



ISO9001: 2015 CERTIFIED COMPANY

Lyophilization Systems India Pvt Ltd

LSIPL\E C - F 003 Rev-02

COMMISSIONING & INSTALLATION REPORT

Name of the Customer and Address	Indian Immunologicals Ltd., Rakshapuram, Gachibowli, Hyderabad-500032, Telangana.
Lyophilizer Model Number	Quanta 36XS-S
Project Number	2276
Installation Period	Start Date: <u>23-June-2021</u> End Date: <u>28-Dec-2021</u>
Service Engineer Attended	<u>Y. Bharu Mahesh, K. Anil Kumar</u>
Team involved from Customer side	<u>S. Srinivasulu Reddy, J. Vamskidas Reddy.</u>
Activities Completed _ PRESAT	<p>RESULTS YES <input checked="" type="checkbox"/> NO <input checked="" type="checkbox"/></p> <ol style="list-style-type: none"> 1. Lyophilizer moved to desired location <input checked="" type="checkbox"/> 2. Product chamber alignment completed <input checked="" type="checkbox"/> 3. Condenser chamber alignment completed <input checked="" type="checkbox"/> 4. Isolation Valve Installed <input checked="" type="checkbox"/> 5. All the Services Lines Completed <input checked="" type="checkbox"/> 6. Computer and SCADA Systems Installed <input checked="" type="checkbox"/> 7. Component verification completed <input checked="" type="checkbox"/> 8. Loader integration completed <input checked="" type="checkbox"/> 9. All the required SAT trails taken <input checked="" type="checkbox"/> <p>Note: the listed points 2, 3, 4 and 8 are not applicable for lab models</p>
Activities Completed _ SAT IQ and OQ	<p>Documentation Completed as per the</p> <ul style="list-style-type: none"> • 2276-130-00 Equipment Qualification Plan • 2276-132-00 Installation Qualifications Mechanical • 2276-133-00 Installation Qualifications Controls • 2276-134-00 PLC and Software Qualification • 2276-135-00 Operational Qualification.doc
Present Status	The Lyophilizer is installed, validated and documented as per the approved protocols and equipment is ready for further use such as Performance Qualification by user

PLOT 26/27, ALEAP ESTATE NEAR PRGATHINAGAR OPP: JNTU ROAD

KUKATPALLY, HYDERABAD - 500090, PH: 9963473091/92/93/94

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QUANTA MODEL

INSTALLATION DATA SHEET

Check Points

Zone-1 Low Stage Discharge Pressure 210 PSI Zone-2 Low Stage Discharge Pressure 200 PSI
 Zone-1 High Stage Discharge Pressure 165 PSI Zone-2 High Stage Discharge Pressure 175 PSI
 Air Pressure 6.0 bar N2 Pressure 0 bar
 C. Water Temperature 12.5 °C C. Water Inlet Pressure 1.8 bar C. Water Outlet Pressure 1.6 bar

Power Cable Type and Size:

3 Phase Supply (Voltage)	R+Y		R+B		B+Y	
	420 V		428 V		415 V	
Single Phase Supply (Voltage)	Isolation T/F Input		Isolation T/F Output			
	420		208V			
DC Supply (Voltage)	+24 V (Controlling)		+5 V (PLC)		+/-15 V (Vacuum Sensor)	
	24 VDC		5.0 VDC		15 VDC	
Description	Starting Amps			Running Amps		
	R (A)	Y (A)	B (A)	R (A)	Y (A)	B (A)
Zone-1 Low Stage compressor	4.9	6.9	5.4	4.7	6.6	5.0
Zone-1 High Stage compressor	4.4	6.4	4.8	4.2	6.5	4.4
Zone-2 Low Stage compressor	5.3	4.3	3.9	5.1	4.0	3.8
Zone-2 High Stage compressor	5.8	7.0	5.3	5.6	6.8	5.0
Vacuum Pump-1	3.5	1.9	2.3	5.6	1.7	2.0
Vacuum Pump-2	3.3	2.2	2.6	3.2	1.9	2.2
Vacuum Pump-3	—	—	—	—	—	—
Vacuum Pump-4	—	—	—	—	—	—
Roots Pump-1	—	—	—	—	—	—
Roots Pump-2	—	—	—	—	—	—
Fluid Pump-1	0.4A	0.3A	0.2A	0.3	0.1	0.1A
Fluid Pump-2	0.9A	0.6A	0.4	0.5	0.2	0.3A
Fluid Pump-3	—	—	—	—	—	—
Fluid Pump-4	—	—	—	—	—	—
Heater-1	3.9	4.3	4.1	3.9	4.0	4.2
Heater-2	—	—	—	—	—	—
Heater-3	—	—	—	—	—	—
Heater-4	—	—	—	—	—	—
Watering Pump	1.3	1.6	1.2	1.0	1.9	1.2
CIP Circulation Pump	8.6	8.3	7.4	8.3	8.0	7.9
Hydraulic Motor	2.6	2.3	2.4	2.3	2.0	1.9

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CONDENSER TEST					
Check Point		Observation	Acceptance Criteria	YES/NO	
Time taken for Condenser Cooling from +20 to -40°C		5 Min	As per Technical Specifications	yes	
Condenser Minimum Temperature		-98.9°C		yes	
VACUUM TEST					
Check Point		Observation	Acceptance Criteria	YES/NO	
Chamber Evacuation duration to reach 100 mTorr		25 Min	As per Technical Specifications	yes	
Ultimate Chamber Pressure		10 MTorr		yes	
VACUUM CONTROLLING TEST					
Pressure Set Point (mTorr)	Calculated Average after 10min		Variation		Confirm YES/NO
	Needle Valve <i>mTorr</i>	Servo Control <i>mTorr</i>	Needle Valve	Servo Control	
100	103	100	± 3 mTorr	0 mTorr	yes
200	206	199	± 6 mTorr	1 mTorr	yes
300	303	299	± 3 mTorr	1 mTorr	yes
SHELF TEMPERATURE TEST					
Check Point		Observation	Acceptance Criteria	Confirm YES/NO	
Minimum Temperature		-63.8°C	As per Technical Specifications	yes	
Shelf cooling duration from +20°C to -40°C		36 Min		yes	
Heating rate from -40°C to +40°C		63 Min		yes	
Max temperature		70°C		yes	
SHELF TEMPERATURE CONTROLLING TEST					
Temperature Set Point (°C)	Calculated Average after 30 minutes		Variation	Confirm YES/NO	
-40°C	-39.4°C		-0.6°C	yes	
0°C	0.1°C		-0.1°C	yes	
+40°C	39.0°C		+1.0°C	yes	
LEAK RATE TEST					
Check Point		Observation	Acceptance Criteria	Confirm YES/NO	
Chamber Pressure Rise		48 mTorr/hr	11 mTorr/hr	yes	
Main Bellow Pressure Rise			50mbar/Hr		
Mushroom Bellow Pressure Rise			50mbar/Hr		

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Pending Jobs if any	
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Customer Feedback and Comments

We request you to rate our services based on our response performance provided by us as per following format.

S.No	Description	Very Good	Good	Satisfactory	Poor
1	Quality of Parts & Materials used	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2	Performance of equipment	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	After Sales Support	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Equipment Operation & Training	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Request elaborate areas of improvements:

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Note: The Machine is in warranty up to 1 year from the date of installation, during the warranty period if any service problems please contact Mr.M.V.Suresh (Mobile :08008868686) Email: suresh@lyogroup.com
 After completion of warranty if any service problems please contact Mr. U. Sudhakar Reddy (Mobile:08106868775) Email: reddy@lyogroup.com

* DOI : 28-DEC-2021, i.e. validity of warranty TO 27-DEC-2022

Note:

- ❖ After completing SAT Document Scan copy must Required.
- ❖ Software backup CD Required.

For Lyophilization Systems India Pvt Ltd.
 For
 Bhanu Mahesh
 Bhanu Mahesh
 28/12/2021

For Indian Immunologicals Ltd.
 Suresh
 28.12.2021

Customer Contact details
 9248540392