PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

Document Name: Performance Qualification Test Datasheet # 3.4 for Lyophilizer	
Equipment/ System ID:	**Document Number:**
Effective Date:	**Version Number:** 00

Test ID #3.4: System Leak rate Test		**Test Run: ____**
Target:	The objective of this test is to verify the Lyophilizer can be leak tested in accordance with the system specification.	
Necessary materials:	The utility supply of compressed air and cooling water are normal.	
Preconditions:	• Chamber door(s) are closed, and all valves are at their no cycle normal state. • Lyophilizer is in Auto mode.	
Test ID	**Test Description**	
1	The automatic "performance test" cycle in the control system of the freeze dryer is used for this purpose.	
2	Set the leak test duration of 60 minutes in the performance test picture.	
3	The pressure is measured with the chamber vacuum gauge, recorded automatically by performance test procedure.	
4	Calculate the volume of chamber and condenser for calculation of rise in pressure.	
5	The initial pressure taken for calculation of pressure rise should be taken after 01 hour of achieving the set pressure, this is due to time required for stabilization of vacuum.	
6	The result is found in the data in the cycle report and calculate as per Appendix-3.4.1	
7	**Rationale:** All acceptance criteria are taken considering as per the vendor design documents specifications. However as per guidelines (Parenteral Inspection Society; Chapter No. 7) the maximum acceptable leak rate should not be more than 10 µbar.l/sec. But on the basis of vendor design document the acceptance criteria is26 µbar.l/s. So, the media fill to be carried out with the same acceptable leak rate as per vendor recommendations. If this process simulation study of media fill will be passed with this leakage then it will be considered as final acceptance criteria and if any failure found with this leak rate, so a corrective action should be taken to reduce the leak rate.	
8	Record the observations & data as per **Appendix 3.4.1.**	
9	Attach the print out of the test cycle taken from the sterilizer with this data sheet.	
	Acceptance criteria	**Acceptance criteria fulfilled? (Y/N)**
1.	Pressure rise of 26 µbar l/s or 10mTorr/hr. or less should be obtained when a steady pressure condition in the chamber is reached.	
Checked by (Signature/ Date)	**Verified by (Signature/Date)**	