



Document Name: Performance Qualification Appendix 3.4.1 for Lyophilizer

Equipment/System ID:

Document Number:

Effective Date:

Version Number: 00

Trial Run #: _____

Appendix 3.4.1
Leak Rate Test

Equipment Name : Lyophilizer

Equipment ID :

Contents

Observation:

Volume V to evacuate	Chamber	litres
	Condenser	litres
	Total volume V	litres

Start time	= t₀	
End time	= t₁	
Trial duration (t₁-t₀)	= t [secondes]	
Starting trial pressure	= P₁ [mbar]	
Final pressure	= P₂ [mbar]	
Pressure rise	= P₂ - P₁ [mbar]	

$$\text{Pressure rise} = \frac{V \times (P_2 - P_1)}{t} = \text{_____} = \text{_____ mbar.l/s}$$

Checkpoint	Acceptance criteria	Observation	Conform	Initials	Deviation
Chamber pressure rise	≤ 26 µbar.l/s or 10 mT/hr	µbar.l/s	Yes / No		

Remarks:

Checked By (Sign. /Date)	Verified By (Sign. /Date)