USER REQUIREMENT SPECIFICATION OF PURIFIED WATER GENERATION SYSTEM

USER REQUIREMENT SPECIFICATION

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1.0	**SYSTEM/EQUIPMENT REQUIREMENT**
1.1	Name of the Equipment/System.
	Purified Water Generation System.
1.2	Purpose of the Equipment/System/facility.
	To produce Purified Water with RO Technology
1.3	Number of equipment/system required.
	01
1.4	Process Description and schematic flow diagram
	Attached as Annexure-I
1.5	Chemical/Physical Characteristics of the process materials.
.	Purified water as per USP-34
1.6	Suggested temperature and RH.
	Ambient
1.7	Language requirements. (Specify such as English, Bilingual/Others)
	English
1.8	Any other Specific Requirement
	NA

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2.0	**OPERATIONAL REQUIREMENTS**
2.1	Production stage at which the equipment/System required.
	Equipment Washing & For manufacturing
2.2	Material inputs to the equipment/system.
	Soft water
2.3	Desired outcome from the equipment/system.
	PW water (For referance specification attached)
2.4	Desirable material charging/loading method into the equipment/system.
	By Pumping
2.5	Expected operational hours per day.
	24 Hrs
2.6	Preferable method of cleaning (Specify CIP/COP/Manual).
	CIP
2.7	Recommended cleaning &/or sanitization agent and its chemical nature.
	Hot water
2.8	Required utilities.
	Steam, Electricity, Air, Soft water
2.9	Process control requirements.
	UV Lamp & conductivity meter
2.10	Stages of Filtration
	MGF → Softener → Ultra Filtration → RO → EDI → UV
2.11	Dosing
	NaoCl Dosing/NaOH Dosing/Sodium Hexametaphosphate/Sodium Metabisulphite

2.10	Desired level of instrumentation.

Type of Control	**Purpose**	**Operation Range**	**Desired Least Count**	**Extent of instrumentation**		
				Indication	**Control**	**Recording**
-	-	-	-	-	-	-
-	-	-	-	-	-	-

2.12	Change over parts requirement.
NA	
2.13	Attachment/connectivity with other equipment's.
Purified Water Storage tank	
2.14	Specification of the room for equipment/system installation (Specify such as layout, available volume, class etc.)
Room Layout attached as Annexure- II	
2.15	Any other specific requirements.
NA	
3.0	**GMP REQUIREMENTS**
3.1	NA
3.2	Working area environmental requirement.
Ambient	
3.3	Desired means for avoiding contamination & cross contamination of the Product (s).
. NA	
3.4	Power failure and recovery (Specify the requirements in case of power failure).

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	NA
3.5	Interfaces (Specify such as interface with supervisors & operators, other systems, equipment etc.).
	HMI
3.6	Data collection (Specify the requirements for recorder, process printout, electronic process printout etc).
	Not required
3.7	Any other specific GMP requirement
	Contact parts shall be of SS 316L having mirror polishing. All joints shall be TIG orbital
4.0	**SAFETY REQUIREMENTS**
4.1	Proper Earthing provision
5.0	**DOCUMENTATION REQUIREMENTS**
5.1	Desired Documents.
DQ, Operating manual, IQ/OQ, Drawing & certificates	
5.2	Any other specific requirement.
6.0	**REFERENCES**

7.0 APPROVAL

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Function	Name	Department	Signature	Date
Prepared by		**User department**		
Reviewed by		**Projects / Engineering**		
Reviewed by		**Quality Assurance**		
Approved by		**Quality Assurance**		