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**CONCURRENT VALIDATION PROTOCOL**

<b>PROTOCOL NO</b>		<b><u>PURIFIED WATER SYSTEM</u></b>	<b>SUPERSEDES</b>	
<b>DATED</b>			<b>PAGE NO</b>	<b>Page</b>

1. PRE-APPROVAL

The per-approval of this concurrent validation protocol shall be the joint responsibility of Following:

<b>DEPARTMENT</b>	<b>NAME</b>	<b>DESIGNATION</b>	<b>SIGNATURE</b>	<b>DATE</b>
Production				
Engineering				
Validation (chemical analyst)				
Validation (Microbiologist)				
<a href="#">Quality Assurance</a>				

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## 2.0 OVERVIEW

The purified water system is installed (Discribe location in your plant ). The system is equipped with, a cation exchanger, anion exchanger, mixed bed, & two UV tubes. The plant has facility of recirculation of water. It has facilities for sanitization with sodium hypochlorite or formaldehyde, dechlorinate by sodium metabisulphite & to regenerate by back wash. At starting of raw water sand & activated charcoal bed are installed.

### 2.1 OBJECTIVE :

The concurrent validation shall assure that the water manufacture through purified water system, confirm to specified quality aspect viz. chemical & microbiological when analysed over the time period for 15 days.

### 2.2 PURPOSE :

To establish that, PURIFIED WATER being used in the manufacturing is as per the specification.

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2.3 RESPONSIBILITY :

Production Manager

Engineering Manager

Validation Manager

Quality Assurance Manager

2.4 REVALIDATION :

1. Any major modification in system.
2. Any major change in SOP of purified water system.
3. Any failure of acceptance criteria during.
4. Substitution of existing equipment by new equipment.

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3.0 EQUIPMENT DETAILS :

NAME OF EQUIPMENT	PURIFIED WATER PLANT
MAKE	AQUATECH
EQUIPMENT NO	xyz
LOCATION	PRODUCTION AERA

CLASSIFICATIO OF PARTS

1. Dosing pump
2. Cation bed
3. Anion bed
4. UV tube before mix bed
5. Conductivity meter before mixed bed
6. Mixed bed
7. Conductivity meter after mixed bed
8. UV tube after mix bed

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4.0 RELATED DOCUMENTS

4.1 STANDARD OPERATION PROCEDURE

SOP NO.

Operation procedure of purified water plant

4.2 IQ Report

Ref No.

Date:

4.3 OQ Report

Ref No.

Date:

4.4 PQ report

Ref No.

Date:

4.5 STANARD TEST PROCEDURE

SOP NO.

1.0 PROCEDURE FOR MONITORING THE QUALITY OF PURIFIED WATER XYZ\*

2.0 PROCEDURE FOR MONITORING THE QUALITY OF POTABLE WATER XYZ\*

\* CURRENT VERSION SOP TO BE FOLLOWED

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## 5.0 SYSTEM DESCRIPTION OF PURIFIED WATER PLANT

### 5.1 SCOPE :

The system has an installed capacity to generate 35,000 liters of water. It has facility to store collected water into 1000 its SS tank & recirculated to [Purified water](#) supply point in close loop with aid of pump to provide the water of desired quality.

### 5.2. SAMPLING PLAN :

The [validation](#) exercise plan has summarized as mentioned below.

1. Monitor the quality of raw water by sampling & analyzing of various locations. Collect sample from mentioned point of raw water. Monitor the sampling & analysis of raw water for 15 days.
2. Confirm the drain period decided for DM water by collecting after for 30 minutes from starting for 05 days.
3. Hold the Dm plant for 16 hrs & collect sample for analysis after 16 hrs without drain of water for one day.
4. Hold the Dm plant for 48hrs & collect sample for analysis after 48 hrs without drain of water to check the worst case for one day.
5. DM water system operating with continues water circulation:  
Run the DM plant continuously; collect the sample from mentioned points below once in day for 10 days.

\* The sampling may change by 1-2 days in case the weeks off.

### 5.3 SAMPLING LOCATION:

#### POTABLE WATER:

1. Before sand filter
2. After sand filter
3. After carbon bed
4. At Dm supply point

#### PURIFIED WATER

1. After cation bed
2. After Anion bed before UV
3. After anion bed After UV
4. After mixed bed before UV
5. After Mixed bed After UV

This sampling frequency is based in initi al validation data.

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#### 5.4 SAMPLING PROCEDURE :

Sampling shall be done as per SOP xyz & ABCD for purified water & potable water respectively from the points shown in water flow diagram.

#### 6.0 ANALYTICAL PLAN

The test requirements shall be determined based on demand of operation or function. For example final potable water shall be evaluated for both chemical & microbiological (both TVC & pathogens) other points are tested for chemical & TVC  
Final purified water analyzed for both chemical & microbiological analysis.

Potable & purified water must passes as followings criteria. The intermediate sample are tested for date generation in support to validation plan.

The analysis requirements may change based on the result of the validation stages.

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7.0 ACCEPTANCE CRITERIA:

7.1 POTABLE WATER

TESTS	SPECIFICATION
Description	Clear; colorless; odorless & tasteless liquid.
PH	7.0 – 8.5
Total Dissolved Solids (mg / lit)	NMT 500
Total Hardness (mg / lit)	NMT 200
Residual Chlorine (ppm)	0.2 – 2.0
Nitrates & nitrites (mg / lit)	NMT 45
Chloride (mg / lit)	NMT 200
Heavy Metals (ppm)	NMT 20
Conductivity (us / cm)	NMT 350
Total bacterial count (cfu / ml)	NMT 500
-E. coli	Must be absent
-Salmonella species	Must be absent
- S.aureus	Must be absent
-pseudomonas species	Must be absent

REFERENCE: YOUR SPECIFICATION



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## 7.2 PURIFIED WATER

TESTS	SPECIFICATION
Description	A clear, colorless, odorless & tasteless liquid.
pH	5.0 - 7.0
Acidity or Alkalinity	Meets requirements.
Oxidisable Substances	Meets requirements.
Chlorides	Meets requirements.
Sulphates	Meets requirements.
Nitrates (ppm)	NMT 0.2
Ammonium (ppm)	Meets requirements.
Caclium & magnesium	Meets requirements.
Heavy Metals (ppm)	NMT 0.1
Residue on Evaporation (% w/v)	NMT 0.001
*Conductivity (us/cm)	Meets requirements.
Total bacterial count (cfu/ml)	NMT 100
-E.coil	Must be absent
-Salmonella species	Must be absent
-S. aureus	Must be absent
-Pseudomonas species	Must be absent

REFERENCE: Your requirement as per BP/USP

8.0 DOCUMENTATION :  
 Qualification report  
 DQ, IQ, OQ, PQ

Other related documents  
 OC Analysis repost

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9.0 POST APPROVAL :

The post approval of this [concurrent validation protocol](#) shall be the joint responsibility of following.

DEPARTMENT	NAME	DESGNATION	SIGNATURE	DATE
Production				
Engineering				
Validation (chemical analyst)				
Validation (microbiologist)				
Quality Assurance				

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10.0 ANNEXURE :

1.0 FLOW DIGRAM OF SAMPLING POINTS -----Please show your own diagram we have removed ours ...ANNEXURE I

2.0 SAMPLING & ANALYSIS OF DIFFERENT SAMPLES ---- ANNEXURE II

3.0 QC ANAYSIS RECONCILLATION DATA OF PURIFIED & POTABLE WATER ----- ANNEXURE III

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# CONCORRENT VALIDATION

REPORT FOR

PURIFIED WATER SYSTEM

<b>CONCURRENT VALIDATION PROTOCOL</b>				
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## CERTIFICATION

Based on SOP No. \_\_\_\_\_ the purified water system operation, monitoring & analyzing purified water quality experimental plan protocol was designed.

As per validation protocol, the quality parameter was carried out. As per [SOP](#) No. \_\_\_\_\_ & USP/BP/EU/Japan/ pharmacopoeia standard. The result of validation was found to meet the acceptance criteria.

Hence the purified water plant stands validated for standard procedure.

This report been reviewed & certified by undersigned.

DEPARTMENT	NAME	DESIGNATION	SIGNATURE	DATE
Production				
Engineering				
Validation (chemical analyst)				
Validation (microbiologist)				
Quality Assurance				

CONCURRENT VALIDATION PROTOCOL				
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CONCLUSION :

It is concluded that DM water system design, construction & operational procedure are suitable for intended purpose & the system is capable of meeting the water quality, cGMP requirements & other regulatory obligation.

Water produced & handled by system meets all predefined chemical specification

Water produced & handled by system meets all predefined microbial specification.

Based on validation data, regeneration of plant is to be continued on weekly basis (first day week starting) Operate the PW plant at flow 300lit/ hr. Every day drain the water for first 30 minutes & then start for collection in SS storage tank.

Regeneration frequency was either 25 hours continuous purified water production or maximum 7500 lts (its a small one you may have big capacity,) of production quantity.

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**OBJECTIVE:**

To assure that the system will consistently produce water of required quality when operated in prescribed manner. This means that all physical aspects of system, related procedure, process & controls should function as per specification.

**REASON FOR VALIDATION:**

- Resin changes.
- To assure stable predictable operations & controls of water system.
- To assure the sampling frequency.
- To verify the quality limits.

**DOCUMENTATION:**

<u>SOP</u>	<u>SOP</u> No.
Operation & cleaning of purified water plant	XYZ
Procedure for monitoring the quality of purified water	XYZ
Procedure for monitoring the quality of potable water	XYZ

\*Current version sop to be followed

Standard test procedure for purified & potable water analysis is as in Specification x & y respectively

**EQUIPMENTS DETAILS**

Flow chart Refer Annexure I

**SUMMARY OF RESULTS**

Test results Refer Annexure III

**SAMPLING PROCEDURE**

Followed SOP No. ABCD\*, XYZ\* & validation protocol

QC ANALYSIS REPORTS Refer Annexure III

## SUMMARY OF FLOW CHART

1. BEFORE SAND FILTER
2. AFTER SAND FILTER
3. AFTER CABON FILTER
4. AT DM SUPPLY
5. AFTER CATION BED
6. AFTER CATION BED BEFORE UV
7. AFTER CATION BED AFTER UV
8. AFTER MIXED BED BEFORE UV
9. AFTER MIXED BED AFTER UV
10. USER POINT

UV Imp  
Conductivity meter O

Prepared by	Checked by	Approved by
Date:	Date:	Date:

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RECONCILLATION DATA OF WATER VALIDATION

SAMPLE	TOTAL VIABLE COUNT	PATHOGENS ( SPECIFIC MICRO ORGANISM )				pH.	CONDUCTIVITY µS/cm	Total hardness Mg/lit	Resi
POTABLE H2O BEFORE SAND BED	210	NA	NA	NA	NA	7.92	310	80	
POTABLE H2O AFTER SAND BED	190	NA	NA	NA	NA	7.90	315	76	
POTABLE H2O AFTER CARBON BED	180	NA	NA	NA	NA	7.86	308	72	
POTABLE H2O DM Supply	160	AB	AB	AB	AB	7.90	312	78	
PURIFIED H2O AFTER CATION/ BEFORE ANION	40	NA	NA	NA	NA	5.30	2.20	NA	
PURIFIED H2O AFTER ANION/ BEFORE UV	45	NA	NA	NA	NA	5.45	2.18	NA	
PURIFIED H2O AFTER ANION/ AFTER UV	40	NA	NA	NA	NA	5.65	2.10	NA	
PURIFIED H2O AFTER MIX- BED/BEFORE UV	35	NA	NA	NA	NA	5.90	1.90	NA	
PURIFIED H2O AFTER MIX-BED/ AFTER UV -48 hrs	30	AB	AB	AB	AB	6.10	1.72	NA	
PURIFIED H2O AFTER CATION/ BEFORE ANION 30 min.	45	NA	NA	NA	NA	5.20	2.20	NA	
PURIFIED H2O AFTER ANION/ BEFORE UV	45	NA	NA	NA	NA	5.35	2.18	NA	
PURIFIED H2O AFTER ANION/ AFTER UV	40	NA	NA	NA	NA	5.40	2.05	NA	
PURIFIED H2O AFTER MIX- BED/BEFORE UV	30	NA	NA	NA	NA	5.75	1.90	NA	
PURIFIED H2O AFTER MIX-BED/ AFTER UV 30 min.	30	AB	AB	AB	AB	6.20	1.80	NA	
POTABLE H2O BEFORE SAND BED	220	NA	NA	NA	NA	7.82	320	78	
POTABLE H2O AFTER SAND BED	210	NA	NA	NA	NA	7.80	318	80	
POTABLE H2O AFTER CARBON BED	180	NA	NA	NA	NA	7.80	322	82	
POTABLE H2O DM Supply	170	AB	AB	AB	AB	7.82	316	80	
PURIFIED H2O AFTER CATION/ BEFORE ANION continue	50	NA	NA	NA	NA	5.10	2.40	NA	
PURIFIED H2O AFTER ANION/ BEFORE UV	45	NA	NA	NA	NA	5.25	2.30	NA	
PURIFIED H2O AFTER ANION/ AFTER UV	40	NA	NA	NA	NA	5.60	2.15	NA	
PURIFIED H2O AFTER MIX- BED/BEFORE UV	40	NA	NA	NA	NA	5.75	1.90	NA	
PURIFIED H2O AFTER MIX-BED/ AFTER UV continue 30 min.	30	AB	AB	AB	AB	6.05	1.80	NA	
Prepared by		Checked by				Approved by			

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**PROPOSED VALIDATION PLAN SAMPLING FREQUENCY & ANALYSIS REQUIREMENT OF PURIFIED WATER**

STARTING DATE	SAMPLING POINTS	SAMPLING FREQUENCY	SAMPLING DURATION	VALIDATION EXECISE PERIOD	MICRO TESTIG	CHEMICAL TESTING	DATE OF COMPLETION
<b>A) DM WATER SYSTEM OPERATION WITHOUT CONTINOUS WATER CIRCULATION</b>							
	POTABLE H2O BEFORE SAND BED	DAILY	ONCE	15 DAYS	TVC	pH, COND, TDS, HARDNESS, CHLORIDE, CHLORINE	
	POTABLE H2O AFTER SAND BED	DAILY	ONCE	15 DAYS	TVC	pH, COND, TDS, HARDNESS, CHLORIDE, CHLORINE	
	POTABLE H2O AFTER CARBON BED	DAILY	ONCE	15 DAYS	TVC	pH, COND, TDS, HARDNESS, CHLORIDE, CHLORINE	
	POTABLE H2O DM Supply	DAILY	ONCE	15 DAYS	TVC & PATHOGEN	pH, COND, TDS, HARDNESS, CHLORIDE, CHLORINE	
	PURIFIED H2O AFTER CATION/ BEFORE ANION	DAILY	ONCE AFTER 30 MIN	5 DAYS	TVC	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
	PURIFIED H2O AFTER ANION/ BEFORE UV	DAILY	ONCE AFTER 30 MIN	5 DAYS	TVC	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
	PURIFIED H2O AFTER ANION/ AFTER UV	DAILY	ONCE AFTER 30 MIN	5 DAYS	TVC	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
	PURIFIED H2O AFTER MIX-BED/ BEFORE UV	DAILY	ONCE AFTER 30 MIN	5 DAYS	TVC	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
	PURIFIED H2O AFTER MIX-BED/ AFTER UV	DAILY	ONCE AFTER 30 MIN	5 DAYS	TVC & PATHOGEN	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
	PURIFIED H2O AFTER CATION/ BEFORE ANION	ONCE	16 HRS HOLD	1 DAY	TVC	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
	PURIFIED H2O AFTER ANION/ BEFORE UV	ONCE	16 HRS HOLD	1 DAY	TVC	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
	PURIFIED H2O AFTER ANION/ AFTER UV	ONCE	16 HRS HOLD	1 DAY	TVC	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
	PURIFIED H2O AFTER MIX-BED/ BEFORE UV	ONCE	16 HRS HOLD	1 DAY	TVC	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
	PURIFIED H2O AFTER MIX-BED/ AFTER UV	ONCE	16 HRS HOLD	1 DAY	TVC & PATHOGEN	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
	PURIFIED H2O AFTER CATION/ BEFORE ANION- 48 hrs	ONCE	48 HRS HOLD	1 DAY	TVC	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
	PURIFIED H2O AFTER ANION/ BEFORE UV	ONCE	48 HRS HOLD	1 DAY	TVC	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
	PURIFIED H2O AFTER ANION/ AFTER UV	ONCE	48 HRS HOLD	1 DAY	TVC	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
	PURIFIED H2O AFTER MIX-BED/ BEFORE UV	ONCE	48 HRS HOLD	1 DAY	TVC	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
	PURIFIED H2O AFTER MIX-BED/ AFTER UV -48 hrs	ONCE	48 HRS HOLD	1 DAY	TVC & PATHOGEN	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
<b>B) DM WATER SYSTEM OPERATION WITH CONTINOUS WATER CIRCULATION</b>							
	PURIFIED H2O AFTER CATION/ BEFORE ANION continue	DAILY	ONCE	10 DAYS	TVC	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
	PURIFIED H2O AFTER ANION/ BEFORE UV	DAILY	ONCE	10 DAYS	TVC	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
	PURIFIED H2O AFTER ANION/ AFTER UV	DAILY	ONCE	10 DAYS	TVC	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
	PURIFIED H2O AFTER MIX-BED/ BEFORE UV	DAILY	ONCE	10 DAYS	TVC	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
	PURIFIED H2O AFTER MIX-BED/ AFTER UV continue	DAILY	ONCE	10 DAYS	TVC & PATHOGEN	pH, COND, , CHLORIDE, RESIDUE ON EVAPORATION	
PREPARED BY :	CHECKED BY		APPROVED BY				
DATE :	DATE		DATE				