual / Automatic modes. |
| **9.2** | **Controlling panel** |
|  | HMI with required switches / push buttons shall be available for controlling the machine operation |
| **9.3** | **Process Control** |
|  | Process control shall be fully manual / automatic. |
| **9.4** | **PLC requirement** |
|  | Vendor to specify during Design Qualification as per the requirements mentioned in the URS. |
| **9.5** | **Sequence of operation** |
|  | Vendor to specify during Design Qualification as per the requirements mentioned in the URS |
| **9.6** | **Power Failure / Recovery Method** |
|  | Vendor should perform Power failure study during qualification. |
| **9.7** | **Minimum Programs require in PLC** |
|  | Vendor to specify during Design Qualification as per the requirements mentioned in the URS |
| **9.8** | **Environment Conditions where Machine will be mounted**   * Temperature: Minimum 20 ºC / Maximum 25 ºC / Design Reference 40 ºC\ * Relative Humidity: 60 % (Maximum) |

# OPERATIONAL INTERLOCKS AND ALARMS

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| **10.1** | Machine shall give alarm and shall stop in case of operator’s intervention. |
| **10.2** | In case of abnormal low pressure or temperature, machine shall give alarm and shall stop. |
| **10.3** | In case of power failure condition machine, UPS of the control system shall keep the control system on to allow the operator to purge and vent the system |
| **10.4** | In case the set pressure limit is exceeded the system shall shut down automatically to prevent damage. |
| **10.5** | Programmable alarm set points shall be available for temperature and pressure to set process warning and fault condition. |
| **10.6** | Programmable alarm set points shall be available for temperature and pressure to set process warning and fault condition for heating jacket. |

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# SAFETY FEATURES

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| **11.1** | **Process Safety** |
|  | * Safety pressure of 1500-3000PSIG (Rated with respect to operating temperature of 10-80℃) can be set up to protect the pump and process piping from over pressurization. In case of over pressure, the pump can automatic reduce the flow rate in order to process under the safety pressure. * Feedback control mechanism to control pump speed in case of over pressurization. * Emergency stop shall be provided for emergency shutting of the system * Visual / audible over pressure and temperature alarm shall be provided on both control station and at extrusion system. * Auto stop option shall be available in case of set pressure limit is exceeded to prevent damage to the system. |
| **11.2** | **Mechanical Safety** |
|  | * Any machine part which may possess safety hazard must be safeguarded. * Physical lock on stainless steel enclosures shall be provided to prevent unauthorized access. * All parts of the machine which move while the machine is in operation shall be suitably safe guarded. The safeguard must prevent hands, arms, and any other part of an operator’s body from making contact with moving parts. * All hot parts shall be suitably guarded / insulated / Warning signs shall be affixed to avoid contact with operator’s body. * The machine shall have minimum vibration. * The machine shall have noise level (NMT 60 dB) within the acceptable limits as per the national / international regulatory standards. * The machine shall have an E-Stop string designed to stop all physical movement of the machinery immediately. The E-Stop buttons shall be located in easily accessible areas around the machine as required by local safety standards. Position of E-stop button to be specified during Design Qualification stage. |
| **11.3** | **Electrical Safety** |
|  | * All the cables coming out from the panel shall be isolated by means of hermetic grommets in order to prevent foreign objects and fluids from entering the panel. * An automatic power switch shall be installed on the door of the electric panel. The power switch shall be provided with required certifications. When tripped, the switch shall disconnect all the electric components of the machine and shall necessarily require the intervention of an operator to reset it to restart the machine. * MCC panel integrated with machine shall be provided with a facility of double earthing. * The MCC panel shall be provided without an exhaust fan for sanitary requirement. |
| **11.4** | **Personal Safety** |
|  | * The machine shall meet the appropriate safety regulations for the safety of operators of equipment with regards to safety, guarding and noise. |

# LIST OF REQUIRED DOCUMENTS

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| One hard copy and one soft copy in English shall be provided for below mentioned documents | |
| **12.1** | **Project Management** |
|  | * Document Control Index (DCI) * Detailed Project Schedule (QPP) * Factory Acceptance Test (FAT) * Site Acceptance Test (SAT) * Installation Qualification (IQ) Plan * Operational Qualification (OQ) Plan * Minutes of Meeting (for all interactions) * Traceability Matrix |
| **12.2** | **Design Documents** |
|  | * Design Qualification DQ – Mechanical Components * Function Design Specification * Hardware Design Specification (HDS) * Software Design Specification (SDS) * Input / Output List (IOL) * Alarm / Inter Lock List (AL) with Risk Assessment & Alarm Categorization * Heat Emission Specifications * Failure Mode and Effect Analysis (FMEA) * Certificates of pressure ratings for the circuit and filter holder shall be provided |
| **12.3** | **Qualification Protocols** |
|  | * Factory Acceptance Test (FAT) Protocol * Site Acceptance Test (SAT) Protocol * Installation Qualification (IQ) Protocol * PLC Validation (PLCV) Protocol * Operational Qualification (OQ) Protocol |
| **12.4** | **Drawings** |
|  | * Mechanic Diagram * General Arrangement Drawing (GAD) – Equipment, MCC Panel, PLC Panel * General Arrangement Drawing (GAD) – Auxiliary / Ancillary Equipment(s) * Assembly Drawings for Various Equipment Components * Power Wiring Drawing – MCC Panel * Control Wiring Drawing – MCC Panel * Control Wiring Drawing (With Terminal Box Details) – PLC Panel * Three Dimensional Drawing - Machine |
| **12.5** | **Manuals / Standard Operating Procedure (SOP)** |
|  | * Installation Manual for Machine * User / Operating Manual for Machine * Maintenance & Troubleshooting Manual for Machine * Installation Manual for MCC Panel * User / Operating Manual for MCC Panel * Maintenance & Troubleshooting Manual for MCC Panel * Installation Manual for IPC * User / Operating Manual for IPC * Maintenance & Troubleshooting Manual for IPC * User / Operating Manual for Auxiliary / Ancillary Equipment(s) * User / Operating Manual for Machine Cleaning * Training Manual for Machine * Software Backup * HMI Operation Training Package Softcopy * Disaster management procedure |
| **12.6** | **Fabrication & Assembly** |
|  | * Material Certificates – Contact & Non-Contact Parts * Calibration Certificates for Auxiliary / Ancillary Equipment(s) * Other Ancillary / Auxiliary Equipment / Bought-out Test Records * Manufacturer’s own Quality System Compliance Certificates / Documents * Declaration of Conformity Certificates for Equipment containing European Community (EC) CE- marked equipment |
| **12.7** | **Lists** |
|  | * Critical and Non-critical Alarm List with Trouble Shooting Guidelines * Critical and Non-critical machine Change Part List * Critical and Non-critical machine Spare Part List * Machine Interlock List * Lubricates List * Valve List * Instrumentation List * Safety Device List * Utility Schedule |
| **12.8** | **Others** |
|  | * Process Failure Mode Effects Analysis (PFMEA) |

# MINIMUM IQ/OQ REQUIREMENT

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| **Installation Qualification (IQ) Requirements** | |
| **13.1** | **Purpose** |
| The purpose of Installation Qualification (IQ) of Equipment’s / Instruments / Utilities / Facility is to ensure that the Equipment’s / Instruments / Utilities / Facility are installed according to the Design Documents, Purchase Specifications, FAT and SAT report. Those parts of the systems, which are disassembled prior to shipping, shall be noted and be verified again after re-assembly at the final site. | |
| **13.2** | **Minimum Acceptance Criteria** |
| Each examined component (equipment, instruments and materials) meets:  a. Check prior documentation for completeness  b. Verify system P&ID as required  c. Verify any system components defined in the protocol  d. Verify utility connections and ensure required utilities as appropriate  e. Verify instrument connections from field to PLC  f. Check connection to peripheral devices (printers, data loggers, etc.)  g. Check manual functionality (all switches, buttons and settings in manual mode)  h. Verify that complete Parts List has been filed in Maintenance Records  i. Verify maintenance and calibration procedures have been approved and filed with Maintenance Department  j. Identify required manuals and vendor prints and location within Engineering or Maintenance Department. Calibrated and supported with documentation of the calibration. | |
| **13.3** | **Required Documents** |
| a. User Manual / Operational Manual / User Guide (as applicable)  b. Maintenance Manual (Service Manual)  c. Electrical Schematics  d. Process and Utility Diagram  e. Installation Order of Components  f. Utility Connections  g. Electrical Connections  h. Spare Parts List  i. Change part List  j. List of Lubricants  k. Installation Layout Drawings  l. Technical Documentation for the Components needed for Operation & Maintenance  m. Documentation to Support Specified Quality of Parts (Example: Materials of Construction) | |
| **13.4** | **Protocol** |
| The protocol for IQ shall address following, but not necessarily limited to:  a. Document Status Verification (URS / DQ / FAT / SAT / PLC Qualification)  b. Instrument Calibration (Instrument available on Equipment)  c. Utility Verification  d. Drawing Verification (P&ID, Schematic, Electrical etc.)  e. Major Component Verification including Operation Panel (PLC & its Software Details)  f. Preventive Maintenance Schedule Entry into the System & Frequency Verification  g. Critical Replacement Parts (Change Parts / Spare Parts) List Availability Verification  Liposome Pharma shall provide the template for protocol creation to vendor. Separate IQ protocol or IQ/OQ combined protocol may be prepared as per the requirement. | |
| **Operational Qualification (OQ) Requirements** | |
| **13.5** | **Purpose** |
| The purpose of Operational Qualification (OQ) is to verify that a system or subsystem performs as intended throughout all anticipated operating ranges. | |
| **13.6** | **Minimum Acceptance Criteria** |
| Each examined component (equipment, instruments and materials) meets:  a. Operate as described in Operations Manual  b. Operate as described in draft Standard Operating Procedures  c. Operate throughout all intended and worst case operating ranges  d. Operate reliably  e. Meet all parameters (such as, flow rates, temperatures, speeds, control sequences)  f. All the challenges shall meet acceptance criteria  g. Safety operation should be checked  h. For PLC which has Real Time Clock, perform PLC Clock Challenge Test.  i. Challenge study for power outage should be performed for applicable critical process Equipment’s  j. Provide the appropriate parameter settings and security levels to control operations as all critical to quality areas. | |
| **13.7** | **Protocol** |
| The protocol for OQ shall address following, but not necessarily limited to:  a. Draft SOP verification against actual planned operations  b. Power Supply challenge test  c. Control Panel verification (Auto / Manual Mode)  d. MMI/HMI Verification — Including all  e. Critical and Non Critical of all process parameters defined during Operation qualification.   * MMI Screen Verification * Test value (Upper Limit and Lower Limit) Verification to assure limits as per protocol. * Test Critical Parameters Upper Limit and Lower Limit challenge test (Qualified range) as per protocol.   f. Power Outage challenge test  g. For PLC which has Real Time Clock, perform PLC Clock Challenge Test  h. Safety / Alarm challenge test (e.g. emergency switch challenge test, Low Compressed air challenge test etc.)  i. Password challenge (including password level) test with their accessibility & wrong password  j. Dummy Run /Auto cycle verification.  k. All the alarm should be covered in Alarm list & in the Printout  Liposome Pharma shall provide the template for protocol creation to vendor. Separate IQ protocol or IQ/OQ combined protocol may be prepared as per the requirement. The IQ should be reviewed and approved prior to OQ beginning. | |