



USER REQUIREMENT SPECIFICATION

Name of Item: HPLC Grade Water Generation System	Protocol No.:
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1.0 Purpose: To describe the specific requirement of HPLC grade Water generation System.

2.0 Scope: This specification is applicable to the HPLC grade Water generation System to be installed at Quality Control laboratory.

3.0 System Description: HPLC grade water shall be used in the analysis of samples on the high pressure liquid chromatograph system. Special grade of water is required which is free from all the impurities, ions etc. for operation of the high pressure liquid chromatographic system. If the water used is of low quality, it could damage the analytical column. The column, where separation takes place is the heart of the liquid chromatograph. Low quality water can generate extraneous peaks which could interfere with the analysis and to investigate the origin of the peaks, as per the regulatory authorities, shall lead to wastage of numerous manpower hours and permanent damage to the sophisticated system. Various problems encountered during the analysis of the chromatographic samples due to poor quality of water are:

1. Irregular baseline due to organic presence
2. Decreased sensitivity due to presence of organic compounds. This is due to competition of the compound with the organic compound already present in the mobile phase for binding on the column for separation.
3. Decrease in resolution time resulting in shorter column life.
4. Some charged organic compounds lead to formation of complex which gets bind to the column and shortens the life.
5. Presences of inorganic compounds in the mobile phase lead to tailing of the peak.
6. Some organic compounds act as nutrient and therefore, can enhance growth in the sample.

The HPLC grade water shall be used for



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- a. Buffer preparation used in liquid chromatography
- b. Diluent for sample preparation
- c. Preparation of chemical solutions for titrations and spectrophotometric analysis.
- d. Microbiological media preparation.

Based on the above listed requirements and usage a system is required to generate a good quality of water. The system shall be considered based on the following minimum requirements. Additional features shall also be considered.

- 3.1** The system should be of compact size as per the space constraint. It should be such that it could be installed on a bench or can be mounted on the wall.
 - 3.2** It should have the display for the critical parameters. The quality of water generated shall be as per the Annexure-1.
 - 3.3** It should be easy to operate/ use.
 - 3.4** It should have the provision for built in system for killing of the microorganism.
 - 3.5** It should have the provision for attachment to the direct tap water. However in routine use the system shall be connected to demineralized water system or soft water.
 - 3.6** The required flow rate should be 2-3ltrs of water per hour.
 - 3.7** The system should have low running cost on day to day basis.
- 4.0 Documentation:** Supplier/Manufacturer shall provide the following document.
- Calibration certificates for all gauges or measuring devices with trace-ability.
 - Test and guarantee certificates.



PHARMA DEVILS
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- Qualification (DQ, IQ, OQ) documentation
- Operation manual

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)	< 18.2 mega ohm at 25°C.
4.	Oxidisable substances	The solution remains faintly pink.
5.	Total Bacterial count	NMT 1 cfu/ml

Prepared By:
Date:

Approved By:
Date: