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User Requirement Specification		


User Requirement Specification: Ultrapure and pure water system

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1. Introduction

1.1 Objective

This document describes the characteristics of the Ultrapure and pure water system as part of the SinaDarou's laboratory equipment. The overall objective for this document is to design and demonstrate a system matching the needs of SinaDarou company.

The overall objective of Ultrapure water system is:

1. to delivering superior quality type 1 and type 2 water directly from a tap water source;
2. to produce water up to 300l/day

1.2 Scope


This Technical Requirements Document outlines the functional, performance and other system requirements compliance to the requirements of SinaDarou company.

The URS details the following requirement types:

- System description
- compliance requirements
- process and operational requirements
- pricing
- suppliers

2. System description


Ref.	System description
2.1 System description	
U1.	<p>The system shall provide a water treatment system, fully piped, wired, instrumented, and tested, consisting of the following as a minimum:</p> <ul style="list-style-type: none"> • Pretreatment: For removal of colloids, particles, free chlorine and minerals. • Advanced reverse osmosis(RO): for removal of 95-99% of contaminations including ions, particles, bacteria and organic molecules(MV>200KDa) and to ensure constant flowrate • EDI module: to remove remaining ions for consistently superior quality pure water • Pure water storage tank • UV lamp • Dispenser • TOC meter • Flow controller • Conductivity cell

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U2.	<p>The system shall provide the following steps for protection of stored pure water:</p> <ul style="list-style-type: none"> • Prior to water production, automatic rinsing of the RO membrane and EDI module to ensures that only the highest quality pure water enters the tank • Within the tank, pure water quality shall preserve by two built in features: <ol style="list-style-type: none"> 1. vent filter that provides improved protection against airborne contamination 2. automatic sanitization module(ASM), with an integrated mercury free UVC LED lamp emitting at 265nm, regularly irradiates stored water and tank walls, preventing bacterial growth and biofilm formation • automatic recirculation of stored water through a bacterial UV lamp preserves water quality in the tank and ensures that water is always on hand and ready to use.
2.1.1 Process configuration	
U3.	<p>The ultrapure system shall combine excellent performance with first class materials, economical consumption, safety and easy operations. Refer to attachment for production flow schematic</p>

3. Requirements


Ref.	Requirements
3.1 compliance requirements	
U4.	The equipment shall be completed in all respects, comply with GAMP and cGMP standards for clean, efficient, safe and secure operation and maintenance and shall have its systems tested and verified as being in correct order to enable full process validation to be performed.
3.2 process and operational requirements	
3.2.1 Capacity	
U5.	Capacity: 300 liter per day
3.2.2 General	
U6.	<p>Supplier should supply the documentation, and the machine test qualifications, including:</p> <ul style="list-style-type: none"> • Installation drawing, • P&ID, • Electrical wiring diagram, • As Built drawing, • Operating Manual • Maintenance Instructions • Safety Instructions • Comprehensive recommended spares parts list. • FAT Protocol • SAT Protocol

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	<ul style="list-style-type: none"> • Design qualification • Installation qualification documents • Operational qualification documents •
U7.	<ul style="list-style-type: none"> • Factory Acceptance Test (FAT) is performed at the supplier site prior to shipping. • Site Acceptance Test (SAT) is performed at the manufacturer site to be witnessed by manufacturer staff. • The supplier has to specify and document the outline and program of the instruction training for the operating and technical personnel.
3.2.3 Ultrapure, type 1 water specification	
U8.	<ul style="list-style-type: none"> • Resistivity at 25 °C 18.2 MΩ·cm • Conductivity at 25 °C 0.055 μS/cm • TOC ≤2 ppb (μg/L)³; typically ≤5 ppb • Particles⁴ No particles with size >0.22 μm • Bacteria⁵ <0.01 CFU/mL • Pyrogens (endotoxins)⁶ <0.001 EU/mL • RNases⁷ <1 pg/mL • DNases⁷ <5 pg/mL • Proteases⁷ <0.15 μg/mL • Flow rate Up to 2 L/min
3.2.4 Pure, Type 2 water specifications	
U9.	<ul style="list-style-type: none"> • Resistivity at 25 °C >5 MΩ·cm; typically, 10–15 MΩ·cm • Conductivity at 25 °C 0.2 μS/cm; typically, 0.1 μS/cm • TOC ≤30 ppb • Production flow rate 3 L/h (Milli-Q® IQ 7003) • 5 L/h (Milli-Q® IQ 7005) • 10 L/h (Milli-Q® IQ 7010) • 15 L/h (Milli-Q® IQ 7015)
3.3 Feed water requirements-	
U9.	<ul style="list-style-type: none"> • Feed water: potable tap water • Pressure 1-6 bar • Temperature, 5-35°C • Conductivity <2000 μS/cm at 25 °C • Dissolved CO₂ <30 ppm • Free chlorine <3 ppm • Fouling Index <10 • pH 4–10 • Total Organic Carbon (TOC) <1 ppm • Langelier Saturation Index (LSI) <0.3 • Hardness (as CaCO₃) <300 ppm • Silica <30 ppm
4. Pricing	
U10.	The water system price is EUR 10,460.00

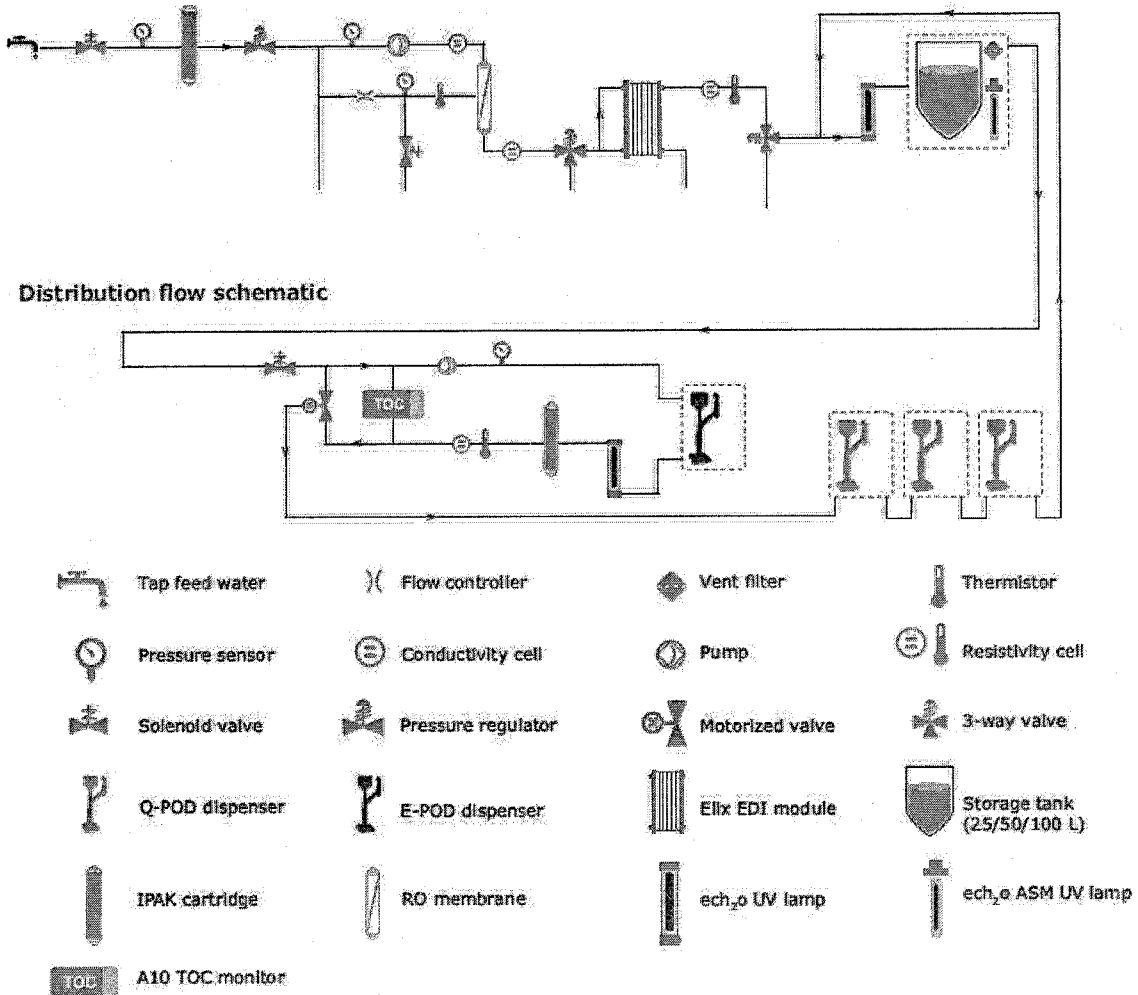
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5. Suppliers	
U11.	<p>The Recommended suppliers are as follows:</p> <ul style="list-style-type: none"> • Milli-Q IQ 7003/7005/7010/7015 ultrapure water purification system from MerckMillipore • Kimia goostar pooyesh

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6. Attachment

the production flow schematic is as following:



Picture1- production flow schematic