PERFORMANCE QUALIFICATION REPORT FOR PURE STEAM GENERATION & DISTRIBUTION SYSTEM

EQUIPMENT ID No.	
LOCATION	
DATE OF QUALIFICATION	
SUPERSEDES REPORT No.	**NIL**

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1.0. REPORT PRE-APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0. OBJECTIVE:

- To compile the Validation report carried out as per Protocol for the **Pure Steam Generation & Distribution System** employed for providing continuously required quantity of WFI with the specified quality.

3.0. SCOPE:

The scope of this particular validation report is applicable to the **Pure Steam Generation & Distribution System** installed.

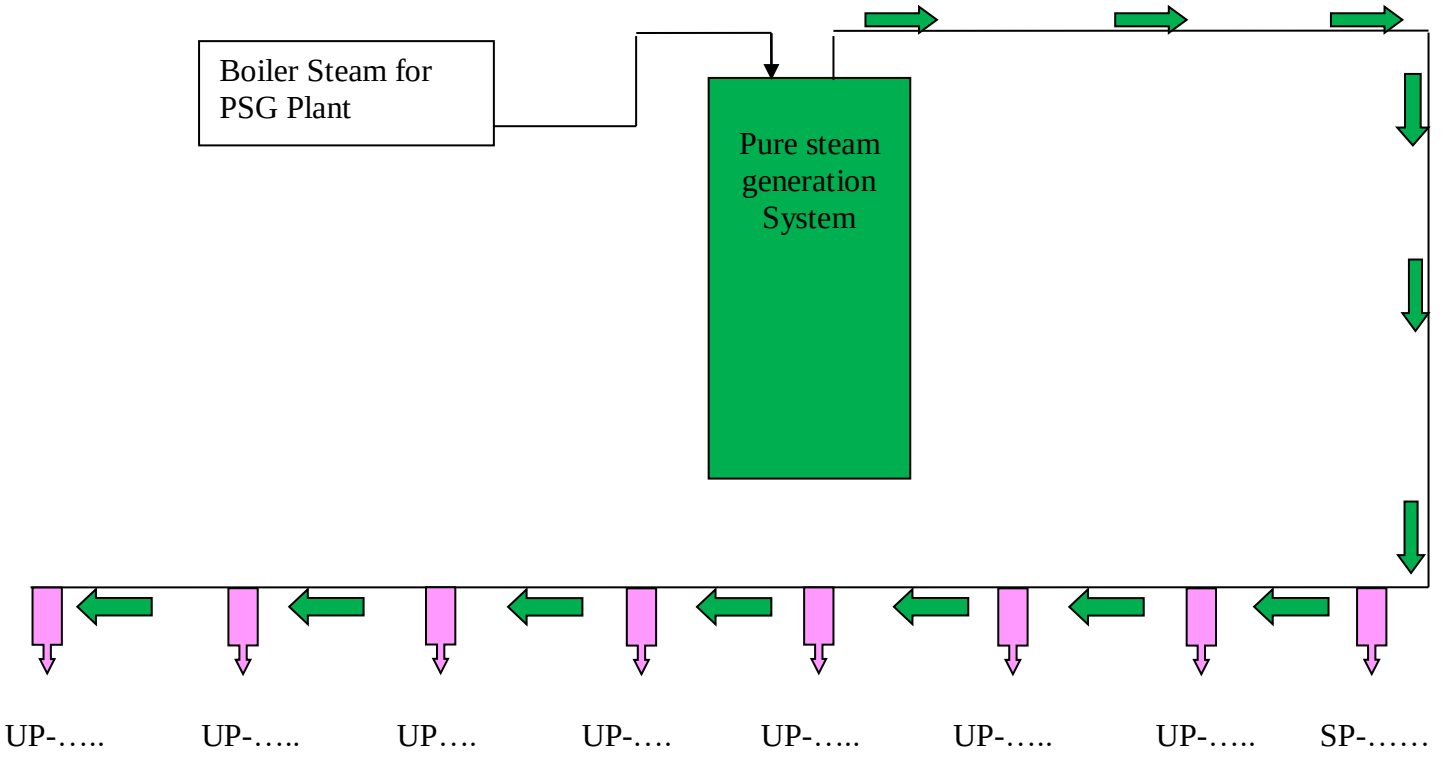
. 4.0 RESPONSIBILITY:

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

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and Compilation of the Performance Qualification Report. • Protocol Training Record. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review & Approval of Report. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Review & Approval of Report. • Analytical Support (Microbiological Testing/Analysis).
Engineering	• Review & Approval of Report. • Co-ordination, Execution and technical support in Area Qualification activity. • Calibration of Process Instruments. • Responsible for Trouble shooting (if occurs during execution).

5.0 EQUIPMENT DETAILS:

FLOW DIAGRAM OF PURE STEAM DISTRIBUTION SYSTEM



PSG GENERATION LVP USER POINT	
	OUT LET OF PSG LINE
	UNIT PREPARATION
	MANUFACTURING 1
	MANUFACTURING 2
	FILTRATION 1
	FILTRATION 2
	FILLING 1
	FILLING 2

UP- USER POINT

5.1 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	08 nos.

6.0 PRE-QUALIFICATION REQUIREMENTS:

6.1 SYSTEM PRE-REQUISITES:

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Verified by (Sign & Date) QA

6.2 INSTRUMENT CALIBRATION

S.No.	Equipment/Instruments Name	Calibration done on	Calibration due on	Verified by (Sign & Date) QA

6.3 TRAINING OF EXECUTION TEAM:

S.No.	Name of Trainee	Department	Designation	Acceptance Criteria	Signature of Trainee	Checked By (Sign & Date) QA
1.				All personnel involved in execution of protocol shall be trained in the required procedure and shall be documented		
2.						
3.						
4.						
5.						

Name of the Trainer: _____

Sign & Date: _____

Inference: _____

_____

_____

_____

Reviewed By: _____
(Manager QA)
(Sign & Date)

7.0 REASON FOR QUALIFICATION:

The study will establish that the parameters are followed, critical variables are under control and the quality of the output is as desired.

After completion of the Operation Qualification of the equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

- Installation of New System.
- Any major modification in the existing system.
- If the system is found to be malfunctioning.
- Change of Location.

8.0 SITE OF STUDY:

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9.0 SAMPLING POINT AND USER POINT LOCATION & SPECIFICATION FOR PURE STEAM GENERATION AND DISTRIBUTION SYSTEM (VALIDATION)

S.No.	Sampling Point Location	S.P. No.	Test to be performed Chemical & Micro	Specification
1.	**PSG Sampling point**		Micro analysis & Chemical complete analysis	As per In-process specification
2.	**PSG User point**			
3.	**PSG User point**			
4.	**PSG User point**			
5.	**PSG User point**			
6.	**PSG User point**			
7.	**PSG User point**			
8.	**PSG User point**			

10.0 SAMPLING PLAN:

Duration: 07 days (01 week)

S.No.	Sample point & User Point no.	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
PURE STEAM GENERATION & DISTRIBUTION SYSTEM								
GENERATION SAMPLING POINT								
1.		√	√	√	√	√	√	√
PSG DISTRIBUTION SYSTEM								
2.		√	√	√	√	√	√	√
3.		√	√	√	√	√	√	√
4.		√	√	√	√	√	√	√
5.		√	√	√	√	√	√	√
6.		√	√	√	√	√	√	√
7.		√	√	√	√	√	√	√
8.		√	√	√	√	√	√	√

PSG validation, the frequency & extent of sampling of water for 07 Days at least one user point. This validation is to be monitored for a period of 01 Week.

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11.0 TESTS AND CHECKS:

11.1 CHEMICAL ANALYSIS RECORD FOR PURE STEAM GENERATION & DISTRIBUTION SYSTEM

SAMPLING POINT: …….

Test →	Description	pH (At 25°C)	Conductivity (At 25°C)	Acidity & Alkalinity	Nitrate	TOC (Off Line)	Compiled By QA (Sign & Date)
Date	Clear Colorless, Odorless & Tasteless Liquid	5.0 - 7.0	NMT 2.1 µS/cm off line	Complies as per IP	NMT 0.2 ppm	NMT 500 ppb	

Acceptable Limit: All test parameters should be complies with specification.

Verified By:
(QA)
Sign & Date

Inference:……

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Reviewed By:_____
(Manager QA)
(Sign & Date)

11.2 MICROBIOLOGICAL ANALYSIS RECORD FOR PURE STEAM GENERATION & DISTRIBUTION SYSTEM:

SAMPLING POINT: ……

Test →	Total Aerobic Microbial Count	BET	Compiled By QA (Sign & Date
Date ↓	NMT 10 CFU/100 ml	NMT 0.25 EU/ml	

Acceptable Limit: All test parameters should be complies with specification.

Verified By:
(QA)
Sign & Date

Inference:……

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Reviewed By:_____
(Manager QA)
(Sign & Date)

11.3 NON-CONDENSABLE GAS TEST:

Sampling Point		**Date of Sampling**	
Sampled By		**Date of Testing**	
Date of Report			

Cycle No.	**Calculation**		
	Vb (Volume of gas in ml)	**Vc (Volume of condensate in ml)**	**Conc. of Non Condensable Gas% (Vb/Vc x 100)**

RECORD OF PARAMETERS

TEST DETAILS (SAMPLING POINT No.:	
Equipment	
Equipment Make	
Equipment Location	
Equipment I. D. No.	
Apparatus I. D. No.	
Date of Test	
Cycle Mode (Auto/Manual)	
Boiler Steam Temperature	
Pure Steam Pressure High	
Pure Steam Pressure Low	
Feed Water Conductivity	
Pure Steam Conductivity	
Percentage of Non Condensable Gases (Vb/Vc) X 10	
Acceptance Criteria for non condensable gases	**non condensable gases NMT 3.5 %**
RESULT	

11.4 DRYNESS FRACTION TEST:

Sampling Point		**Date of Sampling**	
Sampled By		**Date of Testing**	
Date of Report			

RECORD OF PARAMETERS

TEST DETAILS:	
Date of Test	
Equipment	
Equipment Make	
Equipment Location	
Equipment I. D. No.	
Cycle Mode (Auto/Manual)	
Boiler Steam Temperature	
Pure Steam Pressure High	
Pure Steam Pressure Low	
Feed Water Conductivity	
Pure Steam Conductivity	
Initial temperature of water in flask in degree centigrade (Ts)	
Final temperature of water and condensate in flask in degree centigrade (Tf)	
Average temperature of pure steam delivered (Ta)	
Initial mass of empty flask assembly with stopper bush in Kg (Me)	
Initial mass of empty flask assembly with stopper bush 650 ml water in Kg (Ms)	
Final mass of flask assembly, steam condensate and water in Kg (Mf)	
Latent heat of pure steam at temperature [(In kj/kg) hfg on steam table (L)	
Dryness Fraction Test :- $D = \frac{(Tf-Ts)[\{4.18(Ms-Me)\}+0.24]}{L\,(Mf - Ms)} - \frac{4.18(Ta-Tf)}{L}$	
Acceptance Criteria for dryness fraction test	**Dryness value should NLT 0.9 %**
Result	

11.5 DEGREE OF SUPER HEAT TEST:

Sampling Point		**Date of Sampling**	
Sampled By		**Date of Testing**	
Date of Report			

RECORD OF PARAMETERS

TEST DETAILS	
Date of Test	
Equipment	
Equipment Make	
Equipment Location	
Equipment I. D. No.	
Cycle Mode (Auto/Manual)	
Boiler Steam Temperature	
Pure Steam Pressure High	
Pure Steam Pressure Low	
Feed Water Conductivity	
Pure Steam Conductivity	
Temperature in expansion tube in centigrade (Te)	
Boiling point of water at local atmospheric pressure in centigrade(100° cent) (To)	
Super Heat = Te - To	
Acceptance Criteria for degree of super heat test	**Superheat value should NMT 25°C**
Result	

12.0 CHECKLIST OF ALL TESTS AND CHECKS:

TESTS OR CHECKS	EXECUTED [Y/N]	Checked By (Sign & Date) QA	COMMENT
Chemical Test			
Microbial Analysis			
Dryness Fraction Test			
Super Heat Test			
Non-Condensable Gas Determination			

Compiled by:
(QA)
(Sign & Date)

Inference:_____

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Reviewed By:_____
(Manager QA)
(Sign & Date)

13.0 REFERENCES:

The Principle Reference is the following:

- Master Validation 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.

14.0 DOCUMENTS TO BE ATTACHED:

- Protocol Training Record
- Operation And Maintenance Manual
- Final SOP's
- Any Other Relevant Documents

15.0 NON COMPLIANCE:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an impact on operation as well as on performance of the machine, prepare final conclusion.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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17.0 CHANGE CONTROL, IF ANY:

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18.0 ABBREVIATIONS:

MCDP	: Multicolumn Distillation Plant
LPH	: Liter per Hour
µS/cm	: Microsiemens per centimeter
kg/cm^2	: Kilogram per centimeter square
IP	: Indian Pharmacopoeia
ppm	: Per part million
ppb	: Per part billion
CFU	: Colony forming unit
EU	: Endotoxin unit
WHO	: World Health Organization
FDA	: Food and Drug Administration
ISPE	: International Society for Pharmaceutical Engineering
CFR	: Code of Federal Regulation

19.0 REPORT POST-APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			