RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR INSTRUMENTS OF PURIFIED WATER, WATER FOR INJECTION & PURE STEAM GENERATION SYSTEM

DATE OF RISK ANALYSIS	
SUPERSEDE PROTOCOL CUM REPORT No.	**NIL**

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PROTOCOL CUM REPORT CONTENTS

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR INSTRUMENTS OF PURIFIED WATER, WATER FOR INJECTION & PURE STEAM GENERATION SYSTEM

1.0 PROTOCOL CUM REPORT APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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2.0 OBJECTIVE:

- To provide documented evidence that there is little risk in case of instruments malfunctioning attached with Purified Water Generation & Distribution System, Water for Injection Generation & Distribution System, Pure Steam Generation & Distribution System.

3.0 SCOPE:

- This risk analysis study Protocol cum Report is applicable for performing risk analysis study for instruments attached with Purified Water Generation & Distribution System, Water for Injection Generation & Distribution System, Pure Steam Generation & Distribution System.

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4.0 RESPONSIBILITY:

Department	Responsibility
Quality Assurance	• Shall prepare & review the Risk analysis Protocol cum Report. • Execution of the Risk analysis Protocol cum Report with Production Quality Control and Engineering. • Shall compile the data & prepare summary report • Risk analysis Protocol cum Report shall be approved by the QA prior the execution. • Shall review the executed Protocol cum Report to check the compliance and corrective action for any discrepancies found. Also shall prepare the summary and conclusion of the Risk analysis Study.
Engineering	• Reviewing of Risk analysis Protocol cum Report for correctness, completeness and technical excellence. • To provide support for execution of Risk analysis Study as per Protocol cum Report. • Post approval of Risk analysis Protocol cum Report after execution.

5.0 REASON FOR RISK ANALYSIS:

- To evaluate the risk related with instruments of Purified Water Generation & Distribution System, Water for Injection Generation & Distribution System, Pure Steam Generation & Distribution System.

6.0 SITE OF STUDY:

Purified Water Generation & Distribution Systems installed at Q Block & Water for Injection & Pure Steam Generation system installed.

7.0 RISK COMMUNICATION & TRAINING:

- The Risk analysis team shall be authorized by Head-QA or his/her designee.
- Quality Risk Management Team shall be cross functional team comprised of expert from different areas such as QA and Engineering.
- Training shall be imparted to the team members before execution of Protocol cum Report for proper understanding of the procedure. Training shall be recorded in Training attendance Record.

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7.1 TRAINING OF EXECUTION TEAM:

S.No.	Name of Trainee	Department	Designation	Signature of Trainee	Checked by QA (Sign & Date)
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					

Name of the Trainer: _____

Inference:

_____

_____

_____

_____

_____

_____

Reviewed By_____
Manager QA
(Sign & Date)

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8.0 RISK IDENTIFICATION & EVALUATION:

There are different instruments attached with water system which helps in operation of equipment, these instruments are helpful in providing data at each stage, for the proper working these instruments are regularly calibrated by the external agency, this Calibration of the instruments is a scheduled activity. Calibration is done to check the efficiency of the instruments attached with the equipment, as after a period of time the instruments efficiency may drop down. There are 235 number of instruments related to utility, which are calibrated on yearly basis. Instruments are calibrated by the vendors approved by CQA. As per the calibration planner SOP, the calibration shall be done within ±1 month from the scheduled date. Risk shall be identified if Instrument gets malfunctioned. For that, all instruments shall be identified along with their role & risk.

Following are the instruments:

S.No.	Instruments Name	Identification No.	Location	Role of Instrument	Risk Identification
1.	**Pressure Gauge**		CIP tank	Check circulation pressure during sanitization of the generation system.	Pressure shall be maintained for flow continuity during sanitization of generation system.
2.	**Temperature Sensor**		CIP Tank	Verify temperature during sanitization.	Any increase or decrease in temperature during sanitization may impact the microbial load.
3.	**Pressure Gauge**		Hydro Pure Tank	Check the steam pressure in tank during sanitization.	Pressure shall be monitored during filling and emptying of water storage tank, if any malfunction occurs, it may results into collapse or explode of the storage tank
4.	**Pressure Gauge**		TSA Tank	Check the steam pressure in tank during sanitization.	
5.	**Temperature Sensor**		Hydro Pure Tank	Verify temperature inside the tank	Temperature during sanitization shall be NLT 85°C, if goes below the limit, might result into microbial growth.
6.	**Temperature Sensor**			Verify return line temperature	Same is the case with return line temperature; it shall be maintained above 85°C that shall be monitored regularly.
7.	**Compound Gauge**			Verify pressure of tank	Pressure shall be monitored during filling and emptying of water storage tank, if any malfunction occurs, it may results into collapse or explode of the storage tank
8.	**Compound Gauge**		TSA Tank	Verify pressure of tank	Pressure shall be monitored during filling and

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S.No.	Instruments Name	Identification No.	Location	Role of Instrument	Risk Identification
					emptying of water storage tank, if any malfunction occurs, it may results into collapse or explode of the storage tank
9.	**Pressure Gauge**		MFG Outlet	Verifies outlet required pressure of MGF	Outlet MGF pressure shall be between 1.0 to 2.5 kg.cm^2, if pressure crosses the limit it means either MGF sand got degraded and need to be changed or it got choked & need to be back flushed.
10.	**Pressure Switch**		MFG Inlet	Verifies inlet required pressure for MGF	Inlet pressure required for MGF shall be between 1.0 to 2.5 kg/cm^2, if pressure is out of limit, means there is some issue with the flow rate and might be water pump is not working properly.
11.	**Pressure Gauge**		MGF Inlet	Verifies inlet required pressure of MGF	
12.	**Pressure Gauge**		Softener Inlet	Monitor inlet required pressure of Softener	Softener inlet pressure out of limit will results into improper release of Na^+ which further will not be able to replace by Mg^+ & Ca^+ result into hard water production.
13.	**Digital Flow Meter Cum Totalizer**		Softener Outlet	Verifies outlet water flow	Outlet water flow needed (4.0-5.0 m^3/hr) for softener shall be within the limit, if not may result into decrease in output required for Ultrafiltration.
14.	**Pressure Gauge**		Softener Outlet	Verifies outlet required pressure of Softener	Pressure required (0-2.0 kg/cm^2) to maintained outlet flow.
15.	**Pressure Gauge**		UF Cartridge Filter Inlet	Verifies differential pressure of inlet of UF cartridge	If required pressure (0.5-1.5 kg/cm^2) is not maintained, than outlet flow rate will decrease resulting into low output. Further a particular pressure is required from softener to pass the soft water through 150 µ Cartridge filter.
16.	**Pressure Gauge**		UF Cartridge Filter Outlet	Verifies differential pressure of outlet of UF cartridge	If outlet pressure of cartridge filter is less than it means that cartridge filter is choked and need to be cleaned.
17.	**Pressure Gauge**		UF Outlet	Verifies outlet pressure of Ultra filtration	If outlet pressure of water is less than it means that Ultrafiltration is choked and need to be

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S.No.	Instruments Name	Identification No.	Location	Role of Instrument	Risk Identification
					backwashed.
18.	**Pressure Gauge**		UF Backwash	Verifies pressure of line during the backwash	Backwash pressure is must to clean the Ultrafiltration system.
19.	**Pressure gauge**		UF Inlet	Verifies inlet pressure	Inlet pressure is required to pass the soft water through 0.003 µ UF system.
20.	**Pressure gauge**		RO Cartridge Filter Inlet	Verifies differential pressure of RO filter inlet	Differential Pressure out of limit may result into rupture or choking of RO membrane (0.0001µ)
21.	**Pressure gauge**		RO Cartridge Filter outlet	Verifies differential pressure of RO filter outlet	
22.	**pH Meter**		Before RO	Verifies pH of the incoming water	pH shall be within the limit (7-9) if crosses may results into damage of RO membrane
23.	**Pressure Switch**		RO I (LPS)	Verifies pressure during inlet of RO I	Water pressure may increase or decrease resulting into rupture or choking of RO membrane
24.	**Pressure Switch**		RO I (HPS)	Verifies pressure during inlet of RO I	
25.	**Pressure Switch**		RO inlet-II	Verifies pressure during inlet of RO II	
26.	**Pressure Switch**		RO II Inlet	Verifies pressure during inlet of RO II	
27.	**Pressure Gauge**		RO Circulation	Verifies water pressure during circulation	
28.	**Pressure Gauge**		RO I Outlet	Verifies pressure during Outlet of RO I	
29.	**Pressure Gauge**		RO II Outlet	Verifies pressure during Outlet of RO II	
30.	**Pressure Gauge**		RO II Outlet	Verifies pressure during Outlet of RO II	
31.	**Pressure Gauge**		RO I Inlet	Verifies pressure during Inlet of RO I	
32.	**Pressure Switch**		EDI Inlet	Verifies pressure during EDI inlet	If pressure not regulated, it may damage EDI ion exchanger
33.	**Pressure Gauge**				
34.	**Pressure Gauge**		Compressed Air	Regulates pressure	Compressed air is used to regulate pneumatic valves, any fluctuation in air flow may leads to hampering of operational activities
35.	**Pressure Gauge**				
36.	**UV Monitor**		Loop I	Regulates microbial count	Any malfunction in UV may leads to increase in microbial load

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S.No.	Instruments Name	Identification No.	Location	Role of Instrument	Risk Identification
37.	**Temperature Sensor**		Loop I	Monitor temperature during sanitization	Decrease in temperature may leads to increase in microbial load in distribution line
38.	**Flow Meter**		Loop II	Verifies water flow	Flow shall be maintained to avoid stagnancy & for total output
39.	**UV Monitor**		Loop II	Controls microbial count	Any malfunction in UV may leads to increase in microbial load
40.	**Temperature Sensor**		Loop II	Verifies temperature during sanitization	Decrease in temperature may leads to increase in microbial load in distribution line
41.	**Pressure Gauge**		Loop II (Inlet)	Monitor pressure of inlet	Pressure is required to maintain the water flow, if not, it may result into stagnant of water resulting of increase in bio-load.
42.	**Pressure Gauge**		Loop II (Outlet)	Monitor pressure of outlet	Outlet pressure is required to avoid stagnancy & to maintain flow rate for output
43.	**Flow Meter**		Loop III	Monitor water flow	Flow rate shall be NLT 1.2 m^3/hr.
44.	**Pressure Gauge**		Loop III (Inlet)	Monitor pressure of inlet	Pressure is required to maintain the water flow, if not, it may result into stagnant of water resulting of increase in bio-load.
45.	**Pressure Gauge**		Loop III (Outlet)	Monitor pressure of outlet	Outlet pressure is required to avoid stagnancy & to maintain flow rate for output
46.	**Temperature Sensor**		Loop III	Verifies temperature during sanitization	Decrease in temperature may leads to increase in microbial load in distribution line
47.	**UV Monitor**		EDI Outlet	Control's microbial count	Any malfunction in UV may leads to increase in microbial load
48.	**UV Monitor**		Loop III		
49.	**Conductivity Sensor**		After RO Pass-I	Verifies conductivity after RO I	Increased Conductivity may leads to RO membrane damage
50.	**Conductivity Sensor**		EDI	Verifies conductivity after EDI	Increased conductivity results into failure of product
51.	**Conductivity Sensor**		After RO Pass-II	Verifies Conductivity after RO II	Increased conductivity results into failure of product
52.	**Conductivity Sensor**		Loop-1	Verifies Conductivity of return Loop 1	
53.	**Conductivity Sensor**		Loop-2	Verifies Conductivity of return Loop 2	
54.	**Conductivity Sensor**		Loop-3	Verifies Conductivity of return Loop 3	

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S.No.	Instruments Name	Identification No.	Location	Role of Instrument	Risk Identification
55.	**NaOCl Dosing pump**		Q-Block	Control's NaOCl Dosing	Fluctuation in Chlorine dosing may increase microbial growth
56.	**SMBS Dosing pump**		Q-Block	Control's SMBS Dosing	Fluctuation in Sodium Metabisulphite dosing may result into excess Chlorine which may damage RO membrane
57.	**ADS Dosing pump**		Q-Block	Control's ADS Dosing	Fluctuation in Anti-de-scalant dosing may result into scaling in RO membrane which damages the RO membrane
58.	**NaOH Dosing pump**		Q-Block	Control's NaOH Dosing	Fluctuation in NaOH dosing may increase pH resulting into RO membrane damage
59.	**ORP Meter**		Q-Block	Control's Oxidation Reduction Potential	Malfunctioning of ORP meter may increase chlorine level resulting into damage of RO membrane
60.	**Compound Gauge**		Purified Water Tank	Verifies pressure of the tank	Pressure shall be monitored during filling and emptying of water storage tank, if any malfunction occurs, it may results into collapse or explode of the storage tank
61.	**Flow Meter**		Loop 5 (Generation System)	Monitor flow of the distribution loop	Flow shall be maintained to avoid stagnancy & for total output
62.	**Flow Transmitter**		Loop 4 (Generation System)	Measure flow of the distribution loop	Without measurement flow cannot be identified
63.	**Temperature Sensor**		Distribution System (Loop 6)	Measure temperature of the distribution loop	Temperature during sanitization shall be NLT 85°C, if goes below the limit, might result into microbial growth.
64.	**Temperature Sensor**		Distribution System (Loop 5)		Temperature during sanitization shall be NLT 85°C, if goes below the limit, might result into microbial growth.
65.	**Temperature Sensor**		Distribution System (Loop 4)		Temperature during sanitization shall be NLT 85°C, if goes below the limit, might result into microbial growth.
66.	**Pressure Gauge**		Distribution System (Loop 6)	Measure pressure of the flow in distribution loop	Outlet pressure is required to avoid stagnancy & to maintain flow rate for output
67.	**Pressure Gauge**		Distribution System		Outlet pressure is required to avoid stagnancy

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S.No.	Instruments Name	Identification No.	Location	Role of Instrument	Risk Identification
			(Loop 6)		& to maintain flow rate for output
68.	**Pressure Gauge**		Purified Water Tank (3000 ltr.)		Pressure shall be monitored during filling and emptying of water storage tank, if any malfunction occurs, it may results into collapse or explode of the storage tank
69.	**Digital Pressure Gauge**		Distribution System (Loop 5)		Outlet pressure is required to avoid stagnancy & to maintain flow rate for output
70.	**Pressure Gauge**				
71.	**Pressure Gauge**				
72.	**Pressure Gauge**		Generation System (5 kl)		Outlet pressure is required to avoid stagnancy & to maintain flow rate for output
73.	**Pressure Gauge**		Distribution System (Loop 4)		
74.	**Pressure Gauge**				
75.	**Pressure Gauge**		RO System	Measure pressure differential of RO System	Water pressure may increase or decrease resulting into rupture or choking of RO membrane
76.	**Pressure Gauge**				
77.	**Pressure Gauge**				
78.	**Pressure Gauge**				
79.	**Pressure Gauge**				
80.	**Pressure Gauge**				
81.	**Pressure Gauge**				
82.	**Pressure Gauge**				
83.	**Pressure Gauge**				
84.	**Pressure Gauge**				
85.	**Pressure Gauge**		Ultra Filtration System	Measures differential pressure of the UF system	Water pressure may increase or decrease resulting into rupture or choking of UF membrane
86.	**Pressure Gauge**				
87.	**Pressure Gauge**				
88.	**Pressure Gauge**				
89.	**Pressure Gauge**				
90.	**Pressure Gauge**		Softener 1st	Verifies inlet pressure of the Softener	Softener inlet pressure out of limit will results into improper release of Na^+ which further will

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S.No.	Instruments Name	Identification No.	Location	Role of Instrument	Risk Identification
					not be able to replace by Mg^{+} & Ca^{+} result into hard water production.
91.	**Pressure Gauge**		Softener 2nd	Verifies outlet pressure of the Softener	Outlet water flow needed (4.0-5.0 m^3/hr) for softener shall be within the limit, if not may result into decrease in output required for Ultrafiltration.
92.	**Pressure Gauge**		Multi-grade Filter	Verifies inlet pressure of the Multi grade filter	Inlet pressure required for MGF shall be between 1.0 to 2.5 kg/cm^2, if pressure is out of limit, means there is some issue with the flow rate and might be water pump is not working properly.
93.	**Pressure Gauge**			Verifies outlet pressure of the Multi grade filter	Outlet MGF pressure shall be between 1.0 to 2.5 kg.cm^2, if pressure crosses the limit it means either MGF sand got degraded and need to be changed or it got choked & need to be back flushed.
94.	**Flow Meter**		Permeate Flow Rate Water System	Monitor allowable flow of water	If malfunctioned then will not be able to detect the required flow for RO membrane & the system will trip if flow increases or decreases.
95.	**Temperature Sensor**		CIP Tank	Monitors inlet temperature during sanitization	Pressure shall be maintained for flow continuity during sanitization of generation system.
96.	**Pressure Gauge**			Verifies inlet pressure of CIP tank during sanitization	Any increase or decrease in temperature during sanitization may impact the microbial load.
97.	**Digital Flow Meter**		Multi Grade Filter	Monitor inlet flow of water in MGF	Improper inlet floe of MGF will result into choking of the MGF system
98.	**Flow Meter**		RO System	Monitor the flow of water through RO membrane	Improper flow in RO system will trip the system & will effect in water output
99.	**Flow Meter**				
100.	**Flow Meter**				
101.	**Flow Meter**		Ultra Filtration	Monitor the flow of water through UF membrane	Improper flow in UF system results into rupture of choking of the membrane & trip of the system
102.	**Flow Meter**				
103.	**Flow Meter**				

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S.No.	Instruments Name	Identification No.	Location	Role of Instrument	Risk Identification
104.	**Flow Meter**		Multi Grade Filter	Monitor the flow of water from inlet of MGF	Flow of inlet water shall be monitored to avoid choking of the multi grade filter
105.	**Pressure Switch**		RO System	Controls the flow of incoming water	Fluctuation in flow rate may rupture or choke the RO membrane
106.	**Pressure Switch**				
107.	**Pressure Switch**				
108.	**Pressure Switch**				
109.	**Pressure Switch**				
110.	**Pressure Switch**		Ultra Filtration System	Controls the flow of incoming water	Ultrafiltration System may get ruptured of choked if pressure not controlled
111.	**Pressure Switch**		Multi Grade Filter	Controls the flow of incoming water	Inlet pressure required for MGF shall be between 1.0 to 2.5 kg/cm^2, if pressure is out of limit, means there is some issue with the flow rate and might be water pump is not working properly
112.	**Conductivity Sensor**		Loop-5	Monitor the conductivity of distribution loop	Increased conductivity results into failure of product
113.	**Conductivity Sensor**		Loop-4		
114.	**Conductivity Sensor**		RO-II	Monitor the conductivity of incoming water to RO II	Increased conductivity results into failure of product
115.	**Conductivity Sensor**		EDI	Monitor the conductivity of incoming water to EDI	
116.	**Conductivity Sensor**		RO-I	Monitor the conductivity of incoming water to RO I	
117.	**Conductivity Sensor**		Loop-6	Monitor the conductivity of water in distribution loop	
118.	**NaOCl Dosing pump**		Q-Block	Controls the dosing of NaOCl	Fluctuation in Chlorine dosing may increase microbial growth
119.	**SMBS Dosing pump**			Controls the dosing of SMBS	Fluctuation in Sodium Metabisulphite dosing may result into excess Chlorine which may damage RO membrane
120.	**ADS Dosing pump**			Controls the Dosing of ADS	Fluctuation in Anti-de-scalant dosing may result into scaling in RO membrane which

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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S.No.	Instruments Name	Identification No.	Location	Role of Instrument	Risk Identification
					damages the RO membrane
121.	**NaOH Dosing pump**			Controls the dosing of NaOH	Fluctuation in NaOH dosing may increase pH resulting into RO membrane damage
122.	**ORP Meter**			Controls Oxidation Reduction Potential	Malfunctioning of ORP meter may increase chlorine level resulting into damage of RO membrane
123.	**UV Monitor**		Generation	Controls microbial growth	Any malfunction in UV may leads to increase in microbial load
124.	**UV Monitor**		Loop-04		
125.	**UV Monitor**		Loop-05		
126.	**UV Monitor**		Loop-06		
127.	**Pressure Gauge**		Feed Water Line	Verifies inlet feed water pressure	Pressure required to feed the water through MCDP columns, if not sufficient then may lead to improper flow rate
128.	**Temperature Sensor**		Cooling Water Inlet	Verifies cooling water temperature	Cool water condense the hot water circulating in the coils which convert into WFI after several distillation, if temperature not maintained below 25˚C then processing of WFI will take time resulting into low output.
129.	**Flow Meter**		MCDP Feed Water Pump	Monitor flow of inlet line	On water flow basis all other parameters (temperature & steam inlet) are maintained & freeze. If flow meter got malfunctioned then it will difficult to set the temperature of the WFI.
130.	**Flow Meter**		MCDP Cooling Water Pump	Monitor flow of cooling chamber	
131.	**Temperature Sensor**		Boiler Steam Inlet Line	Verifies inlet temperature of Boiler steam	MCDP inlet temperature will not be able adjust with the flow rate
132.	**Temperature Sensor**		WFI Header	Verifies WFI temperature at MCDP outlet	If sensor got malfunctioned, then will not be able monitor WFI temperature (NLT 85˚C) which may result into microbial growth in distribution line.
133.	**Pressure Gauge**		Boiler Steam Inlet Line	Verifies pressure at boiler steam inlet	Without pressure monitoring, will not be able to set the steam pressure, improper pressure may result into damage of the columns.
134.	**Pressure Gauge**		Air FRL	Controls pressure required for opening	Malfunction in pressure gauge may hamper

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S.No.	Instruments Name	Identification No.	Location	Role of Instrument	Risk Identification
				& closing of pneumatic valves	opening & closing of pneumatic valves
135.	**Pressure Switch**		Feed Water Inlet	Controls inlet pressure of feed water	Defective pressure switch will not trip the system during pressure fluctuations resulting into improper flow rate
136.	**Pressure Switch**		Air Inlet Line	Controls inlet air pressure	Fluctuation in air pressure will result into disturbance in opening & closing of pneumatic valves
137.	**Pressure Switch**		Cooling Inlet Line	Controls inlet pressure of cooling line	Outlet parameters will get disturbed
138.	**Pressure Switch**		Feed Pump Line	Controls pressure of feed line	
139.	**Conductivity Sensor**		MCDP-2	Verifies conductivity of inlet feed water	Malfunctioned Conductivity sensor will not be able to identify the fluctuations of Conductivity hence will not be able to ensure the quality of water online and will have to wait for QC results
140.	**Conductivity Sensor**			Verifies conductivity of outlet feed water	
141.	**Conductivity Sensor**		WFI (Loop 1)	Verifies conductivity of return line	
142.	**Conductivity Sensor**		WFI (Loop 2)	Verifies conductivity of return line	
143.	**Conductivity Sensor**		PSG	Verifies conductivity of inlet	
144.	**Conductivity Sensor**			Verifies conductivity of outlet	
145.	**Conductivity Sensor**			Verifies conductivity of inlet	
146.	**Conductivity Sensor**			Verifies conductivity of outlet	
147.	**Pressure Gauge**		In Steam Safety Valve Assembly	Monitor pressure of incoming steam	Column may get damaged
148.	**Compound Gauge**		On top of Tank	Monitor pressure of the Storage tank	Pressure shall be monitored during filling and emptying of water storage tank, if any malfunction occurs, it may results into collapse or explode of the storage tank
149.	**Pressure Gauge**		Return Line of PWD System	Monitor return line pressure	Fluctuation of pressure results into decrease in flow rate in return line which may result into water stagnation which further increases the bio-load.
150.	**Pressure Gauge**		Supply Line of PWD System	Monitor supply line pressure	Fluctuation of pressure results into decrease in flow rate in return line which may result into

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S.No.	Instruments Name	Identification No.	Location	Role of Instrument	Risk Identification
151.	**Pressure Switch**		Supply Line of PWD System	Controls supply line pressure	water stagnation which further increases the bio-load.
152.	**Temperature Sensor**		Return Line of PWD System	Monitor temperature of return line	Return line temperature shall be maintained during sanitization, it not then may result into increase in bio-load.
153.	**Temperature Sensor**		In PWD Storage Tank	Monitor temperature of Storage tank	Storage tank temperature shall be maintained upto NLT 85°C, sensor attached confirms the temperature required.
154.	**Digital Pressure Gauge**		Air Regulator	Monitor pressure of Compressed air	Compressed air is required to regulate the pressure for operating pneumatic valves, if not, then it may alter the operating parameters
155.	**Compound Gauge**		On the Top of T-301	Monitor pressure of Storage tank	Pressure shall be monitored during filling and emptying of water storage tank, if any malfunction occurs, it may results into collapse or explode of the storage tank
156.	**Pressure Gauge**		Return Line of PW Loop	Monitor return line pressure	Fluctuation of pressure results into decrease in flow rate in return line which may result into water stagnation which further increases the bio-load.
157.	**Pressure Gauge**		Supply Line of PW loop	Monitor supply line pressure	Fluctuation of pressure results into decrease in flow rate in return line which may result into water stagnation which further increases the bio-load.
158.	**Pressure Gauge**		Discharge Line of ROFP-201	Monitor pressure of discharge line	Pressure may drop in case of ROFP malfunction further resulting into lowering of flow rate in RO membrane
159.	**Flow Indicator**		Outlet of SF	Monitor flow of outlet of Softener	Flow rate required for inlet of UF, if not maintained will result into water stagnancy & increase in microbial load
160.	**Pressure Switch**		Feed Line UF System	Controls pressure of UF feed line	Trip the system if pressure is not upto mark, in case of malfunctioning, may result into low flow rate in UF feed line
161.	**Flow Transmitter**		Return line of PW loop	Monitor flow rate of return loop line	Low flow in the return loop may result into

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S.No.	Instruments Name	Identification No.	Location	Role of Instrument	Risk Identification
					water stagnancy
162.	**Temperature Sensor**		For EVF-301	Monitor temperature of Electric Vent filter	Electric vent filter temperature shall be monitored to avoid any microbial growth
163.	**Temperature Sensor**		In Return Line of PW Loop	Monitor temperature of return loop line	Return loop temperature shall be monitored during sanitization to avoid any microbial growth
164.	**Temperature Sensor**		In PW Storage Tank	Monitor temperature of PW storage tank	PW Storage temperature shall be monitored & controlled during sanitization to avoid any microbial growth
165.	**Pressure Switch**		Feed line of MGF system	Control pressure of MGF feed line	In case of low pressure the MGF might get choked
166.	**Pressure Gauge**		Discharge Line of UFFP	Monitor pressure of UF discharge line	Pressure shall be maintained to avoid the low flow rate in UF system
167.	**Pressure Gauge**		Outlet of SF	Monitor outlet pressure of Softener	Outlet water flow needed (4.0-5.0 m^3/hr) for softener shall be within the limit, if not may result into decrease in output required for Ultrafiltration.
168.	**Pressure Gauge**		Outlet of SF		
169.	**Pressure Gauge**		Outlet of MGF	Monitor outlet pressure of MGF	Outlet MGF pressure shall be between 1.0 to 2.5 $kg.cm^2$, if pressure crosses the limit it means either MGF sand got degraded and need to be changed or it got choked & need to be back flushed.
170.	**Rota meter**		Discharge line BFP	Monitor flow rate discharge line	Rotameter confirms the flow rate if decrease then output will also decreased
171.	**Rota meter**		Permeate Line of Pre-UF Unit	Monitor flow rate of permeate line	
172.	**Rota meter**		Discharge line UFFP	Monitor flow rate of discharge line	
173.	**Rota meter**		Discharge line RWP		
174.	**Pressure Gauge**		Discharge Line of BFP	Monitor pressure of discharge line	Water amount will not get ensured
175.	**Pressure Gauge**		Discharge Line of BFP		
176.	**Pressure Gauge**		Permeate Line of UF System	Monitor pressure of Permeate line of UF system	Choked filters will not be identified
177.	**Pressure Gauge**		Outlet of CF	Monitor pressure of outlet of Cartridge	

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR INSTRUMENTS OF PURIFIED WATER, WATER FOR INJECTION & PURE STEAM GENERATION SYSTEM

S.No.	Instruments Name	Identification No.	Location	Role of Instrument	Risk Identification
				filter	
178.	**Digital Pressure Gauge**		RO 201	Monitor pressure of RO system	Will not be able to monitor online pressure which may result into damage of RO membrane tube (O-ring)
179.	**Pressure Gauge**		Discharge Line of CIPFP-201	Monitor pressure in discharge line	Will not be able to monitor the tank pressure which further may resulting into emptying of the CIP tank.
180.	**Pressure Gauge**		Inlet of EDI-201	Monitor pressure in inlet of EDI	Ion exchange plates may get damaged
181.	**Pressure Gauge**		Reject line of ROH-204	Monitor pressure in RO system	Will not be able to monitor the differential pressure between the membranes which further results into damage of membranes tubes & O-rings resulting into mixing of raw water and conductivity will get disturbed
182.	**Pressure Gauge**		Reject line of ROH-203		
183.	**Pressure Gauge**		Inlet line of RO-Pass 2		
184.	**Pressure Gauge**		Reject line of ROH-202		
185.	**Pressure Gauge**		Reject line of ROH -201		
186.	**Pressure Gauge**		Inlet of RO Pass -1		
187.	**Pressure Gauge**		Outlet of CF-201	Monitor pressure in outlet of 5µ cartridge filter	Ruptured or choked filter may not be identified resulting into mixing of heavy metal with RO membrane, which further choked the RO membrane
188.	**Temperature Sensor**		CIP Permeate Return Line	Monitor temperature in CIP permeate return line	Return line temperature may not get monitored resulting into microbial growth
189.	**Temperature Sensor**		Discharge line of CIPFP-201	Monitor temperature in discharge line	Will not be able to monitor the discharge temperature which further result into microbial growth
190.	**Pressure Switch**		Discharge line of ROHP-202	Controls pressure in discharge line of ROHP	System will not get trip during pressure fluctuation resulting into RO membrane tubes & O- ring damage, which further will allow raw water to pass through.
191.	**Pressure Switch**		Discharge line of ROHP-201		
192.	**Pressure Switch**		Suction line of EDI-201	Controls pressure in suction line of EDI	High pressure water will get introduced into the ion exchanger and damaged it.
193.	**Pressure Switch**		Suction line of ROHP-202	Controls pressure of suction line of ROHP	System will not get trip during pressure fluctuation resulting into RO membrane tubes

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR INSTRUMENTS OF PURIFIED WATER, WATER FOR INJECTION & PURE STEAM GENERATION SYSTEM

S.No.	Instruments Name	Identification No.	Location	Role of Instrument	Risk Identification
194.	**Pressure Switch**		Suction line of ROHP-201		& O- ring damage, which further will allow raw water to pass through.
195.	**Rota meter**		EDI-201 Concentrate Line	Monitor flow rate of EDI concentrate line	Flow will not be monitored & designed flow parameters will get disturbed
196.	**Rota meter**		EDI-201 Feed Line	Monitoring flow rate of EDI feed line	
197.	**Rota meter**		Reject Recycle line of RO Pass-2 to RO Oass-1	Monitor flow rate of RO system	
198.	**Rota meter**		Reject Recycle line of RO Pass-2		
199.	**Rota meter**		Reject line of RO Pass-1		
200.	**Rota meter**		Reject Recycle line of RO Pass-1		
201.	**Rota meter**		Discharge Line of ROFP-201		
202.	**Pressure Gauge**		Inlet of MGF	Monitor pressure of inlet of MGF	Inlet pressure required for MGF shall be between 1.0 to 2.5 kg/cm^2, if pressure is out of limit, means there is some issue with the flow rate and might be water pump is not working properly
203.	**Conductivity Transmitter**		EDI	Monitor conductivity of EDI line	Increased conductivity results into failure of product
204.	**Pressure Gauge**		Air Regulator	Monitor pressure of incoming Compressed air	Pneumatic valves will not be operated automatically
205.	**Pressure Switch**		At Air Pressure Line	Controls pressure of Compressed air	
206.	**Pressure Switch**				
207.	**Pressure Switch**		At Discharge side of Feed Pump	Controls pressure at discharge side of feed pump	Flow of the water will get disturbed
208.	**Temperature Sensor**		At Cooling water outlet line	Monitor temperature at cooling water outlet line	Temperature fluctuation will not be monitored
209.	**Temperature Sensor**		At WFI water outlet line	Monitor temperature at WFI outlet line	
210.	**Pressure Gauge**		At Plant Steam Line	Monitor pressure at plant steam line	Pressure is needed in plant steam line to

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR INSTRUMENTS OF PURIFIED WATER, WATER FOR INJECTION & PURE STEAM GENERATION SYSTEM

S.No.	Instruments Name	Identification No.	Location	Role of Instrument	Risk Identification
					circulate raw steam through PSG, on pressure basis valves are adjusted to achieve specific flow rate & temperature of pure steam
211.	**Rota meter**		At Discharge side of Cooling Pump	Monitor flow rate at discharge side of cooling pump	On water flow basis all other parameters (temperature & steam inlet) are maintained & freeze. If flow meter got malfunctioned then it will difficult to set the temperature of the WFI
212.	**Rotameter**		At Discharge Side of Feed Pump	Monitor flow rate at discharge side of feed pump	
213.	**Pressure Gauge**		At Discharge Side of Feed Pump	Monitor pressure at discharge side of feed pump	After discharge the purified water is circulated through MCDP columns at specific flow rate, to achieve that flow rate specific pressure is required
214.	**Temperature Sensor**		At Boiler Steam Line	Monitor temperature at boiler steam line	Specific temperature is required at boiler steam line, sensor monitor that temperature, if temperature not maintained then it may result into operational failure of MCDP, as raw steam is being used by PSG which circulate pure steam to MCDP
215.	**Conductivity Sensor**		MCDP	Monitor Conductivity at MCDP line	Specific Conductivity is required, if not achieved then will be tracked by sensor, malfunctioned sensor will not be able to track fluctuated conductivity further which will affect the quality of WFI.
216.	**Conductivity Sensor**		MCDP		
217.	**Flow Transmitter**		Return Line of WFI Loop	Monitor flow rate at return line of WFI loop	Specific flow rate (NLT 1.2 m^3/hr) is required in return line, if not maintained will result into water stagnancy and decreased output. Transmitter monitor the fluctuation in flow rate, if malfunctioned then will not be able to detect.
218.	**Temperature Sensor**		For EVF-402	Monitor temperature of Electric Vent filter	Specific temperature is required to control microbial growth, if not controlled will result into water contamination in storage tank. Contaminated vent filter may got choked if not noted.
219.	**Temperature Sensor**		For EVF-401		

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR INSTRUMENTS OF PURIFIED WATER, WATER FOR INJECTION & PURE STEAM GENERATION SYSTEM

S.No.	Instruments Name	Identification No.	Location	Role of Instrument	Risk Identification
220.	**Temperature Sensor**		In Return line of WFI loop	Monitor temperature of return line of WFI loop	Return line temperature shall be maintained during sanitization & in regular production also. If not then WFI may be susceptible to increased microbial growth
221.	**Temperature Sensor**		In WFI Storage Tank (T-401)	Monitor temperature in WFI storage tank	Temperature shall be maintained in storage tank also, if not then is susceptible to microbial growth, hence shall be monitored regularly.
222.	**Compound Gauge**		On top of T-401	Monitor pressure of WFI storage tank	Pressure shall be monitored during filling and emptying of water storage tank, if any malfunction occurs, it may results into collapse or explode of the storage tank
223.	**Pressure Gauge**		Return Line of WFI Loop	Monitor pressure in return line of WFI loop	Return line pressure is required to maintain required flow rate, while flow rate is directly proportional to microbial growth & production output.
224.	**Pressure Gauge**		Supply Line of WFI Loop	Monitor pressure in supply line of WFI loop	Supply line pressure shall be maintained the flow rate as per the requirement to control microbial growth & to maintain productivity
225.	**Pressure Gauge**		In Steam Safety Valve	Monitor pressure in Steam safety valve	Steam safety valve pressure shall be maintained to avoid any storage tank explosion or collapse, hence pressure shall be monitored regularly
226.	**Conductivity Sensor**		WFI Distribution System	Monitor conductivity in WFI distribution system	Conductivity is an important parameter of Water for injection and it shall be monitored regularly
227.	**Pressure Gauge**		At Plant Steam Line	Monitor pressure at plant steam line	Plant steam line pressure is required to maintain temperature required by PSG & MCDP, if pressure is less than required temperature will not be maintained to operate system & if more than the required, then the system may collapse or get damaged.
228.	**Pressure Switch**		Pure Steam Line	Controls pressure at steam line	If required pressure is not maintained then the system will trip automatically in case pressure

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR INSTRUMENTS OF PURIFIED WATER, WATER FOR INJECTION & PURE STEAM GENERATION SYSTEM

S.No.	Instruments Name	Identification No.	Location	Role of Instrument	Risk Identification
					switch is working properly otherwise the system will get damaged.
229.	**Pressure Switch**		At air pressure line	Controls compressed air pressure at inlet line	Specific pressure is required to operate pneumatic valves of the PSG system, pressure switch trip down the system if required pressure of compressed air not maintained to avoid any miss happening.
230.	**Pressure Switch**		Feed Pump Outlet line	Controls pressure at feed pump outlet line	Through feed pump outlet, the pure steam is transferred to MCDP for production of WFI, pressure switch maintains the required pressure to maintain the required flow & temperature of the MCDP, as all the above parameters are inter related, if any one disturbed will result into system malfunctioning
231.	**Pressure Switch**		Pure Steam Line 01	Controls pressure at Pure Steam line	
232.	**Pressure Gauge**		At Pure Steam Line	Monitor pressure at Pure Steam line	Steam line pressure shall be maintained to operate the MCDP, if not then the required temperature will not be maintained
233.	**Pressure Gauge**		At Plant Steam Line	Monitor pressure at Plant Steam line	
234.	**Conductivity Sensor**		Pure Steam Generator	Monitor conductivity at Pure Steam Generator	Conductivity of Pure Steam shall be maintained, as the same is required to generate WFI, may impact WFI quality if not monitored regularly
235.	**Conductivity Sensor**		Pure Steam Generator		

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR INSTRUMENTS OF PURIFIED WATER, WATER FOR INJECTION & PURE STEAM GENERATION SYSTEM

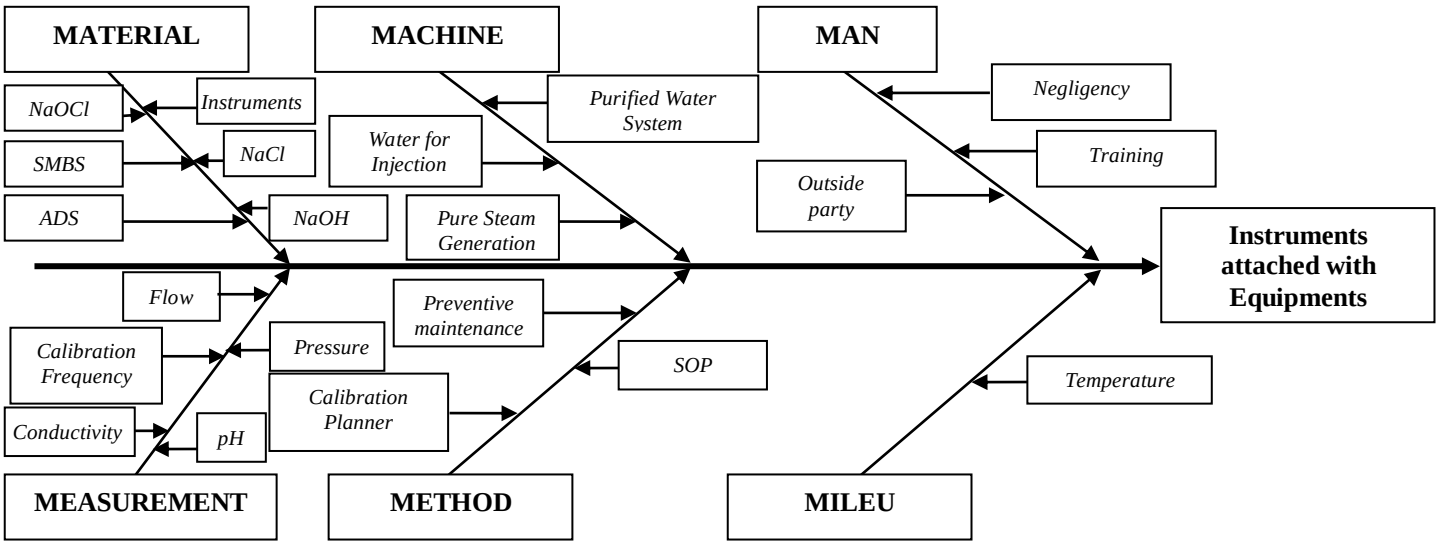
9.0 RISK MITIGATION:

S.No.	CONTROLS	DESCRIPTION
1.	**Scheduled Preventive maintenance**	Preventive maintenance is done on quarterly basis & equipment parameters are verified during scheduled Preventive Maintenance.
2.	**Daily analysis results of Supply & Return sampling points**	All supply & return lines are monitored on daily basis and monthly trend is being prepared for the same. Any malfunction in the system will be captured in result evaluation.
3.	**Continuous monitoring done by QC**	Further each sampling point & user point is being analysed during continuous monitoring as per defined frequency/sampling planner.
4.	**Daily verification of Operational Parameters**	Operational parameters are verified after each set of purification stage and the data is generated & evaluated on daily basis.
5.	**Online verification by SCADA**	Further all instruments results are also captured in SCADA, and any out of trend observed get noted in SCADA through alarm system.
6.	**Dumping valves**	Dumping valves are there which operates automatically itself if any parameter goes beyond limit.
7.	**Alarm System**	Each instrument is connected with alarm system, if any malfunction occurs, then a sound of hooter activates.
8.	**HMI Display**	Indicates the status of all operational activities in equipment. If any malfunction to any instrument happens, then the alarm activates with the sound of hooter & the system trips.
9.	**Safety valves**	At the time of qualification, all storage tanks were gone through Hydro test, if any malfunction occurs in pressure gauge, then there is a safety valve attached at the top of the storage tank, which itself designed in such a way that it releases pressure when it increases.

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR INSTRUMENTS OF PURIFIED WATER, WATER FOR INJECTION & PURE STEAM GENERATION SYSTEM

10.0 RISK ANALYSIS TOOLS, RE-RISK ANALYSIS CRITERIA:

10.1 Fish bone:



Fish bone tool used for risk assessment, area of concern are:

1. **Milieu:**
2. **Method:**
3. **Measurement:**
4. **Man:**
5. **Machine:**
6. **Material:**

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR INSTRUMENTS OF PURIFIED WATER, WATER FOR INJECTION & PURE STEAM GENERATION SYSTEM

10.2 Failure Mode Effect Analysis:

In the following section a table is produced for the risk analysis using FMEA tool. The significance or instruction for each column is described in the following paragraph.

Column 1:	**Serial number** of Risk Analysis item
Column 2:	**Item/Function:** Identify the process step or component associated with the risk.
Column 3:	**Potential Failure Mode:** Identify the type of risk associated with the process or component.
Column 4:	**Effect of Potential Failure/Cause:** Verify that whether risk have **GMP impact.**
Column 5/6/7/8/9:	**Severity/Occurrence/Detection/Risk level/Risk Acceptance:** Risk Priority Number to be calculated by taking Severity, Occurrence & Detection of potential failure into consideration.
Column 10:	**Risk Mitigation**: Write the risk mitigation strategy as considered in design.
Column 11/12/13/14/15:	**Severity/Occurrence/Detection/Risk level/Risk Acceptance:** Risk Priority Number to be calculated after mitigation by taking Severity, Occurrence & Detection of potential failure into consideration.
Column16:	**Recommended action:** Recommended actions should be given for controlling failure occurrence.

Table 1: Instruction for each column given above

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QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR INSTRUMENTS OF PURIFIED WATER, WATER FOR INJECTION & PURE STEAM GENERATION SYSTEM

Procedure: Instruments of Purified Water, Water for Injection & Pure Steam Generation System	**Quality Risk Assessment Date:** **Quality Risk Assessment No.:**

S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN S*O*D
1.	**Scheduled frequency of Instrument's Calibration crosses the limit (±01 month)**	Defective Pressure gauges not identified	Malfunction in pressure gauges	• May result into pressure drop in distribution line. • May result into low flow rate. • May result into collapse of storage tanks • May result into choking of MGF. • May result into decrease in Softener output. • May result into choking of Softener • If pressure not maintained in backwash, it may lead to choking of MGF, Softener, Cartridge filter, UF System, RO membrane. • Low pressure may result into choking of RO membrane. • May result into hampering of pneumatic valves opening. • Low pressure may result into stagnancy of water.	• Pressure switches are there at different stages to monitor pressure fluctuations, if any, than the system will trip accordingly. • HMI & SCADA system is there to monitor the online pressure fluctuations. • Alarm with hooter system installed for any fluctuation. • Plant can be operated manually, semi-automatically & automatically to control the operation of any valve, if required • Multi-grade filters are backwashed when required • Resins are replaced when softener gets choked • Sand filters are replaced whenever required	• SOP of water system qualification • SOP of Operation of Purified water Generation & Distribution System • SOP Water system qualification • SOP of Sanitization of Purified Water Storage and Distribution System • SOP of Integrity testing, handling & replacement of vent filter • SOP of Solution preparation & dosing in Purified water generation system • SOP of Backwash procedure for Multi grade filter • SOP of Cleaning & Sanitization of Softener • SOP of Replacement of sand in Multi grade filter • SOP of Operation and Replacement of UV lamps in Purified Water Generation/Distribution System • SOP of Operation of Multicolumn Distillation & WFI Distribution system	5	5	1	25	NA	NA	NA	NA	NA
2.		Defective Pressure switch not Identified	Malfunction in Pressure switch	• Machine will not trip during pressure disturbance	Alarms are there at every stage, if pressure switch malfunctions then the system will get shut down.		5	1	1	5		NA	NA	NA	NA

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RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR INSTRUMENTS OF PURIFIED WATER, WATER FOR INJECTION & PURE STEAM GENERATION SYSTEM

S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN S*O*D
3.	**Scheduled frequency of Instrument's Calibration crosses the limit (±01 month)**	Defective Rotameter not identified	Malfunction in Rotameter	• Parameters such as adjustment of valves, temperature & pressure will not be able to get inline as per requirement resulting into malfunctioning of the operating system.	Manual valves are available to control the flow rate of the pressure gauge		5	1	1	5	NA	NA	NA	NA	NA
4.		Defective Temperature sensor not identified	Malfunction in Temperature Sensor	• Fluctuation in temperature will result into microbial growth	• Sanitization of system done as per schedule or whenever required		5	1	5	25		NA	NA	NA	NA
5.		Defective Conductivity Sensor not identified	Malfunction in Conductivity Sensor	• Increased conductivity impact the quality of product	• Dumping valve gets open & QC chemical report for off line verification • FDV Challenge test are performed for Conductivity		5	1	1	5		NA	NA	NA	NA
6.		Defective NaOCl Dosing pump not identified	Malfunction in NaOCl dosing pump	• Less dosing will result into microbial growth • More dosing will choke the RO membrane	• Manual checking of Chlorine content • Oxidation Reduction Potential (ORP meter) will gets low		5	1	5	25		NA	NA	NA	NA
7.		Defective SMBS dosing pump not identified	Malfunction in SMBS dosing pump	• Less dosing will not de-chlorinate • More dosing will choke the RO membrane	Chlorine content increases & will be detected by ORP		5	1	5	25		NA	NA	NA	NA
8.		Defective ADS dosing pump not identified	Malfunction in ADS dosing	• Anti-de-scalant will not remove scaling if less in dosing • Over dosing will choke the RO membrane	RO membrane pressure will get increased as the membranes will get choked		5	1	5	25		NA	NA	NA	NA
9.		Defective NaOH Dosin pump not identified	Malfunction in NaOH dosing	• If less in dosing, pH will not be maintained • Over dosing will choke the RO membrane •	• pH Analyzer will detect along with QC report • RO membrane pressure will get increased as the membranes will get choked		5	1	5	25		NA	NA	NA	NA

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR INSTRUMENTS OF PURIFIED WATER, WATER FOR INJECTION & PURE STEAM GENERATION SYSTEM

S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN S*O*D
4..	**Scheduled frequency of Instrument's Calibration crosses the limit (±01 month)**	Defective ORP meter Not identified	Malfunction in ORP meter	• Chlorine content will not be monitored	Alarm will get raised & dumping valve will gets opened		5	1	5	25	NA	NA	NA	NA	NA
5..		Defective UV Monitor Not identified	Malfunction in UV monitor	• Microbial growth will increase	• Microbial count increase in QC report • UV burning hour record • UV replacement whenever required		5	1	5	25		NA	NA	NA	NA
6..		Defective Flow transmitter not identified	Malfunction in Flow transmitter	• Disturbed flow will not get monitored	Velocity decrease & return line flow of water will be decreased		5	1	1	5		NA	NA	NA	NA

Table 2: The above table shows Potential failure mode, effect of potential failure along with Risk Probable Number, Risk Mitigation & Recommended Actions.

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RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR INSTRUMENTS OF PURIFIED WATER, WATER FOR INJECTION & PURE STEAM GENERATION SYSTEM

***The Risk Priority Number (RPN/Overall Risk) changes based upon the risk. The Risk Assessment team shall decide the acceptance criteria. For example the risk priority number is categorized as below:**

Risk Priority Number (RPN)	Risk levels
Up to 25	Low
26-50	Medium
51 to ≤ 125	High

RPN = Severity x Occurrence x Detection

Remark if any:

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Quality Risk Management Team			Reviewed By Head Operations Sign & Date	Approved By Head QA Sign & Date
Name	Department	Sign & Date		
	Engineering			
	QA			

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Facility			
S.No.	Recommended Action	Responsible Person	Target Date of Completion
1.			

Verification of Action Plan:

All the above agreed actions completed, Not Completed.

(*incase any recommendations Not completed, to be tracked through CAPA System)

Remark if any:

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Verified By
(QA)
Sign & Date……..

Reviewed By:
(Manager QA)
Sign & Date……..…..

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR INSTRUMENTS OF PURIFIED WATER, WATER FOR INJECTION & PURE STEAM GENERATION SYSTEM

11.0 CONCLUSION:

Risk analysis data shall be written on Risk Analysis Study Protocol cum Report for Instruments attached with Purified water, Water for Injection & Pure Steam Generation System, clearly stating the achievement or non-compliance of the acceptance criteria, effect of the deviations made during the Risk analysis and in case of failure, investigation carried out and their findings.

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12.0 RECOMMENDATION:

Recommendation shall be written on the Risk Analysis Study Protocol cum Report for instruments attached with Purified water, Water for Injection & Pure Steam Generation System, clearly stating that there is no impact/adverse impact on the product quality& personnel.

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RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR INSTRUMENTS OF PURIFIED WATER, WATER FOR INJECTION & PURE STEAM GENERATION SYSTEM

13.0 REFERENCES:

SOP **"Quality Risk Management"**, SOP.

14.0 DOCUMENTS TO BE ATTACHED:

Reference SOP.

15.0 DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:

Deviations observed from the pre-defined procedures, calibration not performed as per the schedule, matter has been investigated in accordance with QA SOP **"Handling of Deviations"**, **SOP** and has been documented in the Risk analysis Protocol cum report.

16.0 CHANGE CONTROL, IF ANY:

No Change control observed, if observed shall be authorized in accordance with QA SOP **"Change Management"**, and shall be documented in the Risk analysis Protocol cum report.

17.0 ABBREVIATIONS:

FMEA : Failure Mode Effect Analysis
GMP : Good Manufacturing Practices
RPN : Risk Priority Number
WFI : Water for Injection
ORP : Oxidation- Reduction Potential

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR INSTRUMENTS OF PURIFIED WATER, WATER FOR INJECTION & PURE STEAM GENERATION SYSTEM

18.0 PROTOCOL CUM REPORT POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			