



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT  
FOR  
PURE STEAM AIR GENERATION AND DISTRIBUTION SYSTEM**

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<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL CUM REPORT No.</b>	<b>NIL</b>



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**1.0 PROTOCOL PRE – 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)			



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**2.0 OBJECTIVE:**

The Objective of this Protocol cum Report is to provide the information about the specified **Pure Steam Generation & Distribution System** and will be presented for the inspection of equipment to verify the stated attributes & to assure the compliance of the following

- All safety features are accounted for all installation-testing reports are available and maintained on file.
- The system is installed according to the design specification and manufacture's recommendation.
- All critical Instrumentation has been identified for calibration of the equipment.
- The system meets the current Good Manufacturing practice (cGMP) requirements and all other regulatory obligations.
- No unauthorized or unrecorded modifications have taken place.
- All supporting utilities are properly connected.
- The **Pure Steam Generation & Distribution System** should be properly transferred/assembled to proposed operation area before installation.
- During the installation, validation team should ensure that the equipment is installed as per the requirement with all the essential parts & utility connections.
- Technical representative of machine manufacturer should be present during installation of equipment

**3.0 SCOPE:**

- This Protocol cum Report is applicable for Installation qualification of the M/s. .... make **Pure Steam Generation & Distribution System** to be installed at .....



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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 Report:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review and Approval of the Installation Qualification Protocol cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Installation Qualification.</li><li>• Monitoring of Installation Process.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Giving clearance to install the unit.</li><li>• Execution of Installation Qualification activity.</li><li>• Ensure that the equipment is installed as per Protocol cum Report.</li><li>• Review of Protocol cum Report.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• To co-ordinate and support Installation Qualification activity.</li><li>• Calibration of Process instruments.</li><li>• Ensure that the equipment is installed as per Protocol cum Report.</li><li>• Review of Protocol cum Report.</li></ul>



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**5.0 EQUIPMENT DETAILS:**

<b>PURE STEAM GENERATION &amp; DISTRIBUTION SYSTEM</b>	
<b>Equipment ID. No.</b>	
<b>Manufacturer's Name</b>	
<b>Supplier's Name</b>	
<b>Location of Installation</b>	
<b>Capacity</b>	500 kg/hr.
<b>User Points</b>	07 nos.

**6.0 BRIEF SYSTEM DESCRIPTION:**

**6.3 PURE STEAM GENERATION AND DISTRIBUTION SYSTEM:**

Pure Steam Generator 500 PSG produces 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" principal. 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, fermentors 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 innermost 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 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



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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 Main column shell
- Heat Exchanger,
- Two Pre-heaters,
- Feed water line with multistage pump and 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.

### **MAIN HEAT EXCHANGER**

It consists of two no. of concentric cylindrical pipes. The inner pipe is having heat exchanging seamless tubes with suitable arrangement. Preheated water from Pre-heater enters in to the seamless tubes and Boiler steam passes through the inner column and flows through the space among the tubes and heat exchange takes place forming pure steam which takes the passage between the space of inner & outer column. Spiral Baffles on outer surface of inner column helps to make the Pure Steam pyrogen free.

### **PRE HEATERS**

This consists of a cylindrical pipe with seamless tubes. The first Pre-heater takes heat from part of boiler steam supplied to the main heat exchanger and heats the feed water passing through the seamless tubes. The second pre-heater also takes heat from a part of boiler steam supplied to the main heat exchanger. Here the feed water heated almost up to boiling and passes to the main heat exchanger.

### **FEED WATER PUMP**

Vertical, Centrifugal pump having 67.7 Mtr Head, Flow (Q) 1.8 m<sup>3</sup>/Hr, 3 Phase Electrical Power Supply.

### **SAMPLING ARRANGEMENT**

It consists of two nos. of concentric pipes where inner pipe connected to pure steam line and feed water from the pump flows through the space between outer & inner pipes. The Pure Steam hence condenses and can be taken for testing the quality of water so produced as and when required by just opening the valve of pure steam at the top.



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**FEED WATER LINE**

This pipe line is fitted with pressure gauge, Rota meter.

**BOILER STEAM INLET LINE**

This pipe line is fitted with pressure gauge, safety valve, PT-100 sensor and gate valve.

**PURE STEAM OUTLINE**

This pipe line fitted with pressure gauge, safety valve, PT-100 sensor and pressure switch.

**BOILER STEAM CONDENSATE LINE**

These lines is fitted with steam trap and by pass line with a diaphragm valve and extended to preheater-1 & 2.

**EXCESS FEED WATER LINE**

This line is provided with a diaphragm valve. When there is excess water in Main Heat exchanger column then manually operate diaphragm valve to drains out the water.

**CONTROL PANEL**

The Details of the control panel components are provided in the check list the complete machine is fabricated all of SS316L material contact parts and SS304 non - contact parts.

**7.0 PRE -QUALIFICATION REQUIREMENT:**

**7.1 Verification of Documents & General Arrangement Drawing:**

To verify that Approved Drawings and supporting documents of **Pure Steam Generation and Distribution System** conform to the Design Qualification.

**7.1.1 Procedure:**

- Verify that Approved Drawings and supporting documents are available and conform to the DQ Protocol Cum Report.
- If any deviation from DQ is observed during IQ, the same has to be recorded giving reasons for Deviation and Approved. Deviation should be approved by Authorized Person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol.





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**7.1.2 Acceptance Criteria:**

- Drawing and documents should conform to Design Qualification Protocol cum Report. Any Deviations observed must be Recorded and Approved.
- The General arrangement should confer to the approved GA Drawing. Any deviations observed, must be recorded and approved.

Pre-Qualification Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign& Date
<b>Drawing:</b>			
• As build Isometric Drawing	Should be as per Approved Drawing		
• As build P & ID Drawing	Should be as per Approved P & ID Drawing		
<b>Certificates:</b>			
• MOC Certificates for Tubes & Fittings	Available/Not Available		
• Hydro Test Certificate	Available/Not Available		
• Passivation Certificate	Available/Not Available		
• Sanitization Certificate	Available/Not Available		
• Slope Verification Report	Available/Not Available		
• Manuals of major brought out items	Available/Not Available		
• Orbital Welding Printouts	Available/Not Available		
<b>Physical verification:</b>			
• Horizontal leveling of the equipment	Ok/Not ok		
• Positioning of the	Aligned vertically straight		



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Pre-Qualification Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
equipment/Erection of Loop System.	with sufficient space for maintenance		
• Any physical damage to the equipment, floor, or room walls.	No scratches or damage should exist.		
• Weldings	Orbital Welded for All Interconnecting Piping & Argon Welding for Non Contact Parts.		

Checked By:  
(Engineering)  
Sign & Date \_\_\_\_\_

Verified By:  
(Quality Assurance)  
Sign & Date \_\_\_\_\_

Inference:

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Reviewed By:  
(Manager QA)  
Sign & Date \_\_\_\_\_



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**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 Verification of Piping & Instrumentation:**

To verify that the Installation of **Pure Steam Generation & Distribution System** is carried out as per the approved P&ID Drawing.

**8.1.1 Procedure:**

- Perform Physical Check and verify that the Installation has been done as per the approved P&ID Drawing.
- Any Deviation in actual Installation from Approved P&ID has to be recorded and approved giving reasons for Deviation.
- As-built and Approved P&ID would form a part of the IQ Protocol cum Report.

**8.1.2 Acceptance Criteria:**

As-built to the Approved P&ID.

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
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**Piping and Instrumentation Diagram Verification:**

<ul style="list-style-type: none"> <li>• <b>P &amp;ID Verification</b></li> </ul>	The installed Piping and instrumentation should confirm to the approved P&ID. Any Deviations observed, must be Recorded and Approved.		
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**Checked By:**  
**(Engineering)**  
**Sign & Date** \_\_\_\_\_

**Verified By:**  
**(Quality Assurance)**  
**Sign & Date** \_\_\_\_\_

**Inference:**.....  
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**Reviewed By:**  
**(Manager QA)**  
**(Sign & Date)** \_\_\_\_\_



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**8.2 Verification of Major Components:**

To identify the Major Components of **Pure Steam Generation & Distribution System** and verify their technical Specifications with DQ, as basis.

**8.2.1 Procedure:**

- Verify that the Major Components have been installed as per their approved technical Specifications in DQ.
- Any Deviations to be recorded and approved giving reasons for Deviation and recommend follow-up action if required.

**8.2.2 Acceptance Criteria:**

The Technical Specifications of the Major Components should be as per the Approved Technical Data Sheets in DQ Protocol Cum Report.

<b>Installation Checks</b>	<b>Acceptance Criteria</b>	<b>Observation</b>	<b>Observed By (Engineering) Sign &amp; Date</b>
<b>PURE STEAM GENERATOR:</b>			
<b>FEED WATER PUMP:</b>			
<b>LOCATION:</b> Pump for feed water line			
<b>Make</b>	Grundfos		
<b>Type</b>	Vertical, Multi Stage		
<b>Model</b>	CRN-1-15		
<b>Flow &amp; Head</b>	1800 LPH @ 67.6 mwc		
<b>Mechanical Seal</b>	SiC/SiC		
<b>MOC</b>	SS316		
<b>Power</b>	0.75 KW, 3 Phase, 380/415V, 2840 RPM, IP-55		
<b>Quantity</b>	One		



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Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
Application	For pumping feed water		
Physically Checked	Yes/No		
Properly labeled	To be identified with Isometric & PI diagram		
<b>COLUMN SHELL ASSEMBLY:</b> <b>LOCATION:</b> Inlet line of boiler steam line			
Make	Pharmalab		
Type	Vertical		
Operating pressure	6.0 Kg/cm <sup>2</sup>		
Operating temperature	165 °C		
Design pressure	6.6 Kg/cm <sup>2</sup>		
Design temperature	175 °C		
Hydrostatic test pressure	9 Kg/cm <sup>2</sup>		
MOC	316 L		
Inside Surface Finish	Ra ≤ 0.6 μm, electro polished		
Outer surface finish	Mirror ( mechanical polished )		
Quantity	One		
<b>PRE-HEATER DOUBLE TUBE SHEET:</b> <b>LOCATION:</b> Pre heater column			
Make	Pharmalab		



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Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
Type	Vertical		
MOC	SS316L tube side		
Quantity	Two		
<b>Application</b>	Maintaining Pressure in column assembly		
<b>Physically Checked</b>	Variance if any		
<b>Properly labeled</b>	Variance if any		
<b>SAMPLING PRE HEATOR/HEAT EXCHANGER</b>			
<b>Make</b>	Pharma lab		
<b>Type</b>	Vertical		
<b>MOC</b>	SS316 L		
<b>Quantity</b>	One		
<b>Application</b>	Maintaining temperature in column assembly		
<b>Physically Checked</b>	Variance if any		
<b>Properly labeled</b>	Variance if any		
<b>CONDENSER INNER COLUMN DOUBLE TUBE SHEET</b> <b>LOCATION: For feed water</b>			
<b>Make</b>	pharmalab		
<b>Type</b>	Vertical		
<b>Operating pressure</b>	6.0 Kg/cm <sup>2</sup>		
<b>Operating temperature</b>	165 °C		
<b>Design pressure</b>	6.6 Kg/cm <sup>2</sup>		
<b>Design temperature</b>	175 °C		
<b>Hydrostatic test pressure</b>	9 Kg/cm <sup>2</sup>		
<b>MOC</b>	316 L		
<b>Inside Surface Finish</b>	Ra ≤ 0.6 μm, electro polished		



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Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
Physically Checked	Yes/No		
Properly labeled	To be identified with Isometric & PI diagram		
<b>PNEUMATIC VALVE (PN43)</b>			
Make	GEMU		
Type	Pneumatically Operated Angle Seat Valve		
MOC of Body	SS316L		
SIZE	DN-15 BTT End connection		
actuator	Single Acting		
Seal	PTFE		
QTY	01		
Location	At Column Purging Water Line (PN43)		
Application	Flow control of Purging line/Boiler Steam to NCGR drain/Pure Steam sampling		
Physically Checked	Variance if any		
Properly labeled	Variance if any		
<b>PNEUMATIC VALVE (PN2):</b>			
Make	GEMU		
Type	Pneumatically Operated Diaphragm Valve		
MOC of Body	SS316L		
SIZE	DN-15/20 Butt. End connection		
actuator	Single acting ( spring return )		
Seal	PTFE backed by EPDM		
QTY	01		
Location	At feed water in gas cooler (PN2)		
Location	At column purging water line to NCGR (PN53)		



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Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
<b>Plant Steam In Valve:</b>			
<b>Make</b>	MASCOT		
<b>Type</b>	Pneumatically operated globe valve		
<b>size</b>	2''		
<b>MOC of Bonnet</b>	Cast Iron, Epoxy Coated		
<b>End Connection</b>	Flanged end		
<b>Quantity</b>	One		
<b>Location</b>	At inlet of the plant steam (PN61)		
<b>Physically Checked</b>	Variance if any		
<b>Properly labeled</b>	Variance if any		
<b>Sanitary Non return valve (NRV1, NRV2 &amp; NRV3)</b>			
<b>Make</b>	ALFA Laval		
<b>Size</b>	DN 25 ( triclover end connection)		
<b>Quantity</b>	03		
<b>Location-01</b>	At conductivity sampling line (NRV1)		
<b>Location-02</b>	At vacuum break line of GRC ( NRV2)		
<b>Location-03</b>	At outlet side of feed pump(NRV3)		
<b>Physically Checked</b>	Variance if any		
<b>Properly labeled</b>	Variance if any		
<b>Diaphragm valve</b>			
<b>Make</b>	Crane		
<b>Moc</b>	SS 316L		





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Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
Size	DN25		
Diaphragm	PTFE		
Operation	Manual		
Qty	01		
Location	At Feed Water Inlet To PSG Line		
Properly labeled	Variance if any		
<b>Air regulator:</b>			
Make	FESTO		
Model	FRC-1/4-D-MINI		
Range	0-16 kg/cm <sup>2</sup>		
Size	¼"		
Qty.	01		
location	At The Inlet of the Compressed Air APR1		
Physically Checked	Variance if any		
Properly labeled	Variance if any		
<b>Steam Trap ST2 &amp; ST4</b>			
Make	Forbes Marshall		



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Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
<b>Model</b>	15NB FMTL53(threaded end connection)		
<b>TYPE</b>	Balanced pressure thermostatic trap		
<b>QTY</b>	02		
<b>LOCATION-1</b>	At first column air vent line (ST2)		
<b>LOCATION-2</b>	At Endotoxin Removal line (ST4)		
<b>Application</b>	Monitoring Pressure at boiler steam inlet line/For feed water line/Pure steam line		
<b>Physically Checked</b>	Variance if any		
<b>Properly labeled</b>	Variance if any		
<b>Steam Trap ST-1</b>			
<b>Make</b>	Forbes Marshall		
<b>Model</b>	SOFT31,25NB(threaded end connection)		
<b>TYPE</b>	Ball float type trap		
<b>Qty</b>	01		
<b>Location</b>	At plant steam condensate line of first condenser to pre heater PH2		
<b>Properly labeled</b>	Variance if any		
<b>Safety Valve( SV1)</b>			
<b>Make</b>	FROBES MARSHALL		
<b>Model</b>	40NB FMSRV		
<b>Size</b>	1 <sup>1/2</sup> " Threaded end connection		



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Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
<b>Range</b>	75-125 PSI		
<b>Qty</b>	01		
<b>Location</b>	At inlet of the plant steam line		
<b>Application</b>	Controlling flow of air Pressure in operating air pressure/For feed water/For loop system		
<b>Physically Checked</b>	Variance if any		
<b>Properly labeled</b>	Variance if any		
<b>Pressure Gauge (PG1)</b>			
<b>Make</b>	BAUMER		
<b>Model</b>	SS316		
<b>Dial Size</b>	100mm		
<b>Range</b>	0-16 Kg/cm <sup>2</sup>		
<b>Type</b>	Bourdon type		
<b>Qty</b>	01		
<b>Location</b>	At plant steam line		
<b>Physically Checked</b>	Variance if any		
<b>Properly labeled</b>	Variance if any		
<b>Pressure Gauge( PG2)</b>			
<b>Make</b>	Baumer		
<b>Model</b>	SS316L Contact Part		
<b>Dial Size</b>	100mm		
<b>Range</b>	0-16 Kg/cm <sup>2</sup>		
<b>Type</b>	Diaphragm type		
<b>Mounting</b>	Sanitary(Tri clover end connection)		



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Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
Qty	01		
Damping Liquid	glycerin		
LOCATION	At discharge side of feed pump		
<b>Pressure Gauge with Siphon Coil PG3</b>			
Make	Baumer		
MOC	SS316L Contact Part		
Dial Size	100mm		
Range	0-7 Kg/cm <sup>2</sup>		
Type	Diaphragm type		
QTY	01		
Mounting	Sanitary(Tri clover end connection)		
Damping Liquid	glycerin		
Location	At pure steam line PG3		
Application	Required Pressure monitoring		
Physically Checked	Variance if any		
Properly labeled	Variance if any		
<b>Manual Ball Valve BV2</b>			
Make	Shakti		
MOC	SS316L		
Dial Size	¾" (butt end connection)		
Type	3 piece ball valve		
Seal	PTFE		
Qty	01		



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Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
<b>Location</b>	At plant steam condensate drain through steam trapBV2		
<b>Physically Checked</b>	Variance if any		
<b>Properly labeled</b>	Variance if any		
<b>Control Panel</b>			
<b>Model</b>	Automatic With Manual Operation		
<b>Enclosure</b>	rittal		
<b>Panel Location</b>	On the skid		
<b>Size</b>	800mmWX1000mmHX300mmD		
<b>Contactora</b>	Hagger/Siemens/C&S/L&T		
<b>Over Load Relay</b>	Hagger/Siemens/C&S/L&T		
<b>Three pole rotary switch</b>	Salzer		
<b>Single pole rotary switch</b>	Salzer		
<b>Transformer</b>	Bhatt magnetic/Narmada		
<b>MCB</b>	Hagger/Siemens/C&S/L&T		
<b>Emergency off Push Button</b>	Schneider/telemecanic		
<b>PLC</b>	Allen Bradley		
<b>Display HMI</b>	PVP-600		
<b>Application</b>	Open and close correctly.		
<b>Physically Checked</b>	Variance if any		
<b>Properly labeled</b>	Variance if any		
<b>Conductivity sensor</b>			
<b>Make</b>	yokogawa		
<b>End Conn.</b>	Triclover end connection		
<b>MOC wetted parts</b>	SS316L		



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Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
Temp Range	0°C-110°C (Continuous)		
Qty.	02		
Location-1	At GRC Column CS1		
Location-2	At Pure Steam Condensate Sampling Point CS2		
Application	Controlling flow of Pure steam in Distribution line		
Physically Checked	Variance if any		
Properly labeled	Variance if any		
<b>Temperature Sensor TS1&amp;TS2:</b>			
Make	radix		
Model	Pt-100		
MOC	SS316L		
Range	0-200°C		
Type/class	PT100/A		
Connection	Triclover		
Qty	02		
Location-1	Plant Steam Line TS1		
Location-2	Plant Steam Line TS2		
Application	Temperature online display		
Physically Checked	Variance if any		
Properly labeled	Variance if any		
<b>Sanitary Pressure Transmitter (PT1):</b>			
Make	Jumbo		



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Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
Moc	SS316L		
Range	-1 to 5 BarG (0 to 6 bar absolute)		
Out put	4-20m Amp		
Qty	01		
Location	Pure steam line PT1		
Physically Checked	Variance if any		
Application	Distribution line of Pure Steam		
Properly labeled	Variance if any		
<b>Sanitary Pressure Switch (PS2):</b>			
Make	Orion		
Moc	SS316L tri clover end connection		
Diaphragm	Teflon		
Range	1-15 Bar		
Qty	01		
Location	Feed pump outlet line (PS2)		
<b>Pressure Switch (PS4):</b>			
Make	ORION		
Mounting	¼" BSPF		
Moc	Aluminum (threaded end connection)		
Range	0.5-7.0 Bar		
Qty	01		
Location	at air pressure line (PS4)		
<b>Sanitary Pressure Switch (PS3):</b>			
Make	Orion		
Moc	SS316L (tri clover end connection)		
Range	0.5-7.0 Bar		



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Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
Diaphragm	Teflon		
Qty	01		
Location	Pure Steam line (PS3)		
<b>Liquid Level Sensor:</b>			
Make	E+H		
Model	1" TC end connection		
Moc	316L		
Type	fork type		
Qty	01		
Location	on column (LS1)		
<b>Printer:</b>			
Make	Epson		
Model	LX-310,80 column ,dot matrix		
Qty	01		
Location	Below Panel Board		
<b>Pneumatic Valve:</b>			
Make	Gemu		
Moc of body	SS316L		
Type	pneumatically operated angle seat valve		
Seal	PTFE		
Actuator	Single acting (spring return)		
Qty.	01		
Location	at plant steam condensate by pass line (PN44)		
<b>Pneumatic Valve ( PNGRC2 &amp; PNGRC1 )</b>			
Make	GEMU		
Moc of Body	316L		
Type	pneumatically operated angle seat valve		





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Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
Size	DN15 (butt end connection)		
Seal	PTFE		
Actuator	Single Acting		
Qty	02		
Location-1	at gas removal line from gas cooler to Atmosphere (PNGRC2)		
Location-2	at drain line of gas removal column (PNGRC1)		
<b>Liquid Level Sensor a Gas Removal Column Assembly (LSL&amp;LSH)</b>			
Make	sick		
Moc	SS316L		
Type	float type		
Connection	Tri-clover		
Qty	02		
Location	at gas removal column (LSL & LSH)		
<b>Temperature Sensor at Gas Removal Column assembly (TS3)</b>			
Make	Radix		
Model	PT-100		
Moc	SS316L		
Type	PT100/A		
Range	0-200°C		
Qty	01		
Location	At GRC Column (TS3)		
<b>Manual Ball Valve (BV 4)</b>			
Make	Shakti		
Moc	SS316 L		
Size	½”( butt end connection)		
Type	3 piece ball valve		



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Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
Seal	PTFE		
Operation	Manual		
Qty	01		
Location	At Cooling Water Line For Sampling Taking Pre Heater HE2 (BV4)		
<b>Diaphragm Valve( DP2)</b>			
Make	crane		
Moc	SS316 L		
Size	DN15		
Diaphragm	PTFE		
Operation	Manual		
Qty	01		
Location	at sampling taking line (DP2)		
<b>Disposable Vent Filter (VF1)</b>			
Make	Millipore		
Medium	P.T.F.E		
Removal Rate	0.2 micron		
Qty	01		
Location	At GRC air vent line (VF1)		
<b>Heat Exchanger Column:</b>			
	<b>SHELL SIDE</b>	<b>TUBE SIDE</b>	
Operating Pressure	6 Kg/cm <sup>2</sup>	6 Kg/cm <sup>2</sup>	
Operating Temp.	98°C	165°C	
Design Pressure	6.6 Kg/cm <sup>2</sup>	6.6 Kg/cm <sup>2</sup>	
Design Temp.	175°C	175°C	
Hydro test Pressure	9 Kg/cm <sup>2</sup>	NA	
MOC	SS316L	SS316L	



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Installation Checks	Acceptance Criteria		Observation	Observed By (Engineering) Sign & Date
Inside surface finished	Ra ≤ 0.6 μm electro polished	mill polished		
Outer surface finish	Outer surface – mirror (mechanical polished)	mill polished		
<b>Utility requirement:</b>				
Plant Steam To PSG	At 6.0 kg/cm <sup>2</sup>	575 kg/h r		
Feed Water	At 1.5-2 kg/cm <sup>2</sup> pressure & temp 25°C	525 LPH		
Cooling Water as to HE2	at max 2kg/cm <sup>2</sup>	40LPH		
Electricity	At 415 V 50HZ, 3 phase + neutral + earthing	2 KW		
Compressed air	At 6 Kg/Cm <sup>2</sup>	5CFM		
Pure steam out let	MAX. 3kg/cm <sup>2</sup> pressure	----- -----		
<b>Material of construction:</b>				
Square Tubular Stand	Moc-304 Square / Rectangle Pipe Mounting – leg mounting (adjustable 50mm)			
Main Heat Exchanger	Quantity: 1 No. External: Diameter 8” NB x Schedule -5, SS 316L Internal: 6” NB x Schedule-5, SS 316L Seamless Tubes: 14mm OD x 18 SWG, SS 316L			
Construction features	As per GMP contact surfaces- crevice free, rounded corners nozzles – tri clover , fitting – sanitary dead leg ≤ 3D wherever technically possible			
Welding	Pipe joint : orbital/TIG welded , fabricated parts: TIG welded Orbital joints are passivated			
Specific requirement	End toxin test during FAT PLC validation at pharmlab after FAT soft copy of PLC programme			



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Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
Interconnecting Pipelines	SS 316L Quality Electro polished		
Structure	SS 304 Quality		
Sampling Valve	SS316L Quality, Diaphragm type, Saunders Make.		
Gaskets	MOC-PTFE /silicon, Type –Food Grade Temperature - 200°C		
Nut Bolts	SS 304 Quality		
Insulation	Rock wool with K 0.039w/mk		
Cladding	SS304 Quality, with Mirror finish		
Control Panel	Allen Bradley with HMI PVP-600 SS304 Quality, Automatic Panel with PLC and necessary switchgears.		
<b>Inter-locking &amp; safety system</b>			
Inter locking for feed pump MP1	<b>feed pump will off automatically</b> <ul style="list-style-type: none"> <li>boiler steam temperature low</li> <li>GRV water level low</li> <li>Purging on problem</li> <li>Purging off problem</li> <li>Air pressure low</li> <li>Emergency stop</li> <li>Feed water conductivity high</li> <li>F.P outlet pressure low</li> <li>Feed pump over load</li> <li>Pure steam pressure high</li> <li>Power fail</li> </ul>		
Inter locking for Purging Valve PN43	<b>Purging valve will start automatically</b> <ul style="list-style-type: none"> <li>Boiler steam temperature low</li> <li>Column water level high</li> <li>Purging time</li> </ul>		
Inter locking for feed water to G.C valve PN2	<b>Feed water to G.C valve close automatically</b> <ul style="list-style-type: none"> <li>Air pressure low</li> <li>GRC water level high</li> <li>Emergency stop</li> <li>Power fail</li> </ul>		



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Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
interlocking for GRC venting valve (PNGRC2)	<b>GRC venting valve will close automatically.</b> *air pressure low * emergency stop <ul style="list-style-type: none"> <li>• power fail</li> <li>• Process Stop</li> </ul>		
<b>SAFETY PROVISION</b>			
Condenser assembly	<b>Safety valve SV1 provided on the plant steam inlet at column assembly.</b> <ul style="list-style-type: none"> <li>• Set point 6.6 kg/cm<sup>2</sup></li> </ul>		
Feed pump	<b>Thermal over load relay</b> <ul style="list-style-type: none"> <li>• Feed water level switch at GRC (LSL)</li> <li>• Feed water non return valve (NRV3)</li> </ul>		
Column waste water level control	Fork type level controller (LS1)		
Operational safety alarm list	<ul style="list-style-type: none"> <li>• Emergency stop</li> <li>• Air pressure low</li> <li>• GRC water level low</li> <li>• Boiler steam temp low</li> <li>• feed water conductivity high</li> <li>• Pure steam conductivity high</li> <li>• Pure steam pressure high</li> <li>• Pure steam pressure low</li> <li>• Purging on problem</li> <li>• Purging off problem</li> <li>• Feed pump out let pressure low</li> <li>• Feed pump O/L</li> <li>• Power fail</li> <li>• GRC temp low</li> </ul>		
ON/OFF Switch	Pure Steam Generator System Should OFF/ON as required.		
Emergency Stop	Should trip the Entire System		



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**(Manager QA)**  
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**8.3 VERIFICATION OF UTILITY CONNECTION:**

To identify that all Utilities have been installed and connected to the **Pure Steam Generation & Distribution System** as per the DQ.

**8.3.1 Procedure:**

- Verify that all Utilities have been connected as per the requirements in Design Qualification.
- Carryout installation Checks for Utilities to ensure smooth Commissioning.
- The method of Checking & Observations has to be recorded.
- Any Deviations have to be recorded and approved giving reasons for the same.

**8.3.2 Acceptance Criteria:**

- The installation and connection of Utilities should be as per DQ.



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Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
<b>PURE STEAM GENERATION AND DISTRIBUTION SYSTEM :</b>			
<b>Electrical Supply</b>	0.75 KW, 3 Phase, 2840-2870 RPM,		
<b>Electric Connections</b>	Should be tight, weather proof and grounded		
	No loose hanging Cables		
	Well-insulated Electrical Wirings.		
	Located in a safe place well protected from Water Seepage during Machine or Floor Cleaning and also safe for Operator during Operation.		
<b>Electrical Drawing</b>	Electrical Drawing available either pasted in the inside of the circuit box or as in the Manual.		
<b>Compressed Air</b>	Quality: Filtered, Lubricated & free from oil Pressure: @ minimum 6 kg/cm <sup>2</sup> . After Regulator Line Size: ¼ ” Consumption: 1 to 2 CFM		
<b>Drain</b>	3” System Drain		
<b>Feed water</b>	Purified Water Conductivity < 1.3 us/cm		
<b>Boiler Steam</b>	Dry Saturated & Free from Oil, vapor and any impurities at minimum 6 Kg/cm <sup>2</sup>		



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**8.4 VERIFICATION OF MATERIAL OF CONSTRUCTION (MOC):**

To verify that the Material used for construction in Water for Injection Generation and Distribution System is as per the Design Requirement in DQ Protocol Cum Report.

**8.4.1 Procedure:**

- MOC has to be verified during installation by verifying the Certificates.
- Certificates for all Major Components to be identified.
- Material Test Certificates would form a part of the IQ Protocol.

**8.4.2 Acceptance Criteria:**

The Material of Construction of All Components should be as per DQ.

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
<b>PURE STEAM GENERATION &amp; DISTRIBUTION SYSTEM</b>			
<b>Square tubular stand</b>	Make with SS 304		
<b>Column shell</b>	Quantity: 1 No., SS 316L Seamless Tubes: 2.5 mm, 12 SWG,SHEET SS 316L		
<b>Condenser Shell</b>	Quantity: 1 No. , SS 316L Seamless Tubes: 14mm OD x 12 SWG, SS 316L		





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Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
Heat Exchanger	Quantity: 01 No., SS 316L 18 Swg, SS 316L		
Pre Heaters shell	Quantity: 02 No. Diameter 3" OD Thickness, SS 316L 16 SWG, PIPE		
Pre Heaters tubes	12.7mm OD 1.0 mm Thickness, SS 316L 16 SWG, PIPE		
Sampling heat exchanger	Quantity: 1 No. 2" OD X 0.065" thickness SS 316L Quality with Electro polished		
Interconnecting Pipelines	SS 316L Quality Electro polished		
Sampling Valve	SS 316L Quality, Diaphragm type, Saunders Make		
Gaskets	Teflon & Silicone food grade type temperature 200 °C		
Pure steam out let	3" tri-clover		
Feed water inlet	1.5' tri-clover		
Cooling water in	1.5' tri-clover		
Nut Bolts	SS 304 Quality		
Drain line-1 & 02	Ø152 dia. Flange 2" tri-clover		
Insulation	Glass Wool		
Cladding	SS304 Quality, with Mirror finish		
Control Panel	SS304 Quality, Automatic Panel with PLC and necessary switch gears.		



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**8.5 VERIFICATION OF SAFETY FEATURES:**

Before the start- up of the **Pure Steam Generation and Distribution System**, the following safety points should be reviewed and verified.

- Mechanical safety review.
- Electrical safety review.
- Pneumatic safety review.

**8.5.1 Procedure:**

- All the Safety features have to be verified during installation.

**8.5.2 Acceptance Criteria:**

All the Safety features should be as per DQ.

• **MECHANICAL SAFETY REVIEW.**

Visually inspect the installation for damage that may compromise safety during operation qualification work and future operation.

S.No.	Item to be checked	Sign to confirm acceptability to proceed to Operation qualification
<b>URE STEAM GENERATION &amp; DISTRIBUTION SYSTEM</b>		
1.	Machine as whole unit, Machine	



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S.No.	Item to be checked	Sign to confirm acceptability to proceed to Operation qualification
	components, for rusting Machine, for alignment, Lubrication.	
2.	Welding of Joints	
3.	Interlocking for Purging Valve	
4.	Safety Pressure Valves with Interlocking	
5.	Temperature Sensor Air Inlet: Machine shall trip if temperature increases beyond the set limit	
6.	Emergency off: to stop the process immediately	
7.	Three level Password protection	

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• **ELECTRICAL SAFETY REVIEW:**

Visual inspection of the electrical/electronic installation should be carried out to prevent any malfunctioning that may compromise electrical safety during operation of the equipment.

S. No.	Item to be checked	Sign to confirm acceptability to proceed to Operation Qualification
<b>PURE STEAM GENERATION &amp; DISTRIBUTION SYSTEM</b>		
1.	Main control panel unit. All terminals should be tightened properly. Wires should be bunched Electrical power cards to be checked.	

**Checked By:**  
**(Engineering)**  
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**• PNEUMATIC SAFETY REVIEW:**

S. No.	Item to be checked	Sign to confirm acceptability to proceed to Operation Qualification
<b>PURE STEAM GENERATION &amp; DISTRIBUTION SYSTEM</b>		
1.	Service unit (comprising of regulator-cum-filter and lubricator).	
2.	Regulator cum-filter, for accumulated (condensed) water (to be drained).	
3.	Lubricator unit, for oil level.	

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**8.6 VERIFICATION OF CRITICAL INSTRUMENTS CALIBRATION:**

To verify that all Critical Instruments for the Water for Injection Generation & Distribution System have been calibrated before starting Operation Qualification.

**8.6.1 Procedure:**

- All Critical Instruments are to be calibrated before installation and their Calibration Certificates have to be attached with IQ Protocol.
- The next due date for Calibration has to be noted.
- Deviations are to be recorded and follow-up action is to be recommended.

**8.6.2 Acceptance Criteria:**

- All Critical Instruments should be Calibrated and qualified for installation.

Instrument name	Purpose	Date of calibration	Calibration due date	Observed by (Engineering) Sign & date
Vernier Caliper	For checking of nozzle dimension			
Spirit level	For checking of leveling of equipment			
Multimeter	For checking electrical supply			
Molybdenum Kit	To confirm MOC of the stainless steel			

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**(Engineering)**  
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**8.7 GENERAL CHECKS AND LOCATION SUITABILITY:**

Parameters	Acceptance Criteria	Observation	Checked By (Sign & Date)
<b>PURE STEAM GENERATION &amp; DISTRIBUTION SYSTEM</b>			
Grouting and Mounting of Equipment/System	Equipment should be properly Grouted and mounted		
Balanced and leveled of Equipment/System	Equipment should be properly balanced and leveled		
All the metal parts should be properly grounded without any sharp edges	Metal parts should be properly grounded without any sharp edges		
Place of Installation	As per proposed layout/designated area		
Room Condition	Provision of clean environment should be provided		
Illumination	NLT 300 Lux		
<b>LIST OF POINTS OF USE:</b>			
PSG/SP-301 (Outlet line of PSG)	Should be available as per the drawing		
PSG/UP-302 (Inlet line of Bung processor)	Should be available as per the drawing		
<b>WELDING:</b>			
Type	Orbital		
Machine Name	TAMS/Swagelok		
Welder	Welder should be well qualified/certificate.		
Weld Log	Weld log should be maintained		
Boroscopy	Boroscopy should be done on at least 10% of joints		
No. of Orbital Weld Joints	As per as built isometric drawing		
No. of TC joints	As per as built isometric drawing		
No. of manual Weld Joints	As per as built isometric drawing		



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Parameters	Acceptance Criteria	Observation	Checked By (Sign & Date)
<b>INSULATION:</b>			
Type	Hot		
Material	Glass wool		
Cladding	24 SWG Aluminium above mezzanine floor & Pipe in pipe inside clean room		
Size for 2" pipe	50 mm		

**Checked By:**  
**(Engineering)**  
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**Verified By:**  
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**8.8 CHECKS ON DOCUMENTATION:**

The List of Documents (& drawing) to be verified for availability is as follow:

Specified Documents	Certificates Available/Not available	Remark
<b>PURE STEAM GENERATION &amp; DISTRIBUTION SYSTEM</b>		
Ball valve at plant steam condensate drain		
Ball valve for plant steam trap drain		
Diaphragm valve for pure steam outlet		
Pneumatic valve for purging		
Pneumatic valve		
Globe valve for boiler steam inlet		
Column assembly		
First pre-heater assembly		
Second pre-heater assembly		
Sampling point		
Non return valve for feed water		
Pressure transmitter		
Pressure gauge for boiler steam inlet		
Pressure gauge for feed water		
Pressure gauge for pure steam		
Pressure switch for operating air pressure		
Pressure switch for feed water		
Pressure switch for loop system		
Temperature sensor for boiler plant steam inlet		
Temperature sensor cum transmitter for pure steam outlet		
Level sensor for column		
Pump for feed water		
Flow meter for feed water		
Safety valve for plant steam inlet		
Safety valve for plant steam outlet		
Steam trap for steam condensate outlet		



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Specified Documents	Certificates Available/Not available	Remark
Steam trap for column air vent		
Sampling pre-heater assembly		
Conductivity sensor for feed water		
Conductivity sensor for pure steam		
Solenoid valve		
Non return valve		
Air eliminator		
Ball valve		
Actuated valve in PW line		
FRL		
Heat exchanger assembly		
Heat exchanger assembly drain		
PLC		

**Checked By:**  
**(Engineering)**  
**Sign & Date** \_\_\_\_\_

**Verified By:**  
**(Quality Assurance)**  
**Sign & Date** \_\_\_\_\_

**Inference:**.....  
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**Reviewed By:**  
**(Manager QA)**  
**Sign & Date** \_\_\_\_\_



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**9.0 REFERENCES**

**The Principle Reference is following:**

- Validation Master Plan
- Schedule-M – “Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.”
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.

**The following references are used to give addition guidance:**

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition/March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs, General. April 1, 1998.
- Code of Federal Regulations (CFR), Title 21, Part 211, Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals, April 1, 1998.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission’s working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.
- GMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.

**10.0 DOCUMENTS TO BE ATTACHED:**

- A Copy of Purchase order
- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Certificate of MOC
- Calibration Certificates
- Operation and Maintenance Manual
- GA and P & ID Drawings
- Any other relevant documents



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**11.0 DEVIATION FROM PRE-DEFINED SPECIFICATIONS, IF ANY:**

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**12.0 CHANGE CONTROL, IF ANY:**

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**13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):**

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**14.0 CONCLUSION:**

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**16.0 ABBREVIATIONS:**

PSG	: Pure steam generator
PVT.	: Private
LTD.	: Limited
No.	: Number
ID	: Identification
CQA	: Corporate Quality Assurance
IPR	: Intellectual Property Rights
cGMP	: Current Good Manufacturing Practices
SS	: Stainless Steel
POU	: Point of Use
m/s	: Meter per Second
GA	: General Arrangement
P & ID	: Piping & Instrumentation Diagram
MOC	: Make of Construction
kg/cm <sup>2</sup>	: Kilogram per centimeter square
mm	: Millimeter
PTFE	: Polytetra Fluoro ethylene
µm	: Micrometer
IP	: Indian Pharmacopoeia
LPH	: Liter per Hour
RPM	: Round per minute
OD	: Outer diameter
CFM	: Cubic feet per minute
MCDP	: Multicolumn distillation plant
ZDV	: Zero Dead Leg Valve
CFR	: Code of federal Regulation
ISPE	: International Society of Pharmaceutical Engineering
EU	: European Union



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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)			