PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR PURIFIED WATER PRE-TREATMENT, GENERATION, STORAGE & & DISTRIBUTION SYSTEM

S.No.	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
PRETREATMENT SYSTEM										
A. Process										
A.1. Raw Water Tank										
1.	Bore well water (Raw water)	Increased microbial and particle contaminatio n of the in-feed raw water	Yes	The system shall be inefficient to remove the increased microbial and particulate contamination.	Operational	Frequent changes of the RO membrane	Low	The raw water from the bore well shall be transferred to a closed underground storage tank. The transfer piping shall be provided with the facility for adding sodium hypochlorite solution on line to raw water.	Acceptable	IQ/OQ
2.	Bore well water (Raw water)	Water cannot be withdrawn completely from the storage tank	Yes	This is required during cleaning of the tank or when tank is contaminated chemically or microbiologically	No	NA	Low	Tank bottom shall be sloped to a small sump from where water can be pumped out.	Acceptable	IQ/OQ
3.	Bore well water (Raw water)	Tank is directly exposed to environment	Yes	This may lead to increased microbial and particulate contamination	Operational	Cleaning of the tank will be difficult.	Medium	The tank shall be properly closed with lid	Acceptable	IQ

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR PURIFIED WATER PRE-TREATMENT, GENERATION, STORAGE & & DISTRIBUTION SYSTEM

S.No.	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
PRETREATMENT SYSTEM										
4.	Bore well water (Raw water)	Cleaning of the under ground storage tank is not possible.	Yes	After a long period of time the microbial and particulate contamination may be increased and the system may be inefficient to remove the increased microbial and particulate contamination.	No	NA	Low	The tank shall be provided with man entry for cleaning in regular interval. The SOP for cleaning shall be prepared and the frequency of the cleaning shall be established.	Acceptable	IQ/OQ
5.	Bore well water (Raw water)	Insufficient quantity of raw water	No	The quantity of raw water shall not have any impact on the product quality	Operational	The process may stop due to lack of raw water.	Low	The raw water storage tank shall be sized as per the downstream requirements. The tank shall be provided with level indicator for high and low level to have a uninterrupted flow.	Acceptable	IQ/OQ
6.	Bore well water (Raw water)	Tank wall and floor is not leak proof	Yes	Unexpected intrusion of micro- organism	EHS	Water may be contaminated by sewage water or contaminated by heavy minerals.	High	Tank should have suitable construction of RCC with Epoxy coating/Tiles is recommended. In regular basis tank should be inspected for any crack	Low	IQ
A.2. Processing and Process Controls										

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR PURIFIED WATER PRE-TREATMENT, GENERATION, STORAGE & & DISTRIBUTION SYSTEM

S. No.	Process steps/component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
7.	Bore Well Water	Sampling of the bore well water is not possible	Yes	The bore water quality shall decide the final purified water quality and the extent of the pretreatment.	No	NA	High	SOP for raw water sampling shall be prepared. Considering the borewell water quality the pretreatment process shall be established.	Acceptable	IQ/OQ
8.	Raw Water	Overflow of raw water in under ground storage tank.	No	Over flow water shall not affect the product quality	Operational	Spillage of excess wate r requires frequent cleaning of the area	Low	The ground water storage tank shall be provided with level indicator for high water level in the tank.	Acceptable	IQ
9.	Raw Water	Water stagnant in under ground tank.	yes	The water stagnant will rise the microbial content in the water	No	NA	High	An online sodium hypochlorite dosing in water is considered with sampling points. During validation sanitization process and frequency is to be established. SOP should be written, confirmed and implemented.	Acceptable	IQ& OQ.
10.	Chlorine level	Low chemical level in dosing tank	Yes	Low level of chemical will not disinfect as per the requirement	No	NA	High	Level sensor shall be provided in case of low level of chlorine in dosing tank.	Acceptable	IQ
11.	Water filtration	Contamination of the RO unit with the coarse suspended particles in the raw water.	No	The coarse particles shall be removed in the RO and hence no impact on the product quality	Operational	The RO unit shall be chocked and damaged by the coars e particle	Low	Multi grade filter shall be provided for the filtration of coarse particles.	Acceptable	IQ

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR PURIFIED WATER PRE-TREATMENT, GENERATION, STORAGE & & DISTRIBUTION SYSTEM

S. No.	Process steps/component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
12.	Multi Grade Filter	Choking of the filters	No	Choking of the filter shall have no impact on the product quality	Operational	Frequent removal of the filters	Low	Multi grade filter shall be dismantle type for easy removal and installation. -Installing of Pressure Gauge at the inlet of MGF and across the filter to detect the chock. - Sampling Point shall be provided at inlet and outlet. - Backwash with high flow rate. - Operating, Preventive Maintenance SOP & Training.	Acceptable	IQ/OQ
13.	Multi Grade Filter	Material of construction is not compatible with water in long run as the water has chlorine content.	No	NA	Operational	Iron and rust particles may carry over with water and increases the load on the downstream equipment. Life time of the equipment will come down.	Low	The Multi-grade filter MOC to be well designed, Rubber lined mild steel is recommended	Acceptable	IQ
14.	Multi Grade Filter	Required water velocity is not available to pass through the filter.	No	NA	Operational	Reduction in the velocity of water will affect in the total output of the water system. Backwash with high flow rate is not possible.	Medium	Installing of Pressure Gauge at the inlet of MGF and across the filter to detect the water velocity continuously.	Acceptable	IQ

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR PURIFIED WATER PRE-TREATMENT, GENERATION, STORAGE & & DISTRIBUTION SYSTEM

S. No.	Process steps/component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
15.	Multi Grade Filter	As the porosity of the MGF is high only the coarse particle will be withhold	No	NA	Operational	The tiny particle may pass through and chock the R.O membrane.	Medium	Micron filter can be considered to address the same.	Acceptable	IQ
16.	Multi Grade Filter	Microbial growth in filters.	Yes	During non operation of the system the water hold up will be stagnant and possibility for microbial growth.	No	NA	Medium	-Whole installation shall be designed as complete drainable type to avoid such hold up and installation of pressure Gauges. - As the water is chlorinated the possibility of microbial grow this considerable less.	Acceptable	IQ & OQ
17.	SMBS	Chlorine content is high	Yes	The chlorine content in water shall lead to oxidation of the RO membrane and hence shall affect the final water quality.	Operational	The membrane shall need to be replaced frequently.	High	The dosing unit shall be provided for sodium meta-bi-sulfite (SMBS) addition to the water. The ORP sensor shall be provided for monitoring the chlorine content of water with auto dump valve.	Acceptable	IQ/OQ
18.	Antiscalant dosing	Not provided	No	Does not have impact on output quality of the water	Operational	Precipitation of silica on RO membrane can damage the membrane	Low	Anti-scalant dosing shall be provided before RO	Acceptable	IQ

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR PURIFIED WATER PRE-TREATMENT, GENERATION, STORAGE & & DISTRIBUTION SYSTEM

S.	Process	Risk	GMP	Justification	Other Risk	Justification	Risk Level	Risk Control		
19.		Microbial growth in filters.	Yes	During no n operation of the system the water hold up will be stagnant an d possibility for microbial growth.	No	NA	Medium	-System to be designed with sanitization facility. - As the water is chlorinated the possibility of microbial growth is considerable less.	Acceptable	IQ & OQ
20.	Industrial RO unit	Not provided. Sampling after RO is not possible.	Yes	RO unit is required to generate process water required for purified water generation system. Water quality shall not be checked	No	NA	High	Industrial RO unit shall be provided where water is separated from dissolved salts in solution by filtering through a semi permeabl e membrane Sampling point after RO shall be provided and from the R.O product water tank.	Acceptable	IQ/OQ
21.	Feed Pump for Reverse Osmosis -1	Water flow rate is not sufficient.	No	NA	Operational	-If sufficient water flow is not available cavitation of the pump takes place. - Pump can't deliver the required pressure of R.O system.	Medium	It should be designed in such a way that the water passing through CF, should be equipped with level indicator and controller to give a undisturbed continuous flow to the R.O.	Acceptable	IQ & OQ

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR PURIFIED WATER PRE-TREATMENT, GENERATION, STORAGE & & DISTRIBUTION SYSTEM

S. No.	Process steps/component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
22.	Industrial RO unit	Various process parameter like pH, conductivity, flow rate are not monitored	Yes	Critical GMP process parameter	No	NA	High	The RO unit shall be provided with the provision for monitoring, indicating and controlling the pH, conductivity and flow rate of water. If the output water is not meeting the desired result the water will be drained without collecting in the potable water tank.	Acceptable	IQ/OQ
FINAL TREATMENT										
23.	Industrial RO unit	Possibility of microbial growth in the industrial R.O	Yes	Purified water quality will be affected.	No	NA	High	The R.O shall be chemically sanitizable, and the system shall be provide with CIP system to clean and sanitize the R.O. SOP for sanitization and interval for sanitization shall be adopted during validation. The R.O filtered Potable water shall be collected in the HDPE tank for easy cleaning.	Acceptable	IQ/OQ & PQ.
24.	Industrial RO-2	Water quality fails at out let of RO+EDI unit.	Yes	Water quality must meet the specified conductivity	No	NA	High	The water shall be dumped and recirculated to soft water tank.	Acceptable	IQ& OQ
25.	pH correction dosing system	pH dosing not provided	No	Does not have impact on output water quality	Operational	Water with high or low pH may damage the RO membrane	Low	pH correction dosing system shall be provided before industrial RO	Acceptable	IQ

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR PURIFIED WATER PRE-TREATMENT, GENERATION, STORAGE & & DISTRIBUTION SYSTEM

S. No.	Process steps/component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
26.	RO+EDI unit	The operation is not auto controlled	Yes	The water quality may be affected by manual operation of the RO unit due to human errors.	Operational	The manual operation is difficult.	High	The RO unit shall be fully automatic and PLC based.	Acceptable	IQ& OQ
27.	EDI	Various process parameter like pH, conductivity, flow rate, TOC are not monitored. Sampling point after EDI not provided.	Yes	Critical GMP process parameter Water quality shall not be checked	No	NA	High	The unit shall be provided with the provision for monitoring, indicating and controlling the pH, conductivity and flow rate of water. Sampling point after EDI shall be provided	Acceptable	IQ& OQ
STORAGE AND DISTRIBUTION OF PURIFIEDWATER										
28.	Storage Tank	No storage of purified water before use.	No	The water quality shall not be affected if not stored.	Operational	It is difficult for providing several user points from the single point of generation	Low	The purified water generated shall be stored in a storage tank. The purified water from the RO+EDI shall be in the loop and returned to the in-feed water storage tank	Acceptable	IQ& OQ

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR PURIFIED WATER PRE-TREATMENT, GENERATION, STORAGE & & DISTRIBUTION SYSTEM

29.	Storage Tank	Low water level in the storage tank.	No	The water level shall not affect the water quality	Operational	No water in the tank, the Pump will run dry. It may lead to damage the pump and affect the process. Manual observation of the water level is difficult	Low	The storage tank shall be provided with level switch for water low level.	Acceptable	IQ& OQ

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR PURIFIED WATER PRE-TREATMENT, GENERATION, STORAGE & & DISTRIBUTION SYSTEM

S. No.	Process steps/component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
30.		Overflow of Purified water from storage tank.	No	Over flow water shall not affect the water quality	Operational	Overflow of excess water requires frequent cleaning of the area	Low	The Purified water buffer storage tank shall be provided with level indicator for high water level in the tank. The flow to the tank shall be stopped if tank is full and the water flow shall be in the loop return to the RO feed tank.	Acceptable	IQ& OQ
31.		Water stagnant in the purified water collection tank.	Yes	Possibility of Microbial growth.	No	NA	High	Spray balls will be considered at the return flow to create proper agitation.	Acceptable	IQ
A.3. Discharging of output										
32.	Distribution	Water stagnancy in the distribution line to different user points. No sampling point provided	Yes	Water contamination may increase due to the bio-load in the distribution line to different user points. Sampling point is required to check water quality in loop and user points	Operational	Removal of stagnant water each time before use shall be very difficult.	High	-The water distribution shall be in a loop system. The water shall be in continuous flow in the loop. -All pipeline shall have drainable slope of > 1:100 -The dead leg in the loop shall not be more than 1.5d. (d- diameter of the extended part) Sampling points shall be provided at return loop and all user points.	Acceptable	IQ& OQ

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR PURIFIED WATER PRE-TREATMENT, GENERATION, STORAGE & & DISTRIBUTION SYSTEM

S. No.	Process steps/component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
33.	Distribution	Flow rate in the loop is low.	Yes	Low flow rate tends to bio-film formation in the pipe.	No	NA	High	-Specified flow rate will be maintained in the loop at supply and return line. -Flow switch will be considered on the return line with VFD connection to the distribution pump.	Acceptable	IQ& OQ
34.	Distribution	Distribution loop is not provided with UV purifier	Yes	Water contamination may occur	No	NA	Medium	UV purifier shall be provided in the distribution loop with intensity meter for the UVlamp	Acceptable	IQ& OQ
B. Equipment Construction										
B.1. Internal Surface										
35.	Surface	Internal surface is not compatible with the water	Yes	May lead to the water contamination	No	NA	High	Metallic critical contact surfaces (piping, storage tank for purified water) shall be constructed of 316L grade stainless steel or better, electro polished, orbitally welded after the outlet of RO to the user point. For pretreatment stage all interconnecting pipes shall be GI / SS304. Supporting structure shall be of SS304 Diaphragm Valves: SS 316L, electro polished Purified water distribution pipeline shall be of SS316	Acceptable	IQ

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR PURIFIED WATER PRE-TREATMENT, GENERATION, STORAGE & & DISTRIBUTION SYSTEM

S. No.	Process steps/component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
36.	Polymeric materials	Polymeric materials are not compatible and are not replaceable	Yes	Shall lead to water contamination	No	NA	High	Gaskets (shall be high temperature &pressure resistant)als and O-rings coming in direct /indirect contact surfaces shall be made up of food grade polymeric materials only. The easy change of gaskets must be possible. Vendor shall provide the certificate for food grade polymeric material.	Acceptable	IQ
37.	Welding Joints	Weld joints not ground properly and are not passivated	Yes	Uneven and improperly ground weld joints will form a space for dust accumulation	No	Na	High	All welds shall be ground finished to < 1.2 µm Ra and properly passivated and orbital welding should be done.	Acceptable	IQ
38.	Finishing	Internal finish is not proper	Yes	May lead to improper cleaning of the surface which will lead to microbial growth hence product contamination	No	Na	High	All internal metallic surface shall be mirror polished with <0.4µmRa	Acceptable	IQ
39.	Joints	Joints are leaking	Yes	Water contamination may affect the final water quality.	No	NA	High	Suitable gaskets shall be provided for air tight connection which shall be replaceable. Quick release Tri-clover joints are recommended.	Acceptable	IQ
B.2. External Surface										

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR PURIFIED WATER PRE-TREATMENT, GENERATION, STORAGE & & DISTRIBUTION SYSTEM

S. No.	Process steps/component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
40.	Surface	Surface is not clean room suitable	Yes	May lead to the clean room contamination	No	NA	Medium	Supporting structures and frames shall be SS 304.	Acceptable	IQ
41.	Finishing	External finish is not proper	Yes	May lead to the microbial growth	No	NA	Medium	External surface shall be free from sharp edges, corners, crevices etc., all metallic external surface shall be matt finished	Acceptable	IQ
42.	Lubricant	Lubricant used is not food grade and is toxic in nature	Yes	Used lubricants coming in contact of the potential product contact surfaces may lead to the contamination of the product	No	NA	Medium	Lubricant shall not enter in processing zone of equipment. An y lubricant, if used in the equipment must be food grade andnon-toxic. Vendor shall provide the certificate	Acceptable	IQ
43.	Sensors	Sensors not calibratable	Yes	Non calibrated sensors may lead to false machine functions	No	NA	Low	It should be possible to calibrate sensors (3-point calibration, full loop calibration)	Acceptable	IQ
C. Equipment Automation										
44.	Process automation	Process parameters are not controlled automatically.	Yes	Possibility of human error leads to a process which is not validated	No	Na	High	The equipment shall control & detect failure mode automatically. The System shall be PLC based and fully automatic.	Acceptable	IQ& OQ

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR PURIFIED WATER PRE-TREATMENT, GENERATION, STORAGE & & DISTRIBUTION SYSTEM

S. No.	Process steps/component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
45.	Cleaning and sanitization automation	Cleaning and sanitization process parameters are not controlled automatically	Yes	Possibility of human error leads to a cleaning procedure which is not validated	No	NA	High	Cleaning process shall be performed by a automatically controlled system. Suitable PLC control shall be considered.	Acceptable	IQ& OQ
46.	Setting of process and viewing / monitoring of parameters	No means are provided to enter process parameters and indication of control values	Yes	Basic GMP requirement	No	NA	Medium	Human Machine interface: Loca l indication panel, local switch panel auto for operation of control value must be provided.	Acceptable	IQ& OQ
47.	Temperature	Control of jacket temperature is not provided	Yes	Temperature is key parameter for hot water sanitization	No	NA	Medium	Temperature indicator cum controller shall be provided for jacket temperature.	Acceptable	IQ
48.	GMP failure indication	No indication is provided in case of critical parameters are out of limit	Yes	Process critical control parameters out of limit may lead to the product of unacceptable quality	No	NA	High	System shall generate audio-visual alarm and print the alarms in case critical process parameters are out of limit.	Acceptable	IQ& OQ
49.	GMP failure indication	No indication is provided for critical component failure e.g. Pump	Yes	Water flow in the loop continuously is a GMP requirement	EHS	May lead to some accident	Medium	System shall generate audio-visual alarm and print the alarms in case of critical System failure.	Acceptable	OQ
50.	GMP failure indication	No indication is provided for utility supply failure	Yes	May lead to the water out of specification	No	NA	Medium	System shall generate audio-visual alarm and print the alarms in case of utility supply failure	Acceptable	OQ

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR PURIFIED WATER PRE-TREATMENT, GENERATION, STORAGE & & DISTRIBUTION SYSTEM

S. No.	Process steps/component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
51.	Electronic data control system	System does not comply 21 CFR part 11	Yes	It is a basic GMP requirement that software, if used to generate, process, store the quality critical electronic data must be validated and must comply 21 CFR Part 11 requirements	No	NA	Medium	Software used shall comply to 21 CFR part 11. vendor shall provide the 21 CFR part 11 compliance certificate.	Acceptable	IQ& OQ
52.	Electronic data control system	Uncontrolled access to the operating system	Yes	Unauthorized access may lead to uncontrolled change in critical process parameter	No	NA	High	System security shall be provided to access the operating system and configurable parameter values through access password (3 level access to operating parameter shall be preferred)	Acceptable	OQ
53.	Process Display and record printing	No process display and record printing system is provided	Yes	Basic GMP requirement	No	NA	Medium	Local display panel shall be provided to display critical parameter and batch printing system shall be provided for printing of critical process parameters	Acceptable	OQ
D. System Cleaning and sanitization										
54.	Cleaning	Cleaning is not possible	Yes	Cleaning is basic GMP requirement	No	NA	Medium	The external surface shall be smooth for easy manual cleaning. The storage tank and distribution system shall be hot water cleanable.	Acceptable	IQ& OQ

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR PURIFIED WATER PRE-TREATMENT, GENERATION, STORAGE & & DISTRIBUTION SYSTEM

S. No.	Process steps/component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
55.	Sanitization	Sanitization not possible	Yes	Sanitization of the water system is basic process and GMP requirement	No	NA	Low	The industrial RO shall be chemical sanitizable The RO shall be hot water sanitizable The storage tank and distribution line shall be hot water sanitizable	Acceptable	IQ& OQ
E. System safety										
56.	Electrical system	Electrical systems are not verified for safety	No	NA	EHS	May lead to an accident	Medium	All electrical systems shall be tested for safety and shall be provided with safety markings e.g. C.E. marking. The noise liberated by the system shall not be more than 80 db from 1m from the system.	Acceptable	IQ
57.	Electrical system	Emergency stop	No	NA	EHS	NA	Low	Emergency stop shall be in the accessible limit.	Acceptable	IQ
58.	Power failure	System doesn't comes to rest	No	NA	EHS	May lead to some accident	Medium	On power failure System must come to rest to protect operator and System itself	Acceptable	OQ
59.	Power failure	Power restart automatic	No	NA	EHS	May lead to a fatal accident	Medium	Power restart must not be automatic and human intervention must be required.	Acceptable	OQ

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR PURIFIED WATER PRE-TREATMENT, GENERATION, STORAGE & & DISTRIBUTION SYSTEM

S.No.	Process steps/component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
60.	Power failure	Compressed air is low	Yes	Improper function of pneumatic instruments leads to improper output.	Operational	May leads improper function of the system	High	Compressed air pressure shall be indicative with alarm if low. The total system shall be shut down if the compressed air is low.	Acceptable	IQ &OQ
F. Documentation										
61.	Vendor Documents	Technical documentation from vendor not adequate	Yes	Adequate technical documentation is basic GMP requirement for qualification and operation of the System	No	NA	Medium	▪ Vendor documentation (English) shall comprise: -Data sheets -Material certificates -Operating instructions -Maintenance instructions and intervals -Calibration instructions -Parts lists(sufficient detailed: part number, supplier, type) ▪ Drawings - P&I-diagrams - Electrical diagrams - (Certificates of initial calibration of sensors); GA drawings ▪ Running trial certificate. ▪ Certificate of bought out ▪ Relevant SOP components	Acceptable	OQ

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR PURIFIED WATER PRE-TREATMENT, GENERATION, STORAGE & & DISTRIBUTION SYSTEM

9.0 Summary and Conclusion:

- The risk assessment is performed to establish the design parameters of the equipments as to meet the desired performance of the System.
- The critical risks pertaining to GMP and other than GMP were analyzed with justification and mitigation procedures.
- For each recognized GMP-risk and other than GMP risks necessary measures are defined. Organizational measures, like SOP's, are also possible measures for special GMP-risks. The availability of these SOP's will be checked at the time of accomplishment to OQ of the system.
- To control the risk, various mitigation methods shall be verified through SOP's, operation & maintenance manuals, and calibration certificates at respective verification points.
- Based on Risk assessment, the URS shall be prepared.

"It is concluded that the **Risk Assessment** performed for the equipment will mitigate the risk of failures of critical parameters during design, commissioning, installation, operation and performance of the system".