USER REQUIREMENT SPECIFICATION

Name of Item: Demineralized Water Generation System	**Protocol No.:**.....
Functional Area: Quality Control	**Page No.**: 1 of 3

1.0 **Purpose:** To describe the specific requirement of Demineralized Water Generation System.

2.0 **Scope:** This specification is applicable to the Demineralized Water Generation System to be installed at quality control laboratory.

3.0 **System Description:** Soft water shall be used for preparation of demineralized water. The soft water shall be obtained from water treatment plant used for generation of purified water. Raw water shall be filtered through Dual Media Filter (DMF). After pretreatment with chemicals and filtration systems the soft water shall be generated where Calcium and Magnesium ions shall be replaced with Sodium ions. This soft water shall act as the input for generation of demineralized water system. The demineralized water generation system is required for preparation of general use reagents and washing and final rinse of all the glassware used in analytical and microbiological activities. The quality of demineralized water shall comply with defined specification as per annwexure-1. The demineralized water generation system shall be considered based on the following minimum specifications.

3.1 MOC should be consistent throughout distribution, storage and processing system. All the components should be of suitable make so as to obtain the water of desired quality consistently. The complete unit shall consist of corrosion resistant material. Valves design should be such that it will not support microbial growth (Zero Dead leg valve).

3.2 This plant should consist of suitable mechanism for removal of charged particles. The plant should be fully automatic or semi automatic with respect to generation and regeneration cycle.

3.3 It should be easy to operate/ use and with minimum regeneration time.

3.4 It should be operational at 1.5 to 2.5 Kg/cm^2 g pressure.

3.5 The plant should be designed for 200-250 ltrs/ hr generation of demineralized water.

3.6 It should consist of panel for controlling the water generation system. It should consist of multi valve control block.

3.7 The system should be provided with regeneration containers.

3.8 It should be equipped with conductivity measuring device.

3.9 It should be mounted on a stand for easy transport from one place to the other.

4.0 Documentation: Supplier/Manufacturer shall provide the following document.

- P & I diagram.
- Calibration certificates for all gauges or measuring devices with trace-ability.
- Test and guarantee certificates.
- Qualification (DQ, IQ, OQ) documentation
- Individual part certificates.
- Operation manual.

5.0 Other Considerations:

- Line should be slopped to permit free drainage.
- Ensuring no leaks in the system.
- Distribution system should permit sanitation.
- Tubing and piping welds must have smooth internal diameter contour without excessive concavity or convexity, bead wandering, misalignment, porosity and discoloration.

Prepared By:
Date:

Approved By:
Date:

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Annexure-1

S.No.	Test	Specification
1.	Description	A Clear colourless, odourless tasteless liquid
2.	pH (at 25°C)	5.0 to 7.0
3.	Conductivity (at 25°C)	NMT 10 µs at 25 C.
4.	Acidity/Alkalinity	The solution is not red & blue coloured.
5.	Calcium & Magnesium	A pure blue colour is produced.
6.	Chloride	The solution does not show any white precipitate.
7.	Sulphate	The solutions show no change in appearance for atleast 1 hour.
8.	Nitrates	NMT 0.2 ppm
9.	Ammonium	The solution is not more intensely colored then standard sol'n.
10.	Heavy Metals	NMT 0.1 ppm
11.	Oxidisable substances	The solution remains faintly pink.
12.	Residue on Evaporation	NMT 0.001%w/v.
13.	Total Bacterial count	Alert : 60 cfu/ml Action : 80 cfu/ml Maximum :NMT 100 cfu/ml
14.	Fungal count	NMT 10 cfu/ml
15.	Pathogens (*E. coli, Salmonella, S. aureus, Pseudomonas aruginosa*)	Should be Absent

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