STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Pure Steam Quality Test	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for Pure Steam Quality Test.

2.0 SCOPE:

This SOP is applicable for Pure Steam Quality Test during Pure Steam Generator Qualification at ……..

3.0 RESPONSIBILITY:

Officer/Executive- Engineering & QA.

4.0 ACCOUNTABILITY:

Head-QA

5.0 DEFINITION:

Pure Steam:

- The quality of this steam is defined by its condensate which must have WFI quality. This steam quality is applied for the sterilization of primary packaging material for sterile dosage forms or for the sterilization of equipment parts in contact with the product during sterile production, own pharmaceutical definition.

6.0 PROCEDURE:

6.1 Pure Steam Quality test shall be carried out annually during Pure Steam Generator Qualification for respective block as per Performance Qualification Protocol.

6.2 Following test shall be performed by Quality Assurance personnel in coordination with engineering personnel.

6.3 DRYNESS FRACTION TEST:

6.3.1 First fit the steam service pipe (assembly) at the pure steam, sampling point. And also fit the all plugs for the steam supply to the non-condensable gas detections system or for the temperature sensor for the

measuring the temperature also fit the drain valve at bottom side of the steam service pipe for the drain of steam condensate.

6.3.2 After the isolate the steam supply to the steam supply pipe and ensure no differential pressure exists between the pipe pressure and atmosphere.

6.3.3 Fit a pitot tube of the correct orifice concentrically and horizontally within the steam pipe as described by EN 285 with PTFE, insulation. The pitot tubes are marked as 0.8, 0.6 and 0.4 on the flat on the hexagon fitting.

Steam pressure	**3 bar**	**3 to 4 bar**	**4 to 7 bar**
Orifice size	**0.8 mm**	**0.6 mm**	**0.4 mm**

6.3.4 Fit the thermocouple entry gland horizontally to the steam service pipe as described by EN 285 with PTFE tape.

6.3.5 Fit the 3mm diameter thermocouple sensor to the gland with the supplied nut and silicone rubber olive so that the tip of the sensor is positioned centrally in the pope steam flow. Tighten the nut sufficiently to prevent movement and leakage. Do not over tighten.

6.3.6 Connect the probe to input T2 to indicate steam service pipe temperature.

6.3.7 Place the electronic balance on a solid level surface free from draughts, remove the transit screw and turn on. Each time measurements are taken ensure the display the reads zero and is stable before placing any mass on the pan.

6.3.8 Connect the rubber tube to the top of the longer stainless steel tubes fitted to the rubber stopper. Then place the stopper and tube assembly on to the empty flask.

6.3.9 Weigh the apparatus (flask and tube assembly) on the balance note the mass: Me.

6.3.10 Remove the assembly from the balance and also remove the tube assembly and pour 650 ml +/- 5ml clean cold water (below 27^0 centigrade in) to the flask. A stainless steel measuring cup is provided for the pour the water. Also the noted own the initial temperature of water: Ts.

6.3.11 Again weigh the apparatus(flask, tube assembly and water)on the electronic balance and note the mass : Ms.

6.3.12 Place the flask closes enough to permit the rubber tube to be connected to the pitot tube but do not connect. The stainless steel measuring cup provided may be used the mount the flask.

6.3.13 Place the probe connected to input T I into the second vent tube to a depth of approximately 240mm from the top of the flask and connect the other end to the thermometer to indicate flask temperature.

6.3.14 When the flask temperature reaches approximately 80^0 centigrade removes the rubber tube from pitot . And note down the final temperature of water: Tf.

6.3.15 Also measure the average steam supply temperature in to the flask: Ta.

6.3.16 Also weigh the apparatus (flask tube assembly water and steam condensate) on the electronic balance and note the final mass: Mf.

6.3.17 Calculate the Dryness fraction test as per below formula:

Dryness Fraction Test:- $D = \frac{(Tf-Ts)[\{4.18(Ms-Me)\}+0.24]}{L\,(Mf-Ms)} - \frac{4.18(Ta-Tf)}{L}$

Where

Ts : Initial temperature of water in flask in degree centigrade.

Tf : Final temperature of water and condensate in flask in degree centigrade.

Ta : Average temperature of pure steam delivered.

Me: Initial mass of empty flask assembly with stopper bush in Kg.

Ms: Initial mass of empty flask assembly with stopper bush and 650 ml water in Kg.

Mf : Final mass of flask assembly, steam condensate and water in Kg.

L : Latent heat of pure steam at temperature [(In kj/kg) hfg on steam table.]

6.3.18 The test should be considered satisfactory if the dryness value is not less than 0.9 as per EN 285.

6.4 NON - CONDENSABLE GAS TEST:

6.4.1 First fit the steam service pipe (assembly) at the pure steam sampling point and also fit the all thermocouple entry gland for the steam supply to the non-condensable gas detection system or for the temperature sensor for the measuring the temperature. Also fit the drain valve at bottom side of the steam service pipe for the drain of steam condensate.

6.4.2 Erect the tripod to at approximate required height. And than after place the non -condensable gas box on the tripod and ensuring that the spigot fully engages with the socket in the base of the box.

6.4.3 Connect one end of the blue tube to the water inlet on the apparatus and the other red pipe is fit for the drain of feed water. The feed may be taken from a water-filled tank or bucket providing a constant temperature of below 25° cen. and minimum of 1.0 meter head between the "take off' point and bottom of the drain tube.

6.4.4 Close the water flow restrictor valve by turning fully clockwise.

6.4.5 Connect one end of the red tube to the water outlet on the apparatus and the other end in a drain or suitable container. A push fit weight is supplied.

6.4.6 Connect the one end of the green tube to the condensate drain outlet from the Non-condensable gas box apparatus end other end in the drain or suitable container.

6.4.7 Close the steam restrictor valve on the apparatus. Connect the stainless steel elbow to the steam supply pipe work on the SS steam service pipe.

6.4.8 Connect the one end of the flexible steam hose to the steam isolating valve and other end connect at stainless steel elbow to the steam supply pipe work on the ss steam service pipe.

6.4.9 Open the condensate drain valve and the gas relief valve on the apparatus. Also prime the condensate drain reservoir with cold water through the open condensate sight glass tube until the water levels in both sight glasses are approximately zero. The supplied syringe may be used for this Purpose.

6.4.10 Also place the thermometer bracket into the location slot on the left hand side of the apparatus box then place the thermometer on the bracket. Connect one end of the thermocouple connecting cable to the socket on the base of the apparatus and the other end to input of the thermometer.

6.4.11 If a gravity siphon is used, open the restrictor valve fully then prime the system using the syringe and pumping out the air until water flows continually and the inlet water valve of apparatus is continually fully open.

6.4.12 Turn on the steam supply gradually to allow air in the system to vent. Than after water starts to flow from the condensate outlet set the levels in the sight glasses to zero by adjust the sight glass scale slide. Also adjust the steam flow restrictor valve to maintain a condensate outlet temperature of 80 to 95 centigrade. If necessary re-set the levels in the sight glasses to zero by adjusting the sight glass scale slide.

6.4.13 When the steam to the admitted in the apparatus and maintain the temperature 80 to 95 centigrade than after you have to measure a reading up to the two – three min; either before a maximum level is reached in either of the sight glasses, note the levels achieved in both.

6.4.14 Calculate the percentage of non condensable gasses using formula (V1/V2 X100= ---- % <3.5%).

6.4.15 When the samples have been taken and any test cycles have completed, isolate the steam and water supplies at source, ensuring that no differential pressure exists between the supply pipe and atmosphere.

6.4.16 The test should be considered satisfactory if the concentration of Non-condensable gases does not exceed 3.5 %.

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6.5 DEGREE OF SUPERHEAT TEST:

6.5.1 First fit the steam service pipe (assembly) at the pure steam sampling point. And also fit the all plugs for the steam supply to the non-condensable gas detections system or for the temperatures sensor for the measuring the temperature. Also fit the drain valve at bottom side of the steam service pipe for the drain of steam condensate.

6.5.2 After the isolate the steam supply to the steam supply pipe and ensure no differential pressure exists between the pipe pressure and atmosphere.

6.5.3 Fit a pitot tube of the correct orifice concentrically and horizontally within the steam pipe as described by EN 285 with PTFE insulation. The pitot tubes are marked as 0.8, 0.6 and 0.4 on the flat on the hexagon fitting.

6.5.4 Steam pressure 3 bar 3to4bar 4to7bar

6.5.5 Orifice size 0.8mm 0.6mm 0.4mm

6.5.6 Fit the thermocouple entry gland horizontally to the steam service pipe as described by EN 285 with PTFE tape.

6.5.7 Fit the 3mm diameter thermocouple sensor to the gland with the supplied nut and silicon rubber olive so that the tip of the sensor is positioned centrally in the pope steam flow. Tighten the nut sufficiently to prevent movement and leakage. Do not over tighten.

6.5.8 Connect the probe to input T2 to indicate steam service pipe temperature.

6.5.9 Fit the non-sheathed thermocouple sensor through the gland in the expansion tube so that the tip of the sensor is located centrally in the pipe.

6.5.10 Push the expansion tube onto the pitot. Connect the probe to input T1 to indicate expansion tube temperature. Restore the steam pressure.

6.5.11 Turn on thermometer so that T1 and T2 is shown the temperature of expansion tube and pure steam main line temperature.

6.5.12 Measure the temperature of expansion tube at atmosphere pressure above 100° centigrade up to 5 minutes. The test should be considered satisfactory if the superheat value does not exceed 25°C.

Superheat=Te –To

Where,

Te = Temperature in expansion tube in centigrade.

To = Boiling point of water at local atmospheric pressure in centigrade (100° cent).

7.0 ABBREVIATIONS:

SOP	Standard Operating Procedure
QA	Quality Assurance
No.	Number
Ltd.	Limited

8.0 ANNEXURES:

Not Applicable

9.0 DISTRIBUTION:

- Controlled Copy No. 01 Head-Quality Assurance

10.0 REFERENCES:

- EN 285
- HTM

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		