

OPERATIONAL QUALIFICATOIN PROTOCOL CUM REPORT FOR PURE STEAM GENERATION AND DISTRIBUTION SYSTEM

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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR PURE STEAM GENERATION & DISTRIBUTION SYSTEM

EQUIPMENT ID. No.	
LOCATION	
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL CUM REPORT No.	NIL



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PROTOCOL PRE- APPROVAL: 1.0

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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2.0 **OBJECTIVE:**

- To prepare Operational Qualification Protocol Cum Report of Pure Steam Generation & Distribution System.
- To verify that the **Pure Steam Generation & Distribution System** operates in accordance with the Design and User Requirements as defined by set acceptance criteria and complies with relevant cGMP Requirements.
- To demonstrate that the System will operate reproducibly and consistently within its Operating Range.
- To confirm the Suitability of the Standard Operating Procedures for all routine activities associated with the System.
- Successful completion of this Operational Qualification activity will verify that the **Pure Steam** Generation & Distribution System meets all the acceptance criteria and is ready for PQ.

3.0 SCOPE:

- The Protocol Cum Report covers all aspects of Operational Qualification for the **Pure Steam Generation & Distribution System**.
- This protocol Cum Report will define the methods and documentation used to qualify the **Pure Steam Generation & Distribution System.**



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4.0 **RESPONSIBILITY:**

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol:

DEPARTMENTS	RESPONSIBILITIES		
	Preparation, Review, Pre Approval, Compilation and Post Approval of the		
	Operational Qualification Protocol cum Report.		
	Co-ordination with Production and Engineering to execute Operational		
Quality Assurance	Qualification Activity.		
	Monitoring of Operational Qualification Activity.		
	• Verification of Tests & Results.		
	• Compliance of Deficiency (if any) & Corrective Action (if any).		
	Review & Pre-Approval of Operation Qualification Protocol cum Report.		
	• Giving clearance to operate the unit.		
Production	• Execution of Operational Qualification activity.		
	• Ensure that the equipment operates as per protocol.		
	• Post Approval of Operation Qualification Protocol after Execution.		
	Review & Pre-Approval of Operation Qualification Protocol cum Report.		
	• To co-ordinate and support Operational Qualification activity.		
Fu sin sorin s	• Calibration of Process instruments.		
Engineering	• Ensure that the equipment is operates as per protocol cum report.		
	• Responsible for Trouble shooting (if occurs during execution).		
	• Post Approval of Operation Qualification Protocol cum report after Execution		



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5.0 EQUIPMENT DETAILS:

PURE STEAM GENERATION & DISTRIBUTION SYSTEM		
Equipment ID. No.		
Manufacturer's Name		
Supplier's Name		
Location of Installation		
Capacity	500 kg/hr.	
User Points	07 Nos.	

6.0 BRIEF SYSTEM DESCRIPTION:

6.1 <u>PURE STEAM GENERATION & DISTRIBUTION:</u>

Pure Steam Generator capacity 500 kg/cm² produces Pure steam as pyrogen free, Pure Steam. It operates on the Distillation as Unit Process. Sterile steam generation engross with Liquid to Vapor phase change to produce very high purity steam. It removes the impurities at sterile temperature without using any filtration medium.

PSG works on "Falling Film Evaporator" principle. It is most reliable method to produce pure steam. It employs high temperature (Sterile state temperature), which assures constant production with high quality. As unit does not have moving parts, it demands very little maintenance.

Pure Steam is used for steam sterilization in autoclave, pipelines, tanks, furmentors and humidification of sterile area.

The system designed to remove microbial contamination by Three Stage Separation.

PSG has single effect unit. It comprise of a inner most evaporator (Shell & Tube heat exchanger), an intermediate separator and outer columns. Source of energy for the effect is Boiler Steam.

Feed Purified water is preheated by waste recovery method and enters the first effect from tube side. Specially designed distribution plate ensures the water falls down the tube as a "Thin film". The falling film is heated with plant steam and causing it to a instant flash evaporation. This flash evaporation helps the steam to leave behind the heavier particles or droplets. (First Stage of Separation).This



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Transformation from water to steam significantly increases the velocity as it approaches the bottom of the column with high pressure.

This vapour as it moves outside the tubes is forced to change its direction to a 180° urn. This directional changes induces the separation of large water droplets (Secondary Separation), which fall into the bottom of the column, where they are collected with excess feed water that has not evaporated. As the steam moves upwards, the spirals provided on the shell of the evaporator force the steam to move in a circular path. The resulting centrifugal action forces the remaining microscopic droplets and impurities including the Endotoxin to the outer surface, which then gets blown down through the windows provided on the separator. (Third Stage Separation) the resulting steam is Pure Pyrogen free sterile Steam.

The Pure Steam Generator consists of:

- One Column Shell
- One Main Heat Exchanger.
- Two Pre-heaters.
- Feed water line with multistage pump.
- NCGR system with sampling arrangement.
- Boiler steam inlet line.
- Pure steam outlet line.
- Boiler steam condensate line with steam trap.
- Excess feed water (un-evaporated) line.
- Automatic control panel with HMI.



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7.0 PRE –QUALIFICATION REQUIREMENT:

7.1 Verification of Documents:

Verify that the DQ/IQ of the **Pure Steam Generation & Distribution System** have been executed and approved.

Verify that SOP for Operating, Cleaning and Preventive Maintenance of the **Pure Steam Generation & Distribution System** has been prepared.

The following lists all the SOP's and formats, as draft documents that are related to the operation of the

Pure Steam Generation & Distribution System. The validation team should make necessary

amendments to those and record the status on the checklist that will be attached to the report.

S. No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	DQ Protocol Cum Report				
2.	IQ Protocol Cum Report				
3.	Operational qualification protocol cum report of Pure Steam Generator and Distribution				
4.	Cleaning and Sanitization of Pure Steam Generator and Distribution				
5.	Hydro test procedure				
6.	Passivation Procedure				
7.	Slope verification Procedure				
8.	Boroscopy Procedure				
9.	Drainability Procedure				
10.	Welding Procedure				

Check list to be filled by the validation team and attached to the report.



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8.0 **CRITICAL VARIABLES TO BE MET:**

8.1 **Testing of Main Panel/Control Panel:**

To verify the response of the Equipment at the input from various Push Buttons/Switches on control

or Main Panel is as per the System Design.

8.1.1 Procedure:

Give inputs from the various push Buttons & Switches on Control Panel/Main Panel and observe the response from the Machine.

8.1.2 Acceptance Criteria:

The Equipment will respond as per the System Design.

Operational Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
Main Control Panel T	Cesting:		
Main Panel Main	Indicating Lamp on main Panel		
Switch switched on	Shall Glow		
Press emergency stop	Display will shows "Emergency		
button	Stop" & Feed pump will stop, all		
	valves will get OFF & dumping		
	valve will get ON/OFF as per		
	valve Position		
Release emergency	Feed pump will start valves will		
stop button	get On as per interlocking &		
	dumping valve will get OFF		

Checked By: (Engineering) Sign & Date	Verified By: (Quality Assurance) Sign & Date
Inference:	
	Reviewed Rv•
	(Manager QA)

(Sign & Date)_



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8.2 Operational Checks:

Instrument Calibration:

The validation team will test and record the calibration data for the instruments that are going to be used for the calibration of the various equipment in the **Pure Steam Generation and Distribution system**. In cases where the calibration instruments are calibrated/ certified by an external agency, a certificate for the calibration should be attached to the OQ report.

The following checklist should be completed during the Operational qualification by the validation team and added to the report.

S.No.	Name of the Instrument	Calibration Done on	Calibration Due	Calibration
			on	verified by
1.	Pressure transmitter			
2.	Pressure gauge for boiler steam inlet			
3.	Pressure gauge for feed water			
4.	Pressure gauge for pure steam.			
5.	Pressure switch for operating air pressure			
6.	Pressure switch for feed water			
7.	Pressure switch for loop system			
8.	Temperature sensor for boiler plant steam inlet			
9.	Temperature sensor cum transmitter for pure steam outlet			
10.	Level sensor for column			
11.	Flow meter for feed water			
12.	Conductivity sensor for feed water			
13.	Conductivity sensor for pure steam			

Checked By: (Engineering) Sign & Date	Verified By: (Quality Assurance) Sign & Date	
Inference:		
	Reviewed By: (Manager QA) Sign & Date	





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8.3 CRITICAL VARIABLES TO BE MET:

List of Operational Checks on the System.

After starting the system according to the draft SOP, the validation team should perform the following Operational checks to the system according to the specified details that are described in the following checklist.

• <u>PURE STEAM GENERATION & DISTRIBUTION SYSTEM</u>

8.3.2 Feed Water Pumps:

Operate the system as specified by SOP with all points of use closed, perform checks, take readings and record them in the present check list. Check that Electrical connection to pump is done.

Fix the flow meter to the discharge end of the pump. Switch on the supply. Start the pump. Check the rotation of pump. Check for abnormal noise.

Check for any leakages. Check the pressure reading at pressure gauge installed at pump discharge. Check the discharge through pump on flow meter.

Part involved	Tag	Check	Specifications	Results	Checked by	Verified by
Pump	MP1	Direction of rotation	Clockwise from non- driving end			
		Abnormal noise	Absent			
		For leakage	No leakages			
		Abnormal noise	Absent			





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8.3.3 Column Assembly:

Part involved	Tag	Check	Specifications	Results	Checked by	Verified by
Column	CA-301	Column Assembly	Inlets /Outlets	Not open to atmosphere, no leakages		
		Pressure				

8.3.4 First pre heater assembly:

Part involved	Check	Specifications	Results	Checked by	Verified by
First Pre-Heater double tube sheet Assembly	Inlets /Outlets	Not open to atmosphere, no leakages			

8.3.5 Second pre heater assembly:

Second Pre-Heater	Inlets /Outlets	Not open to atmosphere,		
Assembly		no leakages		

8.3.6 Heat exchanger assembly:

Part involved	Tag	Check	Specifications	Results	Checked by	Verified by
Heat Exchanger Assembly	HA-301	Inlets /Outlets	Not open to atmosphere, no leakages			





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8.3.7 Heat Exchanger Assembly Drain:

Part involved	Check	Specifications	Results	Checked by	Verified by
Heat Exchanger Assembly Drain	Inlets/Outlets	Not open to atmosphere, no leakages			

8.3.8 Rota meter:

Part involved	Check	Specifications	Results	Checked by	Verified by
Tube Rota meter	Flow within specifications	100 -1000 LPH			





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8.3.9 Pneumatic Angle Valve:

Part involved	Tag	Check	Specifications	Results	Checked by	Verified by
Pneumatic Angle Valve	PN-43	Open and close correctly	When closed no leakage observed, no pressure drop			
Pneumatic Angle Valve	PN 2	Open and close correctly	When closed no leakage observed, no pressure drop			
Pneumatic Angle Valve	PN 44	Open and close correctly	When closed no leakage observed, no pressure drop			
Pneumatic Angle Valve	PN-53	Open and close correctly	When closed no leakage observed, no pressure drop			
Pneumatic Angle Valve	PN 61	Open and close correctly	When closed no leakage observed, no pressure drop			





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8.3.10 Diaphragm Valve:

Part involved	Tag	Check	Specifications	Results	Checked by	Verified by
Diaphragm Valve	DP-1	Open and close correctly	When closed no leakage, no pressure drop			

8.3.11 Conductivity Sensor & Transmitter:

After having checked the calibration status of the different conductivity indicators, take the readings during operation and report.

Part involved	Tag	Check	Specifications	Results	Checked by	Verified by
Conductivity Sensor	CS-1	Conductivity within specifications	0 to 10 µs/cm			
Conductivity Sensor	CS-2	Conductivity within specifications	0 to 10 µs/cm			

8.3.12 Safety Valve:

Part involved	Tag	Check	Specifications	Results	Checked by	Verified by
Safety Valve	SV-1	Open and close correctly.	When closed no leakage			





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8.3.13 Pressure Gauges.

Operate the system as specified by SOP with all points of use closed, after checking that the different pressure gauges are correctly calibrated take readings and record them in the present check list.

Part involved	Tag	Check	Specifications	Results	Checked by	Verified
						by
Pressure Gauge	PG-1	Pressure within specifications.	0 to 16 kg/cm ²			
Pressure Gauge	PG-2	Pressure within specifications.	0 to 16 kg/cm ²			
Pressure Gauge	PG-3	Pressure within specifications.	0 to 7 kg/cm ²			

8.3.14 Pressure Transmitter:

Part involved	Tag	Check	Specifications	Results	Checked by	Verified by
Pressure Transmitter	PT-1	Pressure within specifications -1to 5 bar	Temperature within specifications			





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8.3.15 Pressure Switch:

Part involved	Tag	Check	Specifications	Results	Checked by	Verified by
Pressure Switch	PS-1	Trip entire system as per Interlocking	Set value within specifications			
Pressure Switch	PS-2	Trip entire system as per Interlocking	Set value within specifications			
Pressure Switch	PS-3	Trip entire system as per Interlocking.	Set value within specifications			
Pressure Switch	PS-4	Trip entire system as per Interlocking	Set value within specifications			

8.3.16 Level Sensor:

Part involved	Tag	Check	Specifications	Results	Checked by	Verified by
Level Sensor	LS-1	Work Effectively	Level within specification			





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8.3.17 Temperature Sensors & Transmitter:

Operate the system as specified by SOP, after checking that the different temperature probes are correctly calibrated take readings and record them in the present check list.

Part involved	Tag	Check	Specifications	Results	Checked by	Verified
						by
Temperature	TS-1	Temperature within	0-200°C			
Sensor		specifications				
Temperature	TS-2	Temperature within	0-200°C			
Sensor cum		specifications				
Temperature	TS-3	Temperature within	0-200°C			
Sensor cum		specifications				
Transmitter						

8.3.18 Ball Valve:

Part involved	Tag	Check	Specifications	Results	Checked by	Verified by
Ball Valve	BV-1	Open and close correctly.	When closed no leakage observed.			
Ball Valve	BV-2	Open and close correctly.	When closed no leakage observed.			
Ball Valve	BV-3	Open and close correctly.	When closed no leakage observed.			
Ball Valve	BV-4	Open and close correctly.	When closed no leakage observed.			





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8.3.19 AIR FILTER REGULATOR:

Part involved	Tag	Check	Specifications	Results	Checked by	Verified by
Air filter regulator	APR-1	Open and close	Air Pressure within			
		correctly no leakage.	specification			

8.3.20 Non Returnable Valve:

Part involved	Tag	Check	Specifications	Results	Checked by	Verified
						by
Non- Returnable	NRV-1	Valve effectively open	When closed no leakage			
Valve			observed,			
Non- Returnable	NRV-2	Valve effectively open	When closed no leakage			
Valve			observed			
Non- Returnable	NRV-3	Valve effectively open	When closed no leakage			
Valve			observed.			

8.3.21 Steam Trap:

Part involved	Tag	Check	Specifications	Results	Checked by	Verified
						by
Steam Trap	ST-1	Tightness	When closed no leakage			
			observed			
Steam Trap	ST-2	Tightness	When closed no leakage			
			observed			
Steam Trap	ST-3	Tightness	When closed no leakage			
			observed			
Steam Trap	ST-4	Tightness	When closed no leakage			
			observed			





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8.3.22 Sampling Valves.

Observe every sample valve for leakage when closed. Open one by one completely and with the aid of a Class A measuring cylinder check the volume delivered in 5 min.

Part involved	Tag	Check	Specifications	Results Open condition	Results Closed Condition	Checked by	Verified by
Sampling Valve	SP-301	Open and close correctly.	When closed no leakage observed,	•			

8.3.23 Electric Control Panel

To conduct this operational check proceed as follows: Switch ON main supply win the PLC, select manual mode with SW1 switch and release

the emergency Stop button. Fill the Storage tank to High Level.

Part involved	Tag	Check	Specifications	observation	Checked by	Verified by
PLC	PLC-101	Emergency push Button	Work as per given system			
		Main supply switch	Work as per given system			
		Light indicator	Work as per given system			



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8.4 OPERATIONAL CHECKS ON ALARMS:

Provoke the following alarms and check for the result of the action and the signaling:

Description of alarm	Action	Observation	Observed By				
			(Engineering)				
			Sign& Date				
PURE STEAM GENERATION & DISTRIBUTION SYSTEM							
Emergency stop:							
EMERGENCY STOP	Emergency stop & check the						
	display &print will shows						
	fault "EMERGENCY						
	STOP " and feed pump will						
	stop &valve will OFF						
Release emergency stop	Release emergency stop						
button.	check display it shows						
	PROCESS OK " and feed						
	pump & all valve will on						
Air Pressure Low:							
Air Pressure switch is set at	Display will shows "AIR						
higher value than Actual air	PRESSURE LOW" &all						
Pressure from pressure	valve will close & Feed pump						
switch value,	stop.						
Air Pressure switch is set at	Display will shows						
Lower value than Actual air	"PROCESS OK" & all valve						
Pressure from switch value.	will open Feed pump start.						
GRC Water Level Low							
Stop air supply given to feed	"GRC WATER LEVEL						
water to GC valve, after	LOW " &feed pump will be						
some time check on the	OFF print will shows fault						
display							
Give air supply to feed water	after some time check on the						
to GC valve, after some time	display which show						
check on the display	"PROCESS OK" & teed						
	pump will be ON as per logic						
Boiler Steam Temperature L	OW						
Close boiler steam valve	Check on display &print will						
&wait till the boiler steam	shows fault "BOILER						
temperature decrease below	STEAM TEMP.LOW" &						
set temperature check on	feed pump will be stop						
display	&purging valve become ON.						



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Description of alarm	Action	Observation	Observed By (Engineering) Sign& Date
Open the boiler steam valve	Check on display it will show		
&wait till the boiler steam	"PROCESS OK" & feed		
temperature increase up to	pump will be ON &purging		
set temperature check on it	valve become OFF.		
display			
Feed Water Conductivity Hig	gh		
Decrease the set parameter	Display will shows		
value than existing	"F. W. conductivity High"		
conductivity	& Feed pump will stop.&		
	GRC to drain valve will open.		
Increase the set parameter	Display will shows "Process		
value than existing	ok" & Feed pump will		
conductivity	start.& GRC to drain valve		
	will close		
Pure Steam Conductivity Hig	çh		
Decrease the set parameter	Display & print will shows		
value than existing	fault "PURE STEAM		
conductivity	CONDUCTIVITY HIGH "		
Increase the set parameter	Display which will shows		
value than existing	"Process OK"		
conductivity check on			
display			
Pure Steam Pressure High			
Close the pure steam out let	check on display &print will		
valve &let the pure steam	shows fault "PURE STEAM		
pressure be increase higher	PRESSURE HIGH"		
than the set pressure for			
pure steam pressure high			
✓ on display &print			
will shows fault			
Pure Steam Pressure Low	· · · · · · · · · · · · · · · · · · ·		
open the pure steam outlet	Display shows "PROCESS		
valve to release the pure	OK"		
steam pressure			
Boiler steam temp. Low			



PHARMA DEVILS QUALITY ASSURANCE DEPARTMENT

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Description of alarm	Action	Observation	Observed By (Engineering) Sign& Date
Close the Boiler Steam Valve	Display shows "BOILER		
& Wait till the boiler steam	STEAM TEMP. LOW" &		
temp. decrease below set	Feed pump will stop.		
temp.			
Open the Boiler Steam Valve	Display shows "PROCESS		
& Wait till the boiler steam	OK " & Feed pump will start.		
temp. Increased up to set			
temp			
Feed Water Pressure Low			
Turn pressure setting knob	Display shows "F.W.		
clock wise to set pressure	PRESSURE LOW"		
more than actual pressure			
till relay of pressure switch			
gets OFF			
Turn pressure setting knob	Display shows "Process		
anti clock wise to set	OK"		
pressure less than actual			
pressure till relay of			
pressure switch gets ON			
Insufficient Feed Water			
Decrease Feed water inlet	Display shows		
pressure less than required	"INSUFF.FEED WATER"		
pressure as soon as water	& Feed Pump will stop		
pressure become less than			
required			
Increase the feed water inlet	Display which shows		
pressure so that pressure is	"PROCESS OK"& Feed		
maintained	pump will start		
Purging on problem			
Stop Air supply given to	Display will show		
Pneumatic Purging Valve	"PURGING PROBLEM" &		
Increase Feed water flow	Feed pump will stop		
rate. Allow water to			
accumulate in Last column			
till it reaches float switch			
high level. Wait for set			
parameter (Ensure that this			
stage will remain			
continuously for set value)			
	II		



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Description of alarm	Action	Observation	Observed By (Engineering)
			Sign& Date
Give Air supply to	Display shows "PROCESS		
pneumatic purging valve.	OK " & feed pump will start		
Now water will be drained			
out			
Purging Off problems			
Decrease Feed water Flow	Display shows "PURGING		
rates. Also Keep pneumatic	PROBLEM " with buzzer		
purging valve open	and feed pump will stop		
manually by turning			
manual operating screw of			
solenoid valve wait for			
purging fault off time			
Increased feed water flow	Display shows "PROCESS		
rate & keep pneumatic	OK " & feed pump will start.		
purging valve in auto			
operation. Ensure that			
water should reach up to			
level sensor. Purging valve			
will close after purging time			
Feed Pump outlet Pressure I	20W		
Setting knob clock wise to	Check on display will shows		
set pressure more than	fault "F.P OUT LET		
actual pressure till relay of	PRESSURE LOW" & feed		
pressure switch gets OFF	pump will stop.		
10 sec.			
Setting knob anti clock wise	Check on display will shows		
to set pressure less than	"PROCESS OK"		
actual pressure till relay of			
pressure switch gets ON.			
Feed Pump Over Load			
While pump running give	Check display which shows		
link between 24VDC &feed	the "FEED PUMP O/L"		
pump O/L i/p, immediately			
feed pump will stop			
automatically			
Remove link between	Check display which shows		
24VDC &feed pump O/L	the "PROCESS OK"		
i/p, immediately feed pump			
will start automatically			
Power Failure	· · · · · · · · · · · · · · · · · · ·		



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Description of alarm	Action	Observation	Observed By (Engineering) Sign& Date
Incase of non UPS supply	POWER FAILURE		
switch off main panel entire			
panel will off OR remove			
physical power fail input,			
&cycle will stop			
Incase of non UPS supply	Power fail after power ON		
switch ON main panel	process will start		
entire panel will ON OR			
connect power fail input			
again, &cycle will stop			
GRC Temperature Low			
Close boiler steam in valve	check on the display it will		
&wait till the GRC	shows fault on display& print		
temperature decrease below	"GRC TEMP.LOW"		
set temperature.			
Open the boiler steam in	Display shows "PROCESS		
PSG valve &wait the GRC	OK " & feed pump will ON		
temperature increases up to	GRC drain valve become		
set temperature.	OFF		
Checked By: (Engineering) Sign & Date		Verified By: (Quality Assuran Sign & Date	ice)
Inference			
			•••••
		Reviewed By:	
		(Manager QA)	
		Sign & Date	



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Sign & Date ____

8.5 Safety Features Verification:

To avoid damage to the operator or **Pure Steam Generation & Distribution System** while operating the Equipment.

8.5.1 Procedure:

- Operate the Equipment in Manual Mode as directed in the User Manual.
- While the Equipment is operating, shutdown the power to the main Control Panel. Record if the equipment stops in a Safe and Secure Condition.
- Perform same Test for three times.

8.5.2 Acceptance Criteria:

Operational Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
PURE STEAM GENE	RATION & DISTRIBUTION SYS	STEM	
Pure Steam Safety	Safety valve should open at 7.0		
Valve	Kg /cm ² Pressure		
Purging Valve	Purging valve should open when		
	column water level is high		
	Purging valve should open		
	when Boiler Steam temp. Low		
Boiler Steam Safety	Safety Valve should open at		
Valve	6.1Kg /cm ² Pressure.		
Earthing	Proper Earthing should be		
	provided.		

Checked By: (Engineering) Sign & Date	Verified By: (Quality Assurance) Sign & Date
Inference:	
	Reviewed By: (Manager QA)



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9.0	REFERENCES	
•	Design Qualification Protocol Cum Report	
•	GA and P&ID Drawings	
٠	Approved Design & Specification.	
•	Any Other Relevant documents.	
10.0	DOCUMENTS TO BE ATTACHED:	
•	Operational and Maintenance Manual	
•	Copy of Draft SOPs	
•	Any other Relevant Documents	
11.0	DEVIATION FROM PRE-DEFINED SPECIFICATIONS, IF AN	Y:
12.0	CHANGE CONTROL, IF ANY:	



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13.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):	
14.0	CONCLUSION:	
15.0	RECOMMENDATION:	



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16.0 BBREVIATIONS:

- PQ : Performance Qualification.
- LPH : Liter per Hour.
- PSG : Pure Steam Generator.
- P &ID : Piping & Instrumentation Diagram.
- SOP : Standard Operating Procedure.



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17.0 PROTOCOL POST- APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			