



FACTORY ACCEPTANCE TEST FOR LYOPHILIZER

Department: Quality Assurance	FAT No.:
Title: Factory Acceptance Test for Lyophilizer	Effective Date:
Supersedes: Nil	Review Date:

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PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FACTORY ACCEPTANCE TEST FOR LYOPHILIZER

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1.0 Approval:

This document is prepared by the Validation and GMP compliance team for the project “Sterile Injectable Facility” (**Project Number:**) of under the authority of their Project Manager. Hence, this document before being effective shall be approved by the Head QA.

PREPARED BY	SIGNATURE	DATE

CHECKED BY	SIGNATURE	DATE

APPROVED BY	SIGNATURE	DATE



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2.0 Introduction:

The aim the document is to try to describe the requirements concerning Factory Acceptance Tastings, FAT, FAT, according to standard IEC 61511. The FAT is customized testing procedure for different types of system and the tests are executed before the dispatch for installation at the plant. FAT is not a requirement but recommended to be carry out.

3.0 Aim of the FAT:

FAT is carried out to verify that all features are taken into consideration to avoid the failure of critical GMP and EHS parameter in the equipment at the factory.

During study, all GMP, EHS and operational parameters will be checked and assessed for the risk, appropriate mitigation will be proposed and verification point will be identified and defined.

The purpose of the document is to describe the parameters to be tested during the Factory Acceptance Test performed at Lyophilization Systems India Manufacturing site for the Model Lyodryer LT3S Lyophilizer by team that will install at M/S

4.0 Reference Documents:

S.No.	Document Title	Document Number
1.	Validation Master Plan	
2.	Project Validation Plan	
3.	Lyophilizer Mechanical IQ	
4	Lyophilizer Control System IQ	
5	Lyophilizer Operational Qualification	



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5.0 System Description:

The freeze dryer consists of following major components:

- Chamber with chamber door
- Product shelves
- Heat exchange system
- Ice condenser
- Main valve
- Refrigeration system
- Vacuum system

Control system: Power cabinet, Instrumentation and control system, control cabinet, sterile room control panel & SCADA system.

This risk assessment is conducted for the Lyophilizer comprising of following salient features:

- The Lyophilizer shall be used to freeze-dry the sterile solution of product filled in half stoppered glass vials. Lyophilizer shall stopper the vial before unloading. The decided capacity to be 20 m² (shelf area).
- The vial loading and unloading shall be done with semi-automatic loading-unloading machine. Stoppering of shelf should be hydraulic type. Stoppering conditions should be under vacuum or inert gas.

In this GMP risk assessment all critical components of the Lyophilizer, based on the technical details, are listed and rated according to their influence of the product quality, EHS and operational requirements.

6.0 Participants:

Name (block letters)	Function	Signature

7.0 Factory Acceptance Test:

In the following section a table is produced for the risk analysis. The significance or instruction for each column is described in the following paragraph



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I. MECHANICAL INSTALLATION QUALIFICATION:

1.0 MECHANICAL DRAWING TO BE CHECKED

S.No.	DRAWING NAME	DRAWING NO.	OBSERVATION	CHECKED BY	VERIFIED BY
1.	P&ID Layout Plan				
2.	P & ID Refrigeration System				
3.	P & ID Vacuum System				
4.	P & ID Fluid System				
5.	P& ID Hydraulic system				

2.0 PRODUCT CHAMBER AND DOOR

S.No	SPECIFICATION								
	Description	Make / vendor	Model / serial No.	Type	Size	Documents	Observation	Checked by	Verified by
01.	Product chamber door	LSI	NA	Full vacuum and round corners, SS 316	660x482x482 (± 5 mm)				
02.	Port 01	LSI	NA	Vacuum vent	1.5"				
03.	Port 02	LSI	NA	Vacuum Control	1.5"				
04.	Port 03	LSI	NA	Product probes	KF 40				
05.	Port 04	LSI	NA	Pressure transmitter	1.5"				



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S.No	Description	Make / vendor	Model / serial No.	Type	Size	Documents	Observation	Checked by	Verified by
06.	Port 05	LSI	NA	Vacuum Sensor	KF16				
07.	Port 06	LSI	NA	Vapour port	4"				
08.	Door gasket for product chamber	LSI	Ami polymer	Silicon	1730mm				
09.	Product chamber door	LSI	NA	SS316L	618x560x35 (± 5 mm overall sizes)				

3.0 PRODUCT SHELVES AND HYDRAULIC STOPPERING

SPECIFICATION

S.No.	Description	Make / vendor	Model / serial No	Type	Size	Documents	Observation	Checked by	Verified by
1.	Product Shelves	LSI	NA	Heat transfer by flowing thermal fluid through the shelves, SS 316 L, 220 grit, 3 usable and 1 radiant, 6 sq. ft (0.559 Sq Mtr	610 X 305X10mm(±3mm)				
2.	Shelf Stop ring	LSI	NA						



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S.No.	SPECIFICATION							Checked by	Verified by
	Description	Make / vendor	Model / serial No	Type	Size	Documents	Observation		
	Platform								
3	Hydraulic Cylinder	LSI	NA	Hydraulic 40 Bore 22mm Shaft	500 mm Stroke Length				
4.	Hydraulic Power pack	Parkers	108 Series	Pressure: 800-1200 PSI Flow Rate: 2.8LPM	1/4"				
5.	Loading Trays	LSI	RB trays	SS 316 L	305mm x 610mm 3 Nos				
6.	Hydraulic Oil	NA	NA	Hydrol 68	NA				

4.0 CONDENSER CHAMBER AND CONDENSER COILS

S.No	SPECIFICATION							Checked by	Verified by
	Description	Make / vendor	Model / serial No	Type	Size	Documents	Observation		
01.	Condenser Chamber	LSI	NA	Cylindrical type, Full Vacuum, SS 316 L, 310 mm OD Dia x 625 mm Straight Wall(± 3 mm), Total Capacity 30 Kg, 20 Kg/24 Hours on	310 mm OD Dia x 625mm Straight Wall				



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S.No	SPECIFICATION							Checked by	Verified by
	Description	Make / vendor	Model / serial No	Type	Size	Documents	Observation		
				Average of 0.8Kg/Hour.					
02.	Condenser Coils	LSI	NA	NA	Coil area 5 Sq Ft (0.466 Sq Mtr) 3 coils				
03.	Port 01	LSI	NA	Vacuum valve	KF25				
04.	Port 02	LSI	NA	Drain	½"				
05.	Port 03	LSI	NA	Vapor Port	4"				
06.	Condenser gasket	Ami Polymer	NA	Silicon	940mm				
07.	Condenser door	LSI	NA	SS 316 L	430x430x35mm (± 5 mm for overall size)				



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5.0 FLUID CIRCULATION SYSTEM

S.No	SPECIFICATION							Checked by	Verified by
	Description	Make / vendor	Model / serial No	Type	Size	Documents	Observation		
01.	Fluid Circulation PUMP	Grundfos	Grundfos UPS 25-60	Canned Rotor Design Power Input: 230 Volts Flow Rate: 2m ³ /h at 3 Mtr Head	1/2"				
02.	Safety Thermostat	JUMO	EM-1	NA	0°C TO +100°C				
03.	Circulation Heater with Safety Thermostat	Geepee electrical	NA	Capacity: 2KW Carbon Steel	2 KW				
04.	Heat Exchanger	Alfa Laval	Model CB27-34H and CB27-24H	Brazed plate Heat Exchanger	NA				
05.	Drain and Fill Valve	Mueller Industries	A15580	Inline valve Solder	1 /4"				



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S.No	SPECIFICATION							Checked by	Verified by
	Description	Make / vendor	Model / serial No	Type	Size	Documents	Observation		
06.	Fluid Discharge Pressure gauge	NRP	N2002	Range: -30 to +120PSI	Size: 2.5" Dial Connection: 1/8" MPT				
07.	Expansion Tank	LSI	NA	NA	3"				
08.	System Fluid	Syltherm XLT	NA	Syltherm XLT	Capacity: 12 Liters				

6.0 VACUUM SYSTEM:

S.No	SPECIFICATION								
	Description	Make / vendor	Model / serial No	Type	Size	Documents	Observation	Checked by	Verified by
01.	Vacuum Pump	Adixen	Model:2015 SD Sr:AM691401	Vacuum pump Ultimate vacuum for this pump 10 µbar	15m ³ /Hour				
02.	Vacuum Pump Inline Valve	ASCO	8262G007	Configuration: NC Coil Voltage: 230 V AC 50 Hz	1"				
03.	Vacuum Control Valve	ASCO	8262G007	Configuration: NC Coil Voltage: 230 V AC 50 Hz	½" FPT				
04.	Vacuum Control	Swagelok	SS4MA2	NA	¼" MPT				



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S.No	SPECIFICATION								
	Description	Make / vendor	Model / serial No	Type	Size	Documents	Observation	Checked by	Verified by
	Needle Valve								
05.	Vacuum Release Valve	ASCO	8262G007	Configuration: NC Coil Voltage: 230 V AC 50 Hz	½” FPT				
06.	Isolation Valve	EL-OMATIC	Model DN 150 Sr:99453688	Full Vacuum to Atmosphere, Pneumatic Type, 24V DC	4”				
07.	Vacuum Fluid	LACO	CVP195	NA	NA				

7.0 REFRIGERATION SYSTEM

S.No	SPECIFICATION								
	Description	Make / vendor	Model / serial No	Type	Size	Documents	Observation	Checked by	Verified by
01.	High Stage Compressor	Copeland USA	CF04K6E-PFV-230 HI stage	Capacity: 208/230V 1ph	NA				
02.	Low Stage Compressor	Copeland USA	CF04K6E-PFV-230	Capacity: 208/230V 1ph	NA				



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S.No	Description	Make / vendor	Model / serial No	Type	Size	Documents	Observation	Checked by	Verified by
			low stage						
03.	Oil Separator	Henry	S5582	NA	1/2"				
04.	Filter Drier	Danfoss	DML163S	NA	3/8"				
05.	HP/LP switch-01	Danfoss	KP-15	100 to 465 PSI	NA				
06.	HP/LP switch-02	Danfoss	KP-15	100 to 465 PSI	NA				
07.	Pressure Gauge discharge pressure	NRP	N2003	0 To 500 PSI	NA				
08.	Pressure Gauge discharge pressure	NRP	N2003	0 To 500 PSI	NA				
09.	line valve for hi stage compressor	Mueller Industries	A15580	Inline valve Solder Size	1 /4"				
10.	line valve for Low stage compressor	Mueller Industries	A15580	Inline valve Solder Size	1 /4"				
11.	Refrigerant	NA	R404A	NA	Charge 160PSI				
12.	Refrigerant	NA	R508B	NA	Charge 340PSI				



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II. CONTROL SYSTEM INSTALLATION QUALIFICATION:

1.0 DRAWING

S.No.	DRAWING NAME	DRAWING NO.	OBSERVATION	CHECKED BY	VERIFIED BY
01	Main Electrical Diagram				
02	Control Details				
03	Hydraulic Control Details				
04	Solenoid Valves Details				
05	Terminal Block Details				
06	Terminal Block Details				
07	SCADA Control Details				
08	In Put / Out Put Rack				



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2.0 ELECTRICAL CONTROL PANEL:

S.No	SPECIFICATION								
	Description	Make / vendor	Model / serial No	Type	Rating	Documents	Observation	Checked by	Verified by
01.	Mains Power MCCB	Schneider Electric	EZC100N	NA	40 Amps				
02.	Compressor 1 – Power Contactor	Schneider Electric	LC1D18	230V AC Coil	18 Amps				
03.	Compressor 2 – Power Contactor	Schneider Electric	LC1D18	230V AC Coil	18 Amps				
04.	Vacuum Pump – Power Contactor	Schneider Electric	LC1D18	230V AC Coil	18 Amps				
05.	Fluid Pump – Power Contactor	Schneider Electric	LC1D18	230V AC Coil	18 Amps				
06.	Safety Thermostat	JUMO	EM-1	NA	0 TO +100° C				
07.	Solid State Relay	ERI	001JDA484000	NA	40 Amps				
08.	Hydraulic UP power contactor	Schneider Electric	LC1K09	230V AC Coil	09Amps				
09.	Hydraulic DOWN Power	Schneider	LC1K09	230V AC Coil	09Amps				



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S.No	Description	Make / vendor	Model / serial No	Type	Rating	Documents	Observation	Checked by	Verified by
	Contactora	Electric							
10.	Defrost Power contactor	Schneider Electric	LC1K09	230V AC Coil	09Amps				
11.	Hydraulic Relay	MEXICO	4CR-1-675	21MOR	NA				
12.	Hydraulic Capacitor	DAYTON	PTMJ161	230V	NA				
13.	Power Supply Unit-PLC 6.5Amps	Phoenix Contact	Step power	NA	5V DC, 4 to 6.5 amps				
14.	Power Supply Unit For Controlling	Mean well,	T-60C	NA	15V DC				
15.	Power Supply Unit For Vacuum Sensor	Mean well	NES-50-24	NA	24V DC,				



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3.0 INSTRUMENT CONTROL PANEL

S.No.	SPECIFICATION							Checked by	Verified by
	Description	Make / vendor	Model / serial No	Type	Rating	Documents	Observation		
01.	Programmable Logic Controller	Opto 22	SANP PAC R-1	NA	NA				
02.	PLC Rack 12 Channel	OPTO 22 SNAP-PACK-RCK-12	SNAP-PACK-RCK-12	12-Module SNAP PACK Rack					
03.	I/O Module 230V AC	OPTO 22	OAC5-3 NO	Output # 4 Channel					
04.	I/O Module	OPTO 22	ODC5-1 No	Output # 4 Channel					
05.	AIMA Module	OPTO 22	AIMA4-2 No	4 Channel					
06.	Computer System	Dell Tower	Intel core 2Gb Ram 2 x 250 Gb hard disk 40 x CD RW 19" LCD Panel	NA					
07.	Printer	HP		B/W					
08.	UPS	APC	1000VA/Sr:H291KH0 126M	NA					
09.	Software installed: Windows 07	NA	NA	NA					
10.	Software installed: Pac R9.0	OPTO 22	NA	NA					



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4.0 FIELD MOUNTED TRANSMITTERS, SENSORS

S.No	SPECIFICATION							Checked by	Verified by
	Description	Make / vendor	Model / serial No	Type	Location	Documents	Observation		
01.	Vacuum Transmitter	MKS Systems	Model:-08XX1 017228454 Sr:-622802TDE	Power Supply: +/- 15VDC Out Put: 0 to 10V DC	Product Chamber				
02.	Temperature Sensor	Omega	NA	T-Type Thermocouple	Condenser Coil				
03.	Temperature Sensor	Omega	NA	T-Type Thermocouple	Shelf Inlet				
04.	Temperature Sensor	Omega	NA	T-Type Thermocouple	Product Probes 1to 4				
05.	Pressure Transmitter	WIKA Germany	SA-10 S#1102FAJR	Power Supply: 10 to 30V DC Range: -1 to +3 Kg/Cm2	Product Chamber				



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5.0 SOLENOID VALVES PERFORMANCE CHECKS

S.No	SPECIFICATION							Checked by	Verified by
	Description	Make / vendor	Model / serial No	Location	Size	Documents	Observation		
01.	Solenoid Valves	DANFOSS	EVU	Shelf	3/8"				
02.	Solenoid Valves	DANFOSS	EVU	Control	3/8"				
03.	Solenoid Valves	DANFOSS	EVU	Condenser	3/8"				
04.	Solenoid Valves	DANFOSS	EVU	Bypass	3/8"				
05.	Solenoid Valves	DANFOSS	EVU	Defrost	3/8"				
06.	Solenoid Valves	ASCO	8215G020	Vacuum Valve	3/4"				
07.	Solenoid Valves	ASCO	8262G007	Vacuum control	1/4"				
08.	Solenoid Valves	ASCO	8262G007	Vacuum Vent	1/4"				



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6.0 LOOP CALIBRATION REPORTS:

S.No	SPECIFICATION								
	Description	Make / vendor	Model / serial No	Application	Size	Documents	Observation	Checked by	Verified by
01.	Temperature sensor	OMEGA	NA	Product Probe-1	NA				
02.	Temperature sensor	OMEGA	NA	Product Probe-2	NA				
03.	Temperature sensor	OMEGA	NA	Product Probe-3	NA				
04.	Temperature sensor	OMEGA	NA	Product Probe-4	NA				
05.	Temperature sensor	OMEGA	NA	Shelf In Temperature	NA				
06.	Temperature sensor	OMEGA	NA	Shelf out Temperature	NA				
07.	Temperature sensor	OMEGA	NA	Condenser Temperature	NA				
08.	Pressure transmitter	WIKA	NA	Chamber Pressure	NA				



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7.0 DIGITAL OUT PUTS LIST

S. No.	Description	Module Location			Result	Checked by	Verified by
		Mod No	CH No	Type of module			
01	High stage compressor	0	1	OAC 05			
02	Low Stage Compressor	0	2	OAC 05			
03	Vacuum Pump	0	3	OAC 05			
04	Fluid pump	0	4	OAC 05			
05	Heater	1	1	OAC 05			
06	Isolation Valve	1	2	OAC 05			
07	Alarm	1	3	OAC 05			
08	Stoppering Active	1	4	OAC 05			
09	Shelf Solenoid Valve	2	1	OAC 05			
10	Control Solenoid Valve	2	2	OAC 05			
11	Condenser Solenoid Valve	2	3	OAC 05			
12	Bypass Solenoid	2	4	OAC 05			
13	Vacuum Valve	3	1	OAC 05			
14	Defrost Valve	3	2	OAC 05			
15	Vacuum Control	3	3	OAC 05			
16	Vacuum Vent	3	4	OAC 05			



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8.0 ANLOG INPUTS:-

S.No.	Description	Module Location			Result	Checked by	Verified by
		Mod No	CH No	Type of module			
01	TP01	4	01	AITM2I			
02	TP02	4	02	AITM2I			
03	TP03	5	01	AITM2I			
04	TP04	5	02	AITM2I			
05	Ambient	6	01	AITM2I			
06	Not In Use	6	02	AITM2I			
07	Shelf In	7	01	AITM2I			
08	Condense	7	02	AITM2I			
09	Chamber Pressure	8	01	AIMA4			
10	Vacuum	8	02	AIMA4			



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8.0 Abbreviations and Definitions:

Acronym	Definition
GMP	Good manufacturing practices
EHS	Environment health and safety
CIP	Cleaning in place
DQ	Design Qualification
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
MOC	Material of construction
m	Meter
N ²	Nitrogen
db	Decibel
SIP	Sterilization in place
SOP	Standard Operating Procedure
URS	User Requirement Specification
UPS	Un-interrupted Power Supply



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1.0 SCOPE:

The purpose of the document is to describe the parameters to be tested and results observed during the Factory Acceptance Test Performed at M/S LYOPHILIZATION SYSTEMS INDIA site for the Model Lyodryer LT3S, By team and Lyophilizer that Lyophilization Systems India Pvt. Ltd. This equipment will install at M/S

This document provides the following information:

Mechanical features, Process definition, data management, control system and human machine interface (HMI).

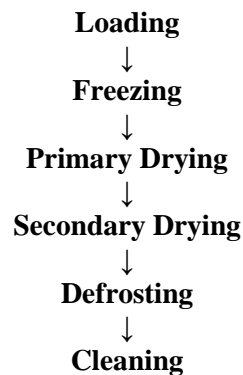
Definition:

The equipment from Lyophilization Systems India Pvt. Ltd has been designed and manufactured according to GxP standards to meet the chemical and pharmaceutical industry requirements, enabling complete freeze drying cycles in a short period of time and maximum reliability.

The purpose of the document is also to verify that the design meets functional specifications. To do the Verification it will be checked that all design points listed in this document are related in the document.

2.0 PROCESS DESIGN:

2.1 The General Process Design in Order to Obtain a Freeze Drier Product





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The Freeze drier equipment is created in order to perform the following cycles

Freeze- drying

Defrosting

System test

Leak rate test



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FAT Protocol & Report for Lyophilizer (Operational Qualification)

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2.2 The equipment has the following features in order to perform the defined cycles

S.No	Specification	Result	Y/N	Checked by	Received by
01	Condenser temperature Blank Off	-80°C			
	Time to decrease the temp. In the condenser from +20 to -40°C	Less than 20minutes			
	Controlled temp. Range on the shelves	-60 to +65 deg. C			
	Shelves cooling time from +20°C to -40°C	Less than 60 min.			
	Heating shelves rate	Greater Than 10C /min			
	Shelves uniformity temperature across the shelves	± 1deg.C			
	Evacuation time from ambient to 100 mTorr	20 min.			
	Leak rate in static condition	20µbar L/Sec			
Ultimate vacuum at the end of the freeze drying cycle	10 µbar				

2.3 Condenser Pull down – Blank Off:-

General Information

The maximum low temperature of the condenser is important to characterize and then periodically retest to verify that the system refrigeration is good.

Acceptance Criteria:

The condenser temperature should reach +20 to -40 oC in 20 minutes after startup. The maximum low temperature of the condenser, -800C° should be achieved within 60 minutes after the system vacuum is below 100µbar.

Test Procedure

Materials: No additional materials will be needed.

Set-Up: The entire system should be clean, dry and empty.



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Challenge: Turn on the condenser and record the time it takes to reach -40°C ($\pm 10\text{C}$). Then turn on the vacuum pump and wait until the system reaches 100 μbar . Then record the time it takes to reach -80°C ($\pm 10\text{C}$) and also the maximum low temperature of the condenser during that period.

Results

- Time to +20 to -40°C (without vacuum):
- Time to -40 to -80°C (with vacuum):
- Maximum low achieved:
- Did the condenser temperature meet all requirements? Y/N

Performed by: _____ **Date:** _____
Lyophilization Systems India Pvt. Limited

Verified by: _____ **Date:** _____
.....



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2.4 Shelf Minimum and Maximum:

General Information

Knowledge of system maximum low temperatures and maximum high temperatures are important to understand in order to make sure that the equipment is the correct choice for processing product. The maximum low temperature should be at least 5 degrees below the lowest product collapse temperature. The maximum high, although often not an issue, should be 5 degrees higher than the maximum high temperature that is required to process the product.

Acceptance Criteria:

The system should reach +20 to -40°C in approx 60 minutes. The system should then reach a maximum low temperature of -60 (±1°C) in approximately 2 hours, but can be longer depending on ambient conditions and the number of shelves. The system should go from -40°C to 20°C (± 10C) in 60 minutes. And reach a maximum temperature of 65°C (± 10C).

Materials: Product thermocouples, heat sink compound, and metal tape.

Challenge: Set the shelf temperature for 5 degrees below the maximum low shelf temperature to -70°C. Note the time it takes for the system to go from room temperature to -40°C (± 10C) and the time it takes to get to the maximum low of -60°C (± 10C). Set the shelf temperature for +65 (5°C above the maximum shelf temperature). Note the time it takes to go to +65°C.

Results

Time from +20°C to -40°C:..... Time from -40°C to -60°C:..... Time from -40°C to +20°C:.....

Time from +40°C to +65°C:

Did the shelf Minimum maximum temperature meet all requirements? Y/N

Performed by: _____ **Date:** _____ **Verified by:** _____ **Date:** _____



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2.5 SHELF UNIFORMITY:

General Information

Shelf mapping is used to verify that the temperature across an individual shelf and from shelf to shelf is not significant. This temperature uniformity is one of the keys to ensuring that the individual product pieces are processed under the same conditions. Heat transfer theory and equipment design dictates that product uniformity must occur when the system is in a stable state (not ramping up or down) and after a reasonable soak period. This shelf-mapping set-up will be used for a series of tests.

Acceptance Criteria:

The system should control within +/-1oC w.r.t average of all the probes within 30 minutes. Of reaching set point at the shelf. This should be able to be accomplished throughout the working range of the system. A survey of 3 different temperatures will be used in this challenge, -40, 0 and +40°C (±1o). .Test Procedure

Materials: Product thermocouples, metal tape.

Set-Up: The system should be clean, dry and empty. Each product Sensor should be taped directly to the shelf by using the metal tape. The pattern for Sensor placement will be determined by the number of thermocouples available as well as the number of shelves. Shelves are numbered from the top down with the shelf below the radiant top plate being number 1. One probe per shelf should be used located at the same position on each shelf.

Challenge: Set the shelf temperature for -40. And let the system soak for at least 30 minutes. Repeat this procedure with set points 0, +40°C. The system should also be under full vacuum to reduce the effects due to convection. At each shelf temperature set point the thermocouples should be within +/- 1°C. After 30 minutes. Record the temperature of each shelf.



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S.No.	Time	SHELF SET POINT	SHELF IN	AVERAGE	TP01	TP02	TP02	TP03	TP04

RESULTS

S.No.	Probes Average Temperature	Probe 01	Probe 02	Probe 03	Probe 04	Probe 05

Are all shelf temperatures within +/- 1.0°C at to average? Y/N:

Performed by: _____ Date: _____ Verified by: _____ Date: _____



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**2.6 Vacuum Pump down and Maximum low Pressure:
General Information**

The pump down time and maximum low pressure of the vacuum system is important to understand in order to verify that the freeze dryer will work within the pressure range required by your product. .

Acceptance Criteria:

The maximum low pressure of this system is 10 µbar. It can take several hours, or even overnight to reach this pressure depending on the size of the vacuum pump and the amount of water vapor in the system. From the atmospheric pressure, it should take 20 minutes. To reach 100 µbar.

Test Procedure

Materials: No additional materials will be needed.

Set-Up: The entire system should be clean, dry and empty.

Challenge: The vacuum pump should be activated when the condenser temperature reaches approximately -40oC (±10)... Let the system run in this condition until the pressure stabilizes. Monitor the time it takes to reach 100 µbar and also the time to reach the maximum low pressure.

RESULTS

- Time to reach 100 µbar:.....
- Maximum low achieved:.....
- Did the system meet the required specifications? Y/N

Performed by: _____ **Date:** _____ **Verified by:** _____ **Date:** _____



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2.7 Vacuum Leak Rate test:-

General Information

The leak rate of the freeze dryer is an important indication of the integrity of the system. A high leak rate indicates that there are penetrations or virtual leaks in the system of enough significance to be contaminating product.

Acceptance Criteria:

The leak rate of this system is 20 μ bar_L/Sec

Test Procedure

Materials: No additional materials will be needed.

Set-Up: The entire system should be clean, dry and empty.

Challenge: The software program includes an automatic leak rate test. Program in the following

Condenser temperature: -40 C

Vacuum Set point: 100 μ bar

Test Time: 30 min

Start the Leak rate test and record the results below.

RESULTS

Pressure Rise per 30Min

Chamber Volume: $V (P_2 - P_1) / T$

Calculated Leak Rate:

NMT 20 μ bar L/Sec

Information: Total Chambers Volume: 200 Ltrs

The Pressure not more than 180 μ bar/30 Min



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2.8 AUTOMATIC RECIPE TEST:

The Automatic screen in the Lyomaster control system can be used to program and run automatic cycles on the Lyophilizer.

The following test will be used to verify that the automatic freeze drying function for the Lyomanager

Control Package operates as expected.

1. From the Main menu click on the **FREEZE DRYING** button.
2. Click on the **EXISTING RECIPE** button. Download the Recipe named **FD Test**.
3. Enter the following data into the freeze drying recipe:
4. Either Fill the information here or attach SCREEN SHOT



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PRESURIZE TEST

START FIRST TEST TIME AFTER:
(MIN)

PRESSURE CONTROL DISABLED TIME
(MIN)

TEST TIME SEC:

INTERVAL TIME MIN:

ADVANCE TO FINAL IF RESULT \leq μ Bar

ALARMS

Condenser Over Load

Vacuum Overload

Power Outage

Once all of the data points are entered into the recipe, the recipe must be saved. To save the recipe, click **SAVE** Button. The recipe must also be printed. This is accomplished by clicking the On Keyboard **PRINT SCREEN** Button.

The recipe is now ready to be run.

Enter the Batch Number; please do not proceed further without entering the batch Number

DO NOT DUPLICATE THE BATCH NUMBER



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USE ONLY ALPHANUMERICAL BATCH NUMBER

To begin cycle press the button labeled **START**.

The recipe will now step through to completion.

Upon completion of the cycle a print out of the cycle needs to be obtained from the reports.

This Data stores in C/Data/Batch Reports folder and C/Data/Numeric Folder

Verified by: _____ Date: _____

The automatic freeze-drying cycle completed the recipe and reached all set points.

Verified by: _____ Date: _____

The Lyomaster is capable of storing multiple freeze-drying recipes. The following test will verify the storage functionality.

1. From the Main Menu click on the FREEZE DRYING Button.
2. Click on **EXISTING RECIPE** and select **TEST 1**.
3. Save the cycle with a label of **TEST 2**.
4. Repeat the save function with the label **TEST 3**.
5. Click on **EXISTING RECIPE**. Verify that **TEST 2** and **TEST 3** appears in the recipe listing.

All recipes were maintained as expected in system memory.

Performed

Performed by: _____ **Date:** _____ **Verified by:** _____ **Date:** _____



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Deviation:

Impact of the deviation:

Corrective Action:

Done by:

checked by:

Corrective action observations (If any):

Approved by LSI: Approved by.....:

With Stamp

with stamp