# User Requirement Specifications Process Chromatography System and Chromatography Columns

| Block Code | Area | Identification # | Quantity | Capacity |
|---|---|---|---|---|
| B4 | Rabies Bulk | B4-CMY 01 | 1 | 5 to 120 LPH |

## Table of Contents


**1.0 APPROVAL SIGNATURE ..... 4**

**2.0 EQUIPMENT DESCRIPTION ..... 5**

**3.0 PROCESS DESCRIPTION ..... 8**

3.1 INPUT & CHARGING METHOD ..... 8

3.2 BRIEF PROCESS STEPS ..... 8

3.3 OUTPUT & DISCHARGING METHOD ..... 8

**4.0 PRODUCTIVITY REQUIREMENT ..... 8**

4.1 DESIRED/ SUGGESTED CAPACITY ..... 8

4.2 STANDARD BATCH SIZE ..... 8

4.3 CHANGE OVER TIME ..... 8

4.4 OTHER PRODUCTIVITY REQUIREMENT ..... 9

**5.0 CONTAINMENT ..... 9**

**6.0 GMP REQUIREMENTS ..... 9**

6.1 PROCESS CONTROL ..... 9

6.2 FAILURE MODE DETECTION ..... 10

6.3 IN –PROCESS CONTROL ..... 10

6.4 LEVEL OF INSTRUMENTATION ..... 10

6.5 BATCH DATA DISPLAY AND RECORD PRINTING ..... 11

6.6 GMP REQUIREMENTS (OTHERS) ..... 11

6.7 SPECIFIC REQUIREMENTS ..... 11

6.8 SPARES AND CONSUMABLES FOR SYSTEM AND COLUMNS ..... 12

**7.0 CONSTRAINTS ..... 12**

7.1 EQUIPMENT LOCATION AND AVAILABLE SPACE ..... 12

7.2 AVAILABLE UTILITY ..... 13

**8.0 ABBREVIATION ..... 13**

**9.0 REVISION INDEX ..... 13**

**URS Annexure List:**

| URS Annex No. | Detail |
|---|---|
| 1 | Layout showing location of the installation of the Process Chromatography system and Chromatography columns for Rabies Bulk block |

## 1.0 APPROVAL SIGNATURE

This document is prepared by the Process, Validation and GMP Compliance team of "NNE Pharmaplan India" for the project "Integrated Vaccines Complex, Chengalpattu, Chennai" (project number: 120310) of HLL BIOTECH LIMITED (Chennai) under the authority of their Project Manager. Hence, this document before being effective shall be reviewed by HBL user/s and project/ engineering team, approved by team lead of user department and QA and authorized by the appropriate Project Authority.

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## 2.0 EQUIPMENT DESCRIPTION

The **chromatography system** shall consist of following parts in order to operate as required by the user

| Sl. No. | Parts | Description |
|---|---|---|
| 1. | cGMP compliance | Required |
| 2. | Flow rate | 5 to 120 LPH |
| 3. | Operational temperature | 2°C to 30°C |
| 4. | Operating pressure | Up to 6 bar |
| 5. | MOC of the system tubing | Polypropylene |
| 6. | Size of the flow path (Internal Diameter) | 6 mm |
| 7. | Number of inlets ports required | 4 (Minimum) |
| 8. | Number of outlet ports required | 4 (minimum) |
| 9. | Bubble trap | With provision to bypass, with low level and high level sensors |
| 10. | Provision for CIP inlet and outlet | Required |
| 11. | pH sensor | Pre and Post column pH measurement is required ( pH range: 0 to 14) |
| 12. | Conductivity sensor | Pre and post column conductivity sensors required ( range: 0 to 900 mS/cm) |
| 13. | Air sensor (2 Nos) | 1 No. to be present in the inlet port to detect and stop the motor pump if air bubble is detected and 1 no. after bubble trap. |
| 14. | Pressure sensor | 1 pressure sensor before bubble trap, one before column and 1 post column required. |
| 15. | Sensor for flow rate | Should be of mass flow meter type. |
| 16. | Leak sensor for diaphragm | Required in pump (Vendor to Confirm) |
| 17. | UV | Simultaneous detection of minimum two wavelengths (260nm and 280nm), from single lamp source. Light Source should be mercury free |
| 18. | Temperature sensor | Measurable range: 0 to 100 °C |
| 19. | Port for injection of sample for HETP | A sample inlet provision near column inlet for HETP measurements- required. |
| 20. | Diaphragm Pumps | Multistage-To transfer buffer and sample with minimum to nil pulsation disturbance and shear force to sample. |
| 21. | Valves | To control the flow rate of the process liquids in feeding lines entering the column. |
| 22. | PLC or equivalent control system | To control all the above parameters and operations. Also it should store data of each sample and unit operation. Data retrieval should be possible. Connectivity to a Central SCADA System has to be an integral part of the System. |
| 23. | Product hold up volume<br>a) Bubble trap full<br>b) Bubble trap minimum<br>c) Column outlet to fraction | Should be minimum<br>(Vendor to specify hold up under each condition) |

| | | |
|---|---|---|
| | outlet<br>d) Sample inlet to column inlet | |
| 24. | ASME-BPE Compliance | Required |
| 25. | Accessories | The package should include and supply all required accessories such as (not limited to)connectors, tubings, seals, O-rings, flanges, bolts, nuts, clamps, Allen screws and keys, springs, gaskets and washers to connect the chromatography system to chromatography column and to operate as specified by the user. |

**Column:** Chromatography columns specifications are as under:

| Sl No | Specifications | Requirements for 100mm Column | Requirements for 450mm Column |
|---|---|---|---|
| 1 | MOC of column tube | Glass | Glass |
| 2 | cGMP Compliance | Required | |
| 3 | Column inner diameter | 100 mm | 450 mm |
| 4 | Column tube Height | 500 mm (Minimum) | 500 mm (Minimum) |
| 5 | Number of adaptors | 2 No. (adjustable top adaptor and fixed bottom adaptor) | |
| 6 | Column medium support mesh size | 20±5μ | |
| 7 | MOC of Column medium support mesh | Poly propylene | |
| 8 | Column support stand with lockable wheels and in-built level indicator | Required | |
| 9 | Pressure rating (min) | 7 bar | 2.5 bar |
| 10 | Temperature rating | +2℃ to 30℃ | +2℃ to 30℃ |
| 11 | Graduated volume level marking on Column tube | Required | |
| 12 | 100% compatibility to connect and operate with chromatography system | Required | |
| 13 | Compliance of all product contact polymeric materials with USP class VI tests for in-vivo toxicity and animal origin-free certification | Required | |
| 14 | Accessories | The package should include and supply all sufficient quantities of accessories/spares such as (not limited to) column medium mesh support, connectors, tubings, seals, O-rings, flanges, bolts, nuts, clamps, Allen screws and keys, springs, gaskets and washers to connect the chromatography column to chromatography system and to operate as specified by the user. | |
| 15 | Vendor to provide all necessary accessories along with the column to connect and operate with the supplied chromatography system | | |

**Note: All points of the IRS except the below mentioned would be applicable for the equipment**

- 4.1.11, 4.1.13, 4.1.17
- FDA Guidance for industry- Documentation for sterilization Process Validation
- ANSI/NSF 49-2008, ISO 14664
- 5.4 – Specifications – ((< 0.5µ Ra for filling line and < 0.8µ Ra for lyophiliser) and external surface matte finish (< 1.2µ Ra).

**Note:**

| | |
|---|---|
| I. | This Technical Specification is the basis for an inquiry to a vendor and therefore the basis for the vendor's proposal. |
| II. | The vendor is asked to state in "REMARKS" column with "yes" if the described requirement will be completely fulfilled and with "no" in case the requirement will not or cannot be fulfilled with the proposed equipment. I n case of an deviation a comment must be inserted or enclosed as a separate annexure by referring to the respective URS specification number. |
| III. | The vendor must clearly comment each item of the Technical Specification. The comments must be in English language. If extra cost for necessary options becomes necessary the item must be clearly stated. |
| IV. | In case that the requirement includes a question or request or information from the vendor, the answer / information should be stated in the "REMARKS" column. |
| V. | The final version of this document including the vendor's comments will become basis of a potential purchase order or contract. |
| VI. | The Technical Specification serves to define a summary of all vendor's requirements concerning scope of delivery and services. |
| VII. | The vendor is responsible for technically unobjectionable function of the equipment. This TS is not intended to dictate a technical design to the vendor. If agreed upon with the vendor, the vendor can apply his practically proven design. |
| VIII. | Special Instruction<br>a. If no comments against any specification shall be considered as "NO" and<br>b. If there is no reply / comments against the complete URS by the vendor then it shall be treated as unresponsive / technically non-compliant and rejected. |
| IX. | All the instruments and controls mentioned in the URS(s) are expected to be standard supply and part of your standard equipment model. In case of any deviation or redundancy or additional scope of supply is noticed, vendor is required to obtain clarification from HBL before submitting the quotes. |
| X. | The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HBL before submitting the offers. |
| XI. | Refer document Installation Requirement Specification and Specific Instructions with URS; NPI_120310_IRS_S1_01 |
| XII. | Refer Tender document with URS; NPI_120310_EQP_TD_04 |

| Specifications | Remarks |
|---|---|
| **3.0 PROCESS DESCRIPTION** | |
| **3.1 Input & Charging method** | |
| 3.1.1 The column packing material shall be introduced into the column from the medium container. | |
| 3.1.2 All the column buffers shall be introduced into the packed column through the feeding lines | |
| 3.1.3 The feed shall be introduced into the packed column through the feeding lines from the container | |
| **3.2 Brief Process Steps** | |
| The system is used for separation /purification, buffer exchange, volume reduction etc | |
| **The process chromatography workstation should be designed to control the following steps involved in the chromatography process.** | |
| 3.2.1 CIP of the process chromatography system and column. | |
| 3.2.2 Equilibration of the column according to the designed program. | |
| 3.2.3 Sample loading into the column. | |
| 3.2.4 Elution with the buffer solution and collection of the purified product. | |
| 3.2.5 Product transfer to the collection container for further processing. | |
| 3.2.6 Sanitization and Regeneration of the column. | |
| 3.2.7 Recording of the process data. | |
| **3.3 Output & Discharging method** | |
| 3.3.1 Transfer of the purified product to the respective holding container for next process | |
| **4.0 PRODUCTIVITY REQUIREMENT** | |
| **4.1 Desired/ suggested capacity** | |
| The equipment should be suitable to operate at the flow rate of 5 to 120 litres per hour. | |
| **4.2 Standard batch size** | |
| Not Applicable | |
| **4.3 Change Over Time** | |
| Not Applicable | |

| | |
|---|---|
| **4.4 Other Productivity Requirement** | |
| Not Applicable | |
| **5.0 CONTAINMENT** | |
| The chromatography system and column should be validated as leak proof system to contain its integrity till the end of the process | |
| **6.0 GMP REQUIREMENTS** | |
| **6.1 Process control** | |
| 6.1.1 It must be possible to select the flow direction of the column in a recipe. | |
| 6.1.2 It must be possible to select that the column is bypassed in a recipe. | |
| 6.1.3 It shall be possible to download data/parameters listed below from the PLC to the Chromatography system before start and during the operation:<br>• All Phase activities/ parameters from beginning to end<br>• Program recipes<br>• Alarm acknowledgements<br>• Ready signals | |
| 6.1.4 It shall be possible to upload/download data/parameters listed below between the Chromatography system and the PLC before start and during the operation:<br>• Process values (Flows, Temperature, Pressures, Conductivities, pH)<br>• Alarms / alarm conditions<br>• Status values<br>• Loggings<br>• Calculation of HETP<br>• Calibration of pH & conductivity sensor<br>• Calibration of UV sensor<br>• Handshakes for:<br>- Alarm acknowledgements<br>- Parameter downloads/ uploads<br>- Process activities(start/ stop, loggings) | |
| 6.1.5 It must be possible to stop an ongoing sequence at any time during the cycle and the system must return to the initial stage. | |
| 6.1.6 It must be possible to pause the system and continue from the same point in the sequence when pause is removed. | |
| 6.1.7 The system must have an emergency stop. At restart after an emergency stop the system must start at the same point in the sequence. | |
| 6.1.8 Based on risk assessment, the system must use secure, computer generated, time-stamped audit trails to independently record<br>• Identity of operator entering or confirming critical data.<br>• date and time of operator entries | |
| 6.1.9 The system must be able to record attempts to unauthorized access. | |

6.1.10 Changes in the control recipe must be recorded with date, time and user ID.

## 6.2 Failure mode detection

**Equipment shall be capable to detect the following failure, notify the operator with alarm (0-10% of the specified range of process parameters) and shutdown the process (if it exceeds 10% of the set value):**

a) Operating Temperature

b) Operating Pressure

c) Conductivity

d) pH

e) Flow rate

f) Air bubble

g) Diaphragm failure

h) High pressure in Column inlet and outlet

i) UV

## 6.3 In –Process control

Should have a provision for sampling of product solution in safe condition, by means of a three way valve with a needle valve that can be placed for this purpose at any point from where the sample needs to be drawn.

## 6.4 Level of instrumentation

Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:

| Type of control | Purpose | Instrumentation |
|---|---|---|
| Temperature | To monitor and indicate the product temperature | Temperature sensor with indicator and controller |
| Pressure | To monitor, indicate and control the column working pressure of process chromatography workstation | Pressure sensor with indicator |
| pH (pre and post column) | Monitoring of pH | pH indicator and transmitter |
| Conductivity (Pre-column and post column) | To indicate and monitor throughout the process | Conductivity indicator and transmitter |

| | | | |
|---|---|---|---|
| UV | To indicate and monitor the elution | UV detector | |
| Flow rate | To control the liquid flow into the system and column | Pumps with VFD (variable frequency drive) | |
| Time | Timer control of process and monitoring CIP process | Timer (HMI) | |

### 6.5 Batch data display and record printing

Basic / standard data acquisition to be done by SCADA or equivalent system. This shall be mainly to collect and store the data in industrial PC. Data output should be in non-editable format with print out option.

### 6.6 GMP requirements (Others)

| | | |
|---|---|---|
| 6.6.1 | Vendor to give code numbers for each component | |
| 6.6.2 | All ports/valves/filters and tubing connections shall be sanitary type, in compliance to ASME BPE. | |
| 6.6.3 | All the tubings for CIP, WFI and waste shall be sanitary type, in compliance to ASME BPE. | |

### 6.7 Specific requirements

| | | |
|---|---|---|
| 6.7.1 | The equipment should operate with minimum operator involvement. The equipment control panel must be provided with a Human machine interface based on English language with appropriate number (a minimum of 10 different recipes) of recipe of process parameters. | |
| 6.7.2 | It should also have a PC to operate the system and store the batch documentation generated during the entire process. | |
| 6.7.3 | The equipment should control all critical parameter automatically by using PLC or vendor defined processor located in the control panel of the workstation. Critical process parameters are listed in the preceding sections. | |
| 6.7.4 | Human – machine interface must be used to enter the process details, which should appear in the print out. Print out must provide results of all critical process parameter and failure alarms. | |
| 6.7.5 | Access to all I/O values and system status bits shall be provided through a data communication link. | |
| 6.7.6 | An operator-interface panel shall be provided and mounted on the equipment. This panel shall provide the necessary switches, indicators, devices to operate the equipment. | |
| 6.7.7 | Fully automatic PLC/ PC based operation<br>The chromatography system software supplied should be fully compatible with Windows 7 operating system. | |
| 6.7.8 | The equipment should have provision for running the column in both the ways. (Upward & downward). | |
| 6.7.9 | Should have provision for column selection (connecting two and selecting one column for operation). | |
| 6.7.10 | It shall not be possible to change parameters or process values without logging in locally on the Chromatography System | |

| | | |
|---|---|---|
| 6.7.11 | The system should have a drain point with non return arrangement. | |
| 6.7.12 | Sanitary connectors are recommended for nozzles and valves. | |
| 6.7.13 | The layout must be taken into account while determining the layouts of the system. | |
| 6.7.14 | A proposal of a possible installation layout should be added to the documentation. | |
| 6.7.15 | The manufacturer has to give the clear details on the total weight and the dimensions of the equipment. | |
| 6.7.16 | The heat given off by the unit must be stated (inside the room). | |
| 6.7.17 | The construction of the complete system should be described in the documentation in detail. | |
| 6.7.18 | System to be skid mounted with sufficient clearance above the floor and behind the skid (when placed against the wall) to allow cleaning. | |
| 6.7.19 | All parts (valves, transmitters etc) should be easy to access and facilitate routine maintenance. | |
| 6.7.20 | In-line calibration of pH and conductivity sensors shall be possible. | |
| 6.7.21 | The equipment should be 21 CFR Part 11 compliant. | |
| 6.7.22 | The equipment should have provision to connect to the alternate power supply (UPS). | |
| 6.7.23 | The system and column components should be chemically compatible for the components (exposed to product) 2M sodium chloride, 2M sodium hydroxide and ethanol. | |
| 6.7.24 | Bubble trap should be by-passable with low level and high level sensors. | |
| 6.7.25 | The system should be CIPable. | |
| 6.7.26 | UV lamp should be manageable (i.e on/off) as required by the user during process | |
| 6.7.27 | The chromatography system should be operationally compatible with 100mm, 450 mm and higher columns sizes. | |
| 6.7.28 | Calibration of UV detector should be done automatically and the same should be completed within 15 minutes before sample loading. Alarm and interlock shall be provided if calibration is not done. | |
| 6.7.29 | The chromatography system should be compatible with automatic column packing option | |
| **6.8** | **Spares and consumables for system and columns** | |
| 6.8.1 | Essential Spares for continuous 1 year of operation after warranty period should be provided. | |
| 6.8.2 | Essential consumables/kits for continuous 2 years of operation should be provided. | |
| **7.0** | **CONSTRAINTS** | |
| **7.1** | **Equipment location and available space** | |
| | This equipment will be installed in the Purification Room of Rabies Bulk, IVC Chengalpattu<br>**Equipment Location:** | |

Room number: B4G057
Floor: Ground Floor
Plant: Rabies Bulk Block
Room Area: 68 m2
False ceiling height: 3.0 m
Room temperature: 22±2 °C
Relative Humidity: Not more than 55 %

## 7.2 Available Utility

a) Electricity: Single (220 V) & 3 phase (420 - 440 V) (Report Requirement)
b) Compressed air 6-8 bar (Report Requirement)

## 8.0 ABBREVIATION

| Abbreviation | Definition |
|---|---|
| CIP | Clean in place |
| BPE | Bioprocessing equipment |
| ASME | American Society of Mechanical Engineers |
| CFR | Code of federal regulations |
| DQ | Design Qualification |
| HETP | Height equivalent theoretical plate |
| HMI | Human Machine Interphase |
| LPH | Liter per hour |
| MOC | Material Of Construction |
| NA | Not applicable |
| PLC | Programmable Logic Controller |
| QA | Quality Assurance |
| SCADA | supervisory control and data acquisition |
| SS | Stainless steel |
| UPS | Uninterrupted Power Supply |
| UV | Ultraviolet |
| CMY | Chromatography |

## 9.0 REVISION INDEX

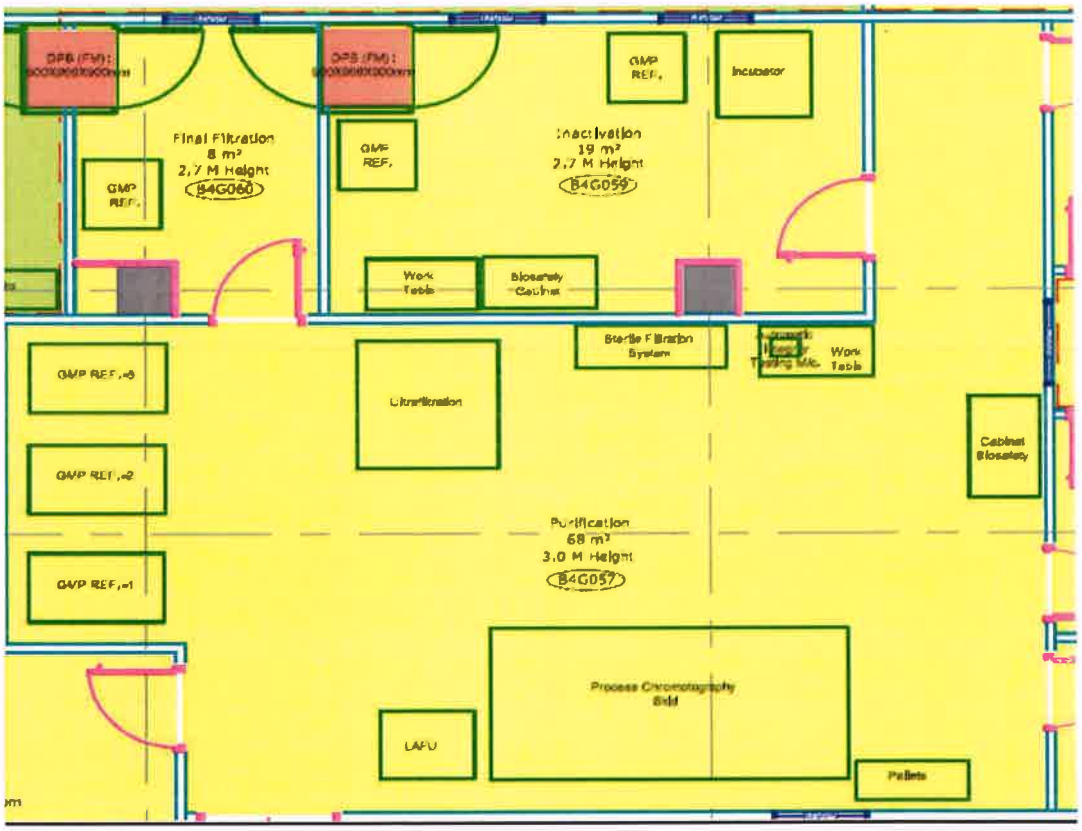
| Revision | Date | Reason for revision |
|---|---|---|
| 00 | 28-02-2014 | First Draft for Client's Review |

| | | | |
|---|---|---|---|
| 01 | 05-03-2014 | Updated as per comments received by HBL through E-mail on 05.03.2014 | |
| | | **Section** | **Revision** |
| | | Approval Signature | Revised and changed |
| | | 2.0 | The chromatography system shall consist of following parts in order to operate as required by the user |
| | | System Specifications: Point 2 | Type of System - Isocratic |
| | | System Specifications: Point 7 | Included: Internal Diameter |
| | | System Specifications:, Point 8 | Changed 8 to 4 |
| | | System Specifications:, Point 9 | Included Minimum |
| | | System Specifications:, Point 12 | Added Post Column |
| | | System Specifications:, Point 13 | And measurement is required- Deleted |
| | | System Specifications:, Point 17 | Added in pump |
| | | System Specifications:, Point 18 | Added Simultaneous detection of minimum two wavelengths from single lamp source |
| | | System Specifications:, Point 18 | Deleted xenon lamp with optic fiber system. |
| | | System Specifications:, Point 23 | Revised PLC or equivalent control system |
| | | | Total minimum holdup volume will be a technically eligible criteria – Deleted |
| | | System Specifications:, Point 24 | Rephrased as: Should be minimum |
| | | Column Specifications, Point 4 | Included: Minimum |
| | | Column Specifications, Point 11 | Calibrated changed to Graduated |
| | | Column Specifications, Point 15 | Rephrased as: Vendor to provide necessary accessories |
| | | 3.1.1 | Deleted: through the designated lines |
| | | 3.1.2 | Deleted via the respective Transfer panel connected to buffer tanks |
| | | 3.1.3 | Rephrased: The feed shall be introduced into the packed column through the feeding lines from the container |
| | | 3.2 | Deleted Gradient |
| | | | Removed Ion Exchange |

| | | | |
|---|---|---|---|
| | | | Chromatography |
| | | 3.2.2 | Deleted: By using different buffers |
| | | 3.2.4 | Deleted: Washing of the column. |
| | | 3.2.5 | With: Included |
| | | 3.3.1 | Deleted: Chromatography |
| | | | Deleted: Further processing |
| | | 4.1 | Deleted: Under gradient mode |
| | | 5.0 | Removed: and Column<br>Included: To contain its integrity till the end of the process |
| | | 6.1.1 | Changed: Of |
| | | 6.1.3 | Changed RP/EP as Reverse Phase and Elution Phase |
| | | 6.2 (h) | Rephrased as: High pressure in the column inlet and outlet |
| | | 6.4 | Deleted: as well the entire and<br>included: of |
| | | | Deleted: To control the formation of gradient as needed.<br>included: to indicate and monitor throughout the process |
| | | | Deleted: To detect sample elution.<br><br>Included: to indicate and monitor the elution |
| | | | Deleted: To control the liquid flow entering the column.<br>Included: into the system and column |
| | | 6.5 | Included: Equivalent system |
| | | 6.7.6 | Deleted: near the equipment |
| | | 6.7.7 | Deleted: The CIP control system can be integrated with the control system of column which shall be an independent system to avoid overlapping of two different operations |
| | | 6.7.11 | Included: Without logging in |
| | | 6.7.13 | Replaced: Tri-clover or novo connectors with Sanitary |
| | | 6.7.16 | Replaced Capacity with Dimensions |
| | | 6.7.28 | The chromatography system should be operationally compatible with 100mm, 450 mm and higher columns sizes. |

| | | | |
|---|---|---|---|
| | | 6.8 | Added 6.8: Spares and consumables |
| | | 6.8.1 | Essential Spares for continuous 1 year of operation after warranty period should be provided. |
| | | 6.8.2 | Essential consumables/kits for continuous 2 years of operation should be provided. |
| 02 | 12-03-2014 | System Specifications: Point 1 (Earlier) | Deleted: Type of system- Isocratic |
| | | System Specifications: Point 7 | Added: Minimum |
| | | System Specifications: Point 11 | Included Pre and Post Column |
| | | System Specifications: Point 12 | Rephrased Conductivity range from 0 to 200 ms/cm to 0 to 900 ms/cm |
| | | System Specifications: Point 17 | Rephrased eco-friendly to mercury free |
| | | System specifications: Point 21 | Deleted: Protein |
| | | Column Specifications, Point 14 | Included: Column medium support mesh |
| | | Column Specifications, Point 14 | Included: Quantity sufficient accessories and spares |
| | | 11 | Changed IRS Reference number |
| | | 6.4 | Rephrased: To monitor, indicate and control the column working pressure of process chromatography workstation |
| | | | pH (pre and post column) |
| | | 6.7.2 | Rephrased: It should also have a PC to operate the system and store the batch documentation generated during the entire process. |
| | | 6.7.28 | Rephrased: Calibration of UV detector should be done automatically and the same should be completed within 15 minutes before sample loading. Alarm and interlock shall be provided if calibration is not done. |
| | | 6.7.29 | Included: The chromatography system should be compatible with automatic column packing option |
| | | 6.8 | Rephrased: Spares and consumables for system and columns |
| | | 8.0 | Deleted DAC |

**URS Annexure 1: LAYOUT POSITION**

**Room No: B4G057:**

**Purification**