



Document Name: Performance Qualification Appendix 3.1.1 for Lyophilizer

Equipment/ System ID:

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Appendix 3.1.1

Report for Non Condensable gases

	TEST 1	FRACTION OF NCGs	TEST 2	FRACTION OF NCGs	TEST 3	FRACTION OF NCGs
VB						
VC						

Acceptance limit: The fraction of non condensable gases should not exceed 3.5%

$$\text{Fraction of NCGs} = 100 \times (V_b/V_c)$$

Where, V_b = Volume of gasses displaced from the burette.

V_c = Volume of condensate collected in the measuring cylinder

Comments: _____

Reviewed by: ----- [Sign & Date]



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Report for Superheat

	TEST 1	SUPERHEAT (°C)
TE		
To		

*Accepted limit of Superheat = NMT 25°C

Superheat (°C) = $T_e - T_o$

Where, T_e = Temperature of steam in expansion tube.

T_o = Boiling point of water at local atmospheric pressure

Acceptance limit: The Superheat measured in the expansion tube should not exceed 25°C

Comments: _____

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Report for Dryness

	TEST 1	DRYNESS VALUE	DONE BY	VERIFIED BY
L				
M1				
M2				
M3				
T0				
T1				
TS				
CPW				
D				
A				
Mw				
Mc				

* Accepted limit of dryness = NLT 0.90

Where,

- L : is the latent heat of dry saturated steam at temp. at Ts.
- M1 : The mass of the Dewar and rubber bung in kg.
- M2 : The mass of the Dewar and rubber bung, water charge in kg.
- M3 : The mass of the Dewar and rubber bung, water charge and condensate in kg.
- T0 : is the initial temperature of the water and the Dewar flask (°C)
- T1 : is the final temp of the water and condensate in the Dewar flask, (°C)
- Ts : is the temperature of dry saturated steam delivered to the sterilizer, (°C)
- Cpw : is the specific heat of water (4.187 KJ/Kg.k)
- D : is the dryness value of the steam.
- A : is the effective heat capacity of the apparatus (0.24 kJ/k).
- Mw : initial mass of water in the flask (kg). $Mw = M2 - M1$.
- Mc : mass of condensate collected (Kg). $Mc = M3 - M2$

Acceptance limit: The Dryness value should be less than 0.95.

Comments: _____

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