User Requirement Specification (URS)

For Dosing pump

Document Code:

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Revision History:

Change from previous version	Date

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2. Purpose and Scope

This specification is intended to cover design, engineering, manufacturing, fabrication and assembly of three skid mounted CHEMICAL DOSING SYSTEMs for following chemicals:

2.1 HCL Dosing System (1 No per unit).

2.1 NaOH Dosing System (1 No per unit).

3. Responsibility

The contractor shall be responsible for providing all material, equipment & services, which are required to fulfil the intent of ensuring operability, maintainability, reliability and complete safety of the complete work covered under this specification,

4. Overview

The Chemical dosing systems are required to dose required quantity of chemicals to maintain the quality of pharmaceutical products in the existing tanks.

5. Operational Requirements

Function specification

5.1 The chemical dosing systems shall be connected to the existing SCADA system.

5.2 Sodium Hydroxide (NaOH) dosing system is provided to dose NaOH solution in preparation Tanks to adjust pH. The dosing is done as per the requirements of the desired pH according to the defined setpoint in the existing SCADA system.

5.3 The dilute solution of NaOH in the NaOH Dosing tank is prepared manually by opening the tank inlet and adding NaOH powder/liquid.

5.4 Hydrochloric acid (HCl) dosing system to dose HCl solution in preparation Tanks to adjust pH. The dosing is done as per the requirements of the desired pH according to the defined setpoint in the existing SCADA system.

5.5 The dilute solution of NaOH in the NaOH Dosing tank is prepared manually by opening the tank inlet and adding NaOH powder/liquid.

5.6 Dosing system shall mainly comprise of the following:

- 5.6.1 SOLUTION PREPARATION TANK for preparing dilute solution
- 5.6.2 Solenoid driven metering pumps (electrically operated, auto stroke adjusted)
- 5.6.3 Level prob
- 5.6.4 Air discharge
- 5.6.5 Foot filter
- 5.6.6 Standby/alarm
- 5.6.7 Suction hose
- 5.6.8 Delivery hose
- 5.6.9 Injection valve

5.7 Protection degree: IP65

Capacity

Capacity of solution tanks in liters:

5.8 The First chemical dosing system in compounding 1 area must have two chemical tanks with capacity of 4 liters.

5.9 The Second chemical dosing system in compounding 2 area must have two chemical tanks with capacity of 4 liters.

5.10 The Third chemical dosing system in holding area must two chemical tanks with capacity of 20 liters.

5.11 The Capacity of pump in the first and second systems: 20 LPH

5.12 The Capacity of pump in the first and second systems: 60 LPH

6. Environment

6.1 Indoor location with dry surfaces and walls

6.2 No direct or indirect exposure to sunlight

6.3 Min. / max. operating temperature between 10°C and 24 °C

6.4 Maximum humidity: 50%

6.5 Utilities:

6.5.1 compressed air 6 bar

7 Constraints

7-1- Milestones and Timelines

The skid filtration systems shall be installed, commissioned and ready for operation till **June 2024**

7-2- Equipment Constraints

The space dedicated to fit one appliance in the Holding room is limited. The approximate space available is 0.5 meter (W) × 0.5 meter (L) × 1 meter(H)

The space dedicated to fit the other two appliances in the compounding rooms is limited. The approximate space available is meter 0.5 (W) × 0.5 meter (L) × 1 meter(H)

7-3- Compatibility and Support

The equipment shall be completed in all respects, comply with GAMP 5 and cGMP standards for clean and verified as being in correct order to enable full process validation to be performed., efficient, safe and secure operation and maintenance and shall have its systems tested

7-4- Availability/Maintenance

The System shall be maintained on a schedule as indicated by the supplier. Supplier is to provide (at minimum) the following maintenance instructions:

7.1.1 A comprehensive recommended maintenance (regular recommended

inspection intervals, wear points, recommended spare parts list)

7.1.2 Supplier shall supply Operation, Installation, Maintenance manuals

8 Lifecycle

8-1- Testing

8.1.1 Functional Design Specification (FDS)

8.1.1 Factory Acceptance Test (FAT)
8.1.2 Commissioning

8.1.4 SAT protocol

8.1.3 Installation Qualification (IQ)
8.1.4 Operational Qualification (OQ)
8.1.5 Gassing Cycle Development (GCD)
8.1.6 Performance Qualification (PQ)

Factory Acceptance Test (FAT) may include but not limited to the following Inspections:

8.1.7 Dimension and layouts
8.1.8 Connection size, orientation, position as drawings
8.1.9 Components and instrumentation as required
8.1.10 Materials and surface finish to the specification
8.1.11 documentation (certificates and drawing)

8-2-Delivery/ Documentation

Supplier should supply the documentation, and the machine test qualifications, including:

8.1.12 Installation drawing,
8.1.13 P&ID,
8.1.14 Electrical wiring diagram,
8.1.15 As Built drawing,
8.1.16 Operating Manual
8.1.17 Maintenance Instructions
8.1.18 Safety Instructions
8.1.19 Comprehensive recommended spares parts list.
8.1.20 FAT Protocol
8.1.21 SAT Protocol
8.1.22 Design qualification
8.1.23 Installation qualification documents
8.1.24 Operational qualification documents
8.1.25 Calibration certificates
8.1.26 Alarm list
8.1.27 Component list
8.1.28 Parts List / Mechanical and Electrical

8-3- Support and training

Training course should be performed by manufacturer on site

9 References

9.1 USP 43

9.2 PICs

10 Definitions, Acronyms and Abbreviations

DQ = Design Qualification

FAT = Factory Acceptance Test

USP = United States Pharmacopoeia

HMI = Human-Machine Interface

P&ID = Piping and Instrumentation Diagram

cGMP = Current Good Manufacturing Practice

IQ = Installation Qualification

OQ = Operational Qualification

SAT = Site Acceptance Test

PICS = Pharmaceutical Inspection Co-operation Scheme

11 Document Distribution

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