

## Pharmatherm the Steam Quality Specialists

### Steam Quality Test SOP

SOP No:	V01/PTL/500/15
Version No:	01
No of Copies issued:	01
Copy Number:	01

#### Circulation

1), Pharmatherm Limited

#### Master Copy

Pharmatherm Limited.

#### Issue Date

20<sup>th</sup> January 2015

### Revision History

This is the first issue of this document.

Revision:	Date:	Comments
01	20.01.2015	Issued for Client comment
02		Client comments added
02		Issued to Client

SOP Approval: this section must be signed-off before distribution and use of this document.

Written By - Andrew Varley 20 January 2015 [Date]

Validation Engineer Andrew Varley, Pharmatherm Limited

## **CONTENTS:**

- 1.0 Purpose
- 2.0 Scope
- 3.0 Principle
- 4.0 Related Documents
- 5.0 Responsibility
- 6.0 General
- 7.0 Precautions
- 8.0 Equipment Required
- 9.0 Test Periods
- 10.0 Steam Tests
- 11.0 Appendices

### **1.0 PURPOSE**

Effective steam sterilization is reliant on good quality steam. This SOP is to provide test procedures to monitor the quality of the steam at the clean steam generator and points of use.

### **2.0 SCOPE**

This SOP is applicable to the clean steam generator and sample points for clean steam distribution systems.

### **3.0 PRINCIPLE**

To ensure that the steam supplied to the user points complies with the quality requirements of EN 285: 2006 +A2:2009.

### **4.0 RELATED DOCUMENTS**

EN 285: 2006 +A2:2009.

Appendix No.1 Non condensable gas test equipment set up.

Appendix No. 2 Super heat test equipment set up.

Appendix No. 3 Dryness test equipment set up.

Appendix No. 4 Sample points

### **5.0 RESPONSIBILITY**

Pharmatherm Limited to provide steam quality test results for review.

## 6.0 GENERAL

Prior to the commencement of this work, confirm that an appropriate Permit to Work and an associated Safe Plan of Action has been issued. Also, check that it has been countersigned by all Authorities, relevant to the work to be undertaken, as described in this procedure.

Much of the work described in this SOP will require line breaks on the Clean Steam Distribution system. The isolations required in association with these line breaks will be performed by a client representative. Ensure that the isolations required for each line break is sufficient to facilitate equipment set up. Confirm that the system is safe for the break to be made before proceeding with any line break associated with system set up.

The results of the tests are to be recorded on the test sheet provided by Pharmatherm Limited. On completion of the tests, pass the completed report on to the allocated Engineer for review and signing. The engineer will then pass it on to the other signatories for reviewing, signing and filing.

Inform the Site Engineer immediately should anything arise that will prevent the rapid return of the sterilizer or steam distribution system back into service. If it is found that the operational validity is, or has been affected, the Investigation report procedure should be started

## 7.0 PRECAUTIONS

A Permit to Work, Safe Plan of Action should be obtained from the Safety Officer and all precautions regarding protective clothing etc. to be observed. Arrange with the client contact for the required Line Break Permits.

A percentage of the test equipment may become hot during use. Care should be taken to prevent exposure to the elevated temperatures. Live steam will be present during all of the tests and thermally insulated gloves and safety glasses/visor must be available.

Barriers, signage and cordons should be in place to prevent non-essential personnel entering the area where sampling is being performed.

## 8.0 EQUIPMENT REQUIRED

### General

Thermometric indicator with 1 channel and a resolution of 0.1°C. The Steam Quality Test Kit to test superheat, dryness value and non-condensable gas levels in accordance with the requirements of EN 285 Sterilization - Steam Sterilizers - Large Sterilizers - 2006. Weighing scales with a range of at least 2 Kilograms and a resolution of 0.1 g. A test

spool will be used at each sample point to provide the appropriate connections for the equipment associated with each of the required tests.

## **9.0 TEST PERIODS**

To satisfy the requirements of EN 285: 2006 +A2:2009 each sterilizer/sample point should be tested annually (normally during the course of revalidation). Client Validation and Qualification Plan requirements may determine a different frequency of re-testing.

## **10.0 STEAM QUALITY TESTING**

### **10.1 TEST SPOOL INSTALLATION**

Ensure the required permit, risk assessment forms have been completed

Ensure that double valve isolations are in place before completing the line break.

Install the sample point and steam quality test spool fittings.

### **10.2 NON-CONDENSABLE GAS TEST**

Reference Appendix 1 and 4

- 10.2.1 Isolate the main steam valve of the system.
- 10.2.2 Connect the non-condensable gas condenser to the steam supply via a suitable valve and connect the steam supply to the condenser using the small-bore insulated pipe. Connect the cooling water supply to the condenser. If a submersible pump is to be used place it in a water source and connect the water tubes. See Appendix 1.
- 10.2.3 Ensure the cooling water valve is open fully and the steam valves on the steam main and condenser are shut.
- 10.2.4 Turn on the water supply (apply power to the submersible pump), and ensure the coolant water is exiting via the condenser outlet pipe.
- 10.2.5 The steam isolation valve may be opened slowly to avoid excessive condensing in the steam system.
- 10.2.6 Slowly open the steam valve on the condenser and by reducing or increasing the flow through each valve, achieve a flow rate of condensate of 10 to 30 ml per min at a temperature of between 50 °C and 95°C as indicated on the dial temperature indicator.

- 10.2.7 Fill the condensate collection chamber with water either by filling with water from an external source, or allow to fill with condensate.
- 10.2.8 Suck up condensate into the burette with the bulb to get a water level near the top. Remember to isolate the burette from the rubber bulb by shutting the valve before testing commences.
- 10.2.9 Fill the condensate collection chamber (5) with more water until it overflows.
- 10.2.10 Begin steam blow down via the test spool, ensuring the condensate is routed via a cooler to aqueous waste (where available, or a temporary collection vessel if there is no connection to aqueous waste available).
- 10.2.11 When the steam supply to chamber first opens: -
- 10.2.12 Ensure the measuring cylinder is empty. Make a note of the water level in the burette.
- 10.2.13 Any non-condensable gases present in the steam being sampled will rise to the top of the burette. Overspill formed by the condensate and the water displaced by the gases will collect in the measuring cylinder
- 10.2.14 When a minimum of 100ml of condensate has been collected in the measuring cylinder. Note the volume of gas collected in the burette (mL) (volume of water displaced) ( $V_b$ ) and the volume of water (mL) collected in the measuring cylinder ( $V_c$ ).
- 10.2.15 Calculate the fraction of non-condensable gases as a percentage as follows:

$$\text{Percentage of non-condensable gas} = 100 \times (V_b/V_c)$$

**Acceptance Criteria.**

- The test should be considered satisfactory if the fraction of non-condensable gases does not exceed 3.5% ( $100 \times (V_b/V_c)$ ).
- The test should be carried out three times in total to check consistency. If the results of the tests differ significantly, then the cause should be investigated before proceeding further.

### 10.3 SUPER HEAT TEST

Reference Appendix 2 and 4.

- 10.3.1 Isolate the main steam valve of the system, check steam loop pressure gauges and see that steam pressure has decreased in the main steam line.
- 10.3.2 Connect up pipes and apparatus as per appendix No. 2.
- 10.3.3 The steam isolation valve may be opened slowly to avoid excessive condensing in the steam system.
- 10.3.4 Begin steam blow down via the test spool, ensuring the condensate is routed via a cooler to aqueous waste (where available, or a temporary collection vessel if there is no connection to aqueous waste available).
- 10.3.5 From the measured temperatures, note the temperature in the test spool (for use in the dryness test) and in the expansion tube ( $T_e$ ) when the steam supply to the chamber first opens.
- 10.3.6 Calculate the superheat in °C from the following equation.

Superheat =  $T_e - T_o$ , where  $T_e$  is the boiling point of water at local atmospheric pressure.

The test should be carried out three times in total to check consistency. If the results of the tests differ significantly, then the cause should be investigated before proceeding further.

Acceptance Criteria: The test should be considered satisfactory if the superheat measured in the expansion tube does not exceed 25 °C.

### 11.4 DRYNESS VALUE TEST

Test to be carried out immediately after the superheat test  
Reference Appendix 3 and 4

- 11.4.1 Isolate the main steam valve of the system, check steam loop pressure gauges and see that steam pressure has decreased in the main steam line.
- 11.4.2 Connect up pipes and apparatus as per appendix No. 3.
- 11.4.3 Remove the rubber hose from the tube on the flask as well as the thermocouple lead. Weight the whole assembly and note the mass ( $M_1$ ).

- 11.4.4 Remove the stopper and tube assembly and pour 650 +/- 50 ml of cold water (below 27 °C) into the flask. Replace the stopper and tube assembly, weigh the flask and record the mass ( $M_2$ ).
- 11.4.5 Support the flask close to the Pitot tube, and ensure that the steam feed tube and flask are protected from excess heat and draughts. Do not connect it to the Pitot tube yet.
- 11.4.6 Introduce the second temperature sensor through the shorter of the two pipes in to the stopper and into the water in the flask. Note the temperature of the water in the flask ( $T_0$ ).
- 11.4.7 The steam system.
- 11.4.8 Begin steam blow down via the test spool, ensuring the condensate is routed via a cooler to aqueous waste (where available, or a temporary collection vessel if there is no connection to aqueous waste available).
- 11.4.9 Ensure the feeder tube is fully warmed and when the steam supply to the chamber first opens, connect the feeder tube to the 6mm stainless steel tube in the rubber bung. Lag the tube with insulation and ensure the tube drains freely.
- 11.4.10 During the test obtain the average steam temperature in the test spool ( $T_s$ ).
- 11.4.11 When the temperature in the flask is approximately (80 °C), disconnect the feeder tube from the 6mm stainless steel tube. Agitate the water in the flask to make sure it is thoroughly mixed. Note the temperature of the water ( $T_1$ ).
- 11.4.12 Weigh the flask and stopper assembly and note the mass ( $M_3$ ).
- 11.4.13 The initial mass of water in the flask is given by ( $M_w$ ) =  $M_2 - M_1$
- 11.4.14 The mass of condensate collected is given by ( $M_c$ ) =  $M_3 - M_2$
- 11.4.15 Calculate the dryness value of the steam from the following equation:

$$D = \frac{(T_1 - T_0) (4.18M_w + 0.23)}{L M_c} - \frac{4.18(T_s - T_1)}{L}$$

Where:

D = Dryness value of the steam

$T_0$  = initial temperature of the water in the flask (degrees celsius)

$T_1$  = final temperature of the water and condensate in the flask (degrees celsius)

$T_s$  = average temperature of the steam delivered to the flask (degrees



celsius)

$M_w$  = initial mass of water in the flask (Kg)

$M_c$  = mass of condensate collected (Kg)

$L$  = latent heat of dry saturated steam at temperature  $T_s$  ( $\text{kJ Kg}^{-1}$ )

4.18 = Specific heat capacity of water ( $\text{kJ/Kg.K}$ )

0.23 = Effective heat capacity of the apparatus ( $\text{kJ/K}$ )

#### 11.4.16

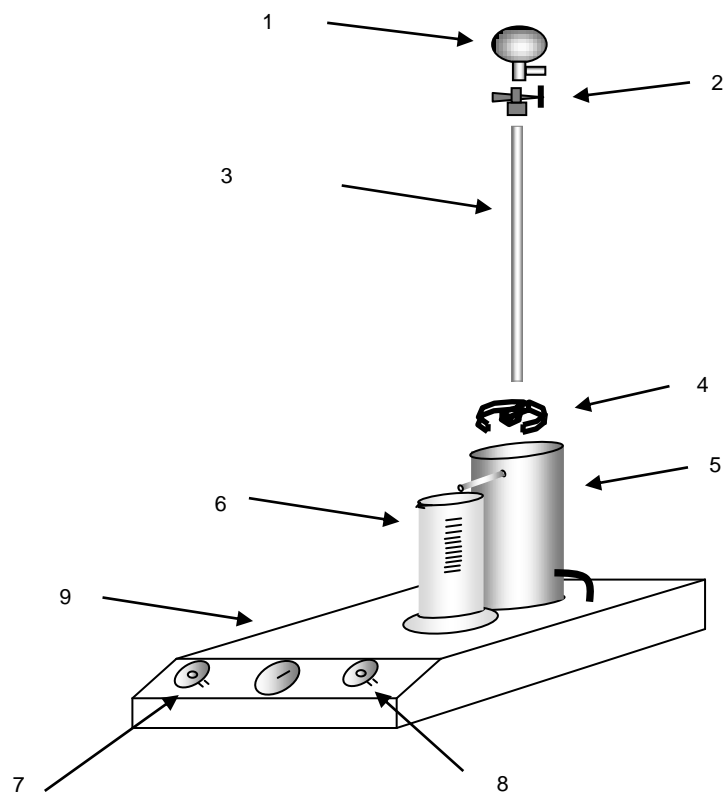
##### Acceptance Criteria

The test should be done three times in total to check consistency. If the results of the tests differ significantly, then the cause should be investigated before proceeding further.

- Throughout the operating cycle the temperature measured in the steam service pipe is within  $3^\circ\text{C}$  of that measured during the superheat test.
- Dry saturated steam should have a dryness value of not less than 0.95

## Appendix 1

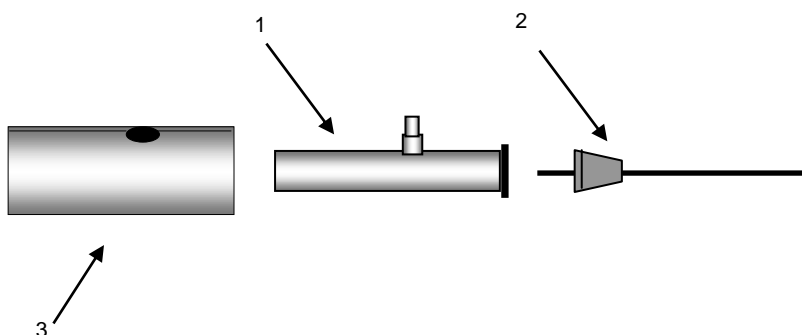
### Non condensable gas test rig



1. Burette Bulb
2. Burette Valve
3. Burette
4. Burette Guide
5. Condensate collection cylinder
6. 250 ml Measuring Cylinder
7. Steam Valve
8. Cooling water Valve
9. Steam condensing Unit
10. Cooling Water Inlet (at back of condensing unit)
11. Cooling Water Outlet (at back of condensing unit)
12. Steam inlet (at back of condensing unit)

## Appendix 2

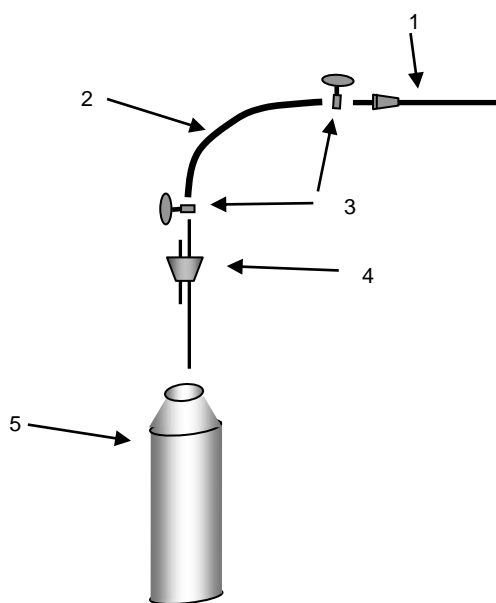
### Superheat test rig



1. Superheat Expansion Tube
2. Pitot Tube
3. Insulation

### Appendix 3

#### Dryness value test rig



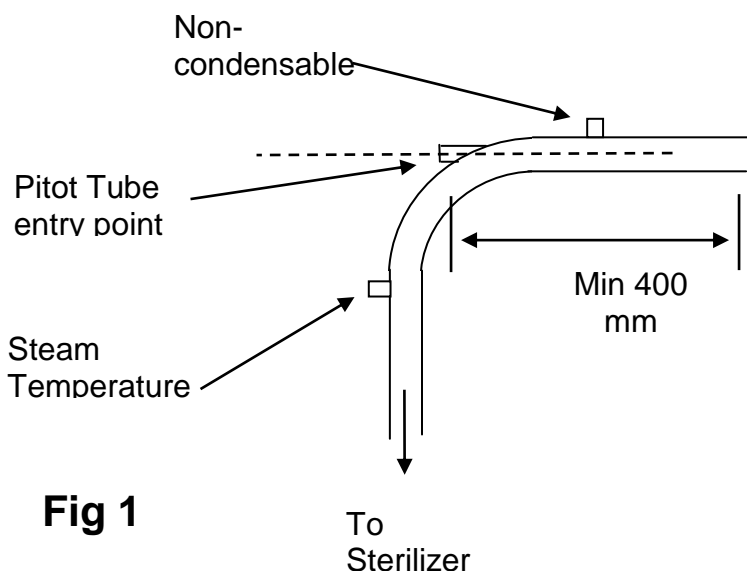
1. Pitot Tube
2. Tubing
3. Tube Clamps
4. Rubber Bung and Tube Assembly
5. 1 Litre Flask

## Appendix 4 Steam Quality Tests Points


In order to test the steam quality.

Specific test points on the steam line are required.

Fig 1 illustrates the location of the three test points on the steam supply pipe just prior to the sterilizer.



**Fig 1**

 It is important the pitot tube entry point is level and parallel with the steam pipe as any deviation towards the edge of the pipe can influence the results detrimentally.

**Note** All entry points are ½ Triclover fittings. Holes drilled through pipes should be full size.

Standard Notification of Conformity: -

.....

### Certificate of Conformity

### STEAM QUALITY TEST KIT

The **Steam Quality Test Kit** is supplied to test superheat, dryness value and non-condensable gas levels in accordance with the requirements of EN 285 Sterilization - Steam Sterilizers - Large Sterilizers - October 1996. (***"This European Standard specifies requirements and the relevant tests for large steam sterilizers"***).

Specifically: -

The **dryness value** test equipment and methodology employed complies with sections 24.2 - 24.2.1.17 with a single variation. The US version test kit is supplied with NPT threaded components and not metric versions.

The **superheat test** equipment and methodology employed complies with sections 24.3.1 - 24.3.2.8 with no exceptions.

The non-condensable gas test equipment and methodology differs from EN 285 as it utilises a condenser system. Section 24.1 - Note 2: makes provision for this ***"An alternative procedure to the one described in 24.1 can be used providing it has been calibrated against this standard"***. Such work has been conducted with satisfactory results obtained. The difference between the EN 285 method and the system supplied was 0.03% over five tests with values between 0.4 and 1.6%. The test principles and methodology are in line with those described in sections 24.1 - 24.1.2.12 and the acceptance criteria used is identical.

The **Steam Quality Test Kit** comes ready to use and does not require any qualification or validation prior to use, if the test instructions supplied with the kit are strictly followed.

Contact Pharmatherm for a steam quality test quotation however large or small the project maybe. We aim to provide a competitive validation service. Please 'don't delay and contact PharmaTherm today' email: [info@pharmatherm.ie](mailto:info@pharmatherm.ie)

See the Pharmatherm website please log onto [www.pharmatherm.ie](http://www.pharmatherm.ie)



**Please consider your environmental responsibility before printing this e-document. Thank you.**

Confidentiality Notice: This electronic message transmission and any attachments may contain confidential or legally privileged information and is solely for the intended recipient. If you are not the intended recipient, disclosure, copying, use or distribution of the information included in this message is prohibited. Please delete immediately.