



**PHARMA DEVILS**

QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**INSTALLATION QUALIFICATION  
FOR  
LYOPHILIZER**



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION FOR LYOPHILIZER

The signatures below indicate approval of this protocol and its attachments and indicate that it is ready for execution. Any changes or modifications to the intent or the acceptance criteria of this protocol, following approval, requires the generation of an amendment which must be approved prior to execution.

### INSTALLATION QUALIFICATION (IQ)

<b>Type of Equipment</b>	Lyophilizer
<b>Customer</b>	
<b>Model</b>	
<b>Revision</b>	
<b>Department</b>	Quality Assurance
<b>Page</b>	71

### IQ Protocol Approval

	<b>Name</b>	<b>Department</b>	<b>Date and Signature</b>
<b>Prepared by</b>		Quality Assurance	
<b>Reviewed by</b>		Quality Assurance	
<b>Approved by</b>		Technology Department	



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**TABLE OF CONTENTS**

INSTALLATION QUALIFICATION (IQ).....	I
IQ PROTOCOL APPROVAL .....	I
1. SCOPE: .....	1
2. PURPOSE: .....	1
3. BACKGROUND:.....	1
4. INTRODUCTION:.....	2
5. SYSTEM DESCRIPTION: .....	2
6. TESTING PROCEDURES:.....	3
7. ACCEPTANCE CRITERIA:.....	4



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

ATTACHMENT 1–DRYING CHAMBER DATA SHEET .....	5
A. Dimension and Material .....	5
B. Chamber internal surface roughness.....	5
C. Chamber Door .....	6
D. Door surface roughness .....	6
E. Automatic slot door .....	7
F. Connection Port.....	8
ATTACHMENT 2–PRODUCT SHELVES DATA SHEET .....	9
ATTACHMENT 3–ICE CONDENSER DATA SHEET.....	12
A. Dimension and Material .....	12
B. Connection Port.....	12
ATTACHMENT 4–REFRIGERATION DATA SHEET .....	14
A. Compressor.....	14
B. Water-cooling condenser.....	14
C. Oil separator .....	15
D. Gas-liquid .....	15
E. Filter .....	15
F. Thermostatic expansion valve .....	15
G. Pressure meter .....	16
H. Pressure relay .....	16
I. Sight glass .....	17
J. Solenoid valve.....	17
K. Other valves.....	18
ATTACHMENT 5–VACUUM DATA SHEET .....	19
A. Vacuum pump .....	19
B. Booster pump .....	19
C. Valves .....	19
ATTACHMENT 6–HYDRAULIC SYSTEM DATA SHEET.....	21
A. Hydraulicpump.....	21
B. Mushroom valve cylinder parameters.....	21
C. Stoppering cylinder parameters .....	21
D. Pressure relay .....	21
E. Valves .....	22
ATTACHMENT 7–PNEUMATIC SYSTEM DATA SHEET .....	23
A. Pneumatic units .....	23
B. Airprssure relay .....	23
C. Solinoid .....	23
ATTACHMENT 8–CIRCULATION SYSTEM DATA SHEET .....	25
A. Circulation Pipeline .....	25
B. Plate heat exchange .....	25
C. Circulation pump.....	25
D. Pressure controller .....	25
E. Electric heater.....	26
F. Insulating resistance for electric heater .....	26



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

ATTACHMENT 9–CIP/SIP SYSTEM DATA SHEET .....	28
A. CIP/SIP Inlet Pipeline.....	28
B. CIP/SIP Drain Pipeline.....	28
C. Water-ring pump .....	28
D. Steam trap.....	28
E. Safety valve .....	29
F. Pneumatic valve .....	29
G. Nozzle.....	30
ATTACHMENT 10–VENTING SYSTEM DATA SHEET .....	31
A. Venting pipeline .....	31
B. Pneumatic valve .....	31
ATTACHMENT 11–ELECTRICAL SYSTEM DATA SHEET .....	32
A. Main Components .....	32
B Insulating resistance .....	34
C Whole Equipment Creepage Current.....	34
D AC Voltage.....	35
E Motor Rotation.....	35
ATTACHMENT 12–CONTROL SYSTEM DATA SHEET .....	37
A. Computer software .....	37
B. Touch Screen.....	37
C. Control Panel.....	37
ATTACHMENT 13–MEASURE INSTRUMENTS .....	39
A. Temperature probe .....	39
B. Electric-contact pressure gauge.....	39
C. Pressure transducer.....	40
D. Proximity sensor.....	40
E. Vacuum gauge.....	40
ATTACHMENT 14- PLC INPUT/OUTPUT TEST.....	41
A. Analog Input.....	41
B. Digital Input .....	43
C. Digital Input.....	48
ATTACHMENT 15-UTILITY DATA SHEET.....	57
A. Electrical.....	57
B. Compressed Air.....	57
C. Cooling Water.....	58
D. Water for Injection .....	58
E. Water drain.....	58
F. Steam discharge.....	59
ATTACHMENT 16-ENGINEERING DRAWING LIST .....	61
ATTACHMENT 17-LUBRICANT LIST.....	62
ATTACHMENT 18-MAJOR COMPONENT LABELING LIST .....	63
ATTACHMENT 19-SPARE PARTS LIST.....	69



## INSTALLATION QUALIFICATION FOR LYOPHILIZER

### 1. SCOPE:

This Installation Qualification (IQ) study will be performed on the Lyophilizer, located in .....

IQ is a checklist activity that ensures the installation performed by meets the design specifications.

This protocol describes the equipment, test procedures, specifications, documents used to establish that the Freeze Dryer has been installed and operates in accordance with the manufacturer's design specifications, and those of ..... Company. The factory will be referred to as ..... through out the rest of this document.

This documentation package has been prepared by Findnovo personnel. This document will provide for the delineation of responsibilities of ....., appropriate approval signatures, support documentation, and other factors that are normally included in a protocol package. All supporting data and documentation will be attached to this validation protocol when completed.

### 2. PURPOSE:

The execution of this protocol will demonstrate and document that the Freeze Dryer has been installed according to the manufacturer's specifications requirements.

The purpose of the Installation Qualification is to provide documented evidence to demonstrate that the equipment is installed following the design specifications.

Installation validation documents supply prove that the equipment has been manufactured according to design specification. Test result of each component will be recorded in the document.

### 3. BACKGROUND:

The Lyophilizer is a new system purchased specifically for use at the facility.



## INSTALLATION QUALIFICATION FOR LYOPHILIZER

### 4. INTRODUCTION:

Installation checks will be performed to verify and document that the system is installed with the proper supporting utilities, services, and components. All instrument calibration, standardization, or adjustment will be performed for the measuring equipment used during the execution of this protocol.

Documentation associated with the system, such as operator's manuals, system drawings, component specification sheets, materials listings, installation diagrams, component plans, and other data, etc., will be reviewed in this report. Copies of these will be included in this report.

Any deviations from the protocol or from specifications or any exceptional conditions encountered will be documented and identified for review on the Protocol Deviation Report Form. The deviations and exceptional conditions noted will be investigated and appropriate actions determined and implemented. The investigations, along with the corrective actions and their justifications, will be documented on the Protocol Deviation Report Form.

### 5. SYSTEM DESCRIPTION:

The Lyophilizer System, Model No. .... is produced by .... The Lyophilizer system has several components: a Chamber, a Condenser, a Vacuum System, a Refrigeration and Heat transfer system, Hydraulic System, Pneumatic System, Control Systems, CIP System, SIP System, and other associated Valves and Instruments.

The Chamber internal surface is constructed of 316L stainless steel and is rated for full vacuum. The chamber is insulated with polymer foam and exterior is 304 stainless steel. The chamber has 1 unit (available) + 1 thermal balance) shelf of 316L stainless steel shelves with a total surface area of 29.7 square meters for product. The shelves provide a temperature range of  $-55^{\circ}\text{C}$  to  $+70^{\circ}\text{C}$ . The front access door constructed of stainless steel provides visibility into the chamber through an observation window. The chamber is equipped with ball sprays and nozzles for a Clean In Place system utilizing WFI.

The Condenser is 600 kg capacity unit, horizontal type circle bucket in shape. It is designed for an unloaded ultimate low temperature of  $-75^{\circ}\text{C}$  (no-load). The Condenser is constructed of 316L stainless steel with a condensing surface comprised of 8 units independent stainless steel coils. It is rated for full vacuum. The condenser is insulated with aluminum silicate polyisocyanurate foam and exterior is stainless steel. A mushroom valve connects the condenser with the chamber. Two water/steam ball sprays are mounted in the condenser for cleaning, sterilization and defrost ice.

The Vacuum System utilizes two vacuum pumps and a booster pump to achieve vacuum. The system is connected to the condenser with stainless steel piping. A pneumatically activated butterfly valve is located close to the condenser to isolate the vacuum system from the Lyophilizer.

The Refrigeration System consists of four 25 P two-stage, semi-hermetic reciprocating compressors utilizing R404A fluid as the refrigerant. Four refrigeration circuits are designed to service the shelves or condenser during various stages of the process.

### 6. TESTING PROCEDURES:

The installation qualification will be performed using the protocol attachments. All pertinent information will be recorded on these forms. Copies of forms may be obtained from QA. Document results and data concurrently with the execution of this protocol. Mark through any unused spaces with a single line and initial and date. Mark spaces that do not apply to the system being qualified with Not Applicable (N/A) and provide an explanation where appropriate. Document any deviations or abnormalities observed during the execution of



## INSTALLATION QUALIFICATION FOR LYOPHILIZER

the protocol.

**NOTE:** Any exceptions to this protocol must be fully investigated and documented. This IQ can be considered acceptable with exceptional data only if the cause of the exception has been determined or an assignable cause can be attributed to it and it can be proven that such data will not invalidate the protocol studies. Quality Assurance is responsible for determining the acceptability of any exceptional data.

### 7. ACCEPTANCE CRITERIA:

- Test Equipment and Materials- All test equipment used during protocol execution must be documented.
- BOM—The associated BOM with this equipment will be attached.
- Drawings and P&IDs-All drawings must be current.
- Components Labeling-All instruments and critical components must be identified.
- Spare Parts-A spare parts list must be available for the system and its associated pieces of equipment.
- Installation/Startup Procedures - All system installation and startup procedures must have been properly executed and documented.
- Utility Verification- All utilities must be verified to meet the manufacturer's specifications.
- All data forms required for execution of the protocol must be completely, accurately, and properly filled out.
- All criteria specified on the data sheets must be met.





**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Attachment 1–Drying Chamber Data sheet**

**Purpose:** Verify all system components are as specified by the manufacturer.

**A. Dimension and Material**

Item	Expected Result	Actual Result
Internal surface material	316 L	Yes ( ) No ( )
Dimension (internal)	2150 × 1800 × 2000	Yes ( ) No ( )
Shape	Rectangle	Yes ( ) No ( )
Internal surface	Polish	Yes ( ) No ( )
Hinge position (face to door)	Left	Yes ( ) No ( )
Viewing port	A sight glass with illumination	Yes ( ) No ( )
Locking type	Automatic bolts	Yes ( ) No ( )
Insulation	Aluminum silicate poly iso cyanurate foam	Yes ( ) No ( )
External decorated board	Stainless steel	Yes ( ) No ( )

**B. Chamber internal surface roughness**

Item	Expected Result	Actual Result
Top	Ra≤0.4μm	R <sub>1</sub> = ___ R <sub>2</sub> = ___ R <sub>3</sub> = ___ R <sub>4</sub> = ___ R <sub>5</sub> = ___
Back		R <sub>1</sub> = ___ R <sub>2</sub> = ___ R <sub>3</sub> = ___ R <sub>4</sub> = ___ R <sub>5</sub> = ___
Bottom		R <sub>1</sub> = ___ R <sub>2</sub> = ___ R <sub>3</sub> = ___ R <sub>4</sub> = ___ R <sub>5</sub> = ___
Left		R <sub>1</sub> = ___ R <sub>2</sub> = ___ R <sub>3</sub> = ___ R <sub>4</sub> = ___ R <sub>5</sub> = ___
Right		R <sub>1</sub> = ___ R <sub>2</sub> = ___ R <sub>3</sub> = ___ R <sub>4</sub> = ___ R <sub>5</sub> = ___



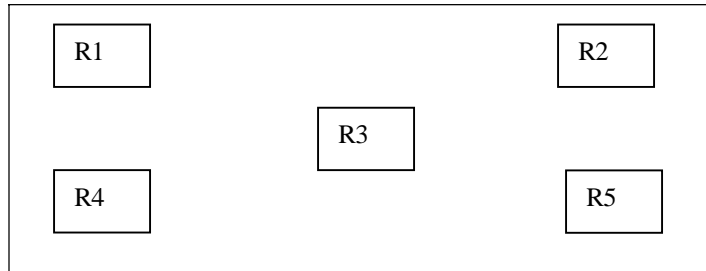
**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Methods:**

Inspect if there is obvious defect of internal surface visually.

Choice five points at chamber every surface and test surface roughness (see chart 1)

Record test value of all of points.



**Figure 1**

**Comments:**

**Acceptance Criteria:** The maximum test value should be less than 0.4µm

**Meets Acceptance Criteria:** Yes ( ) No ( )

**C. Chamber Door:**

Item	ExpectedResult	Actual Result
Internal surface material	316L	Yes ( ) No ( )
View port	Included	Yes ( ) No ( )
External decorated board	Stainless steel	Yes ( ) No ( )
Door Sealing	T-shaped silicone rubber single gasket	Yes ( ) No ( )

**D. Door surface roughness:**

Item	ExpectedResult	ActualResult
Top	Ra≤0.4µm	R <sub>1</sub> = ___ R <sub>2</sub> =___ R <sub>3</sub> =__ R <sub>4</sub> =___ R <sub>5</sub> =___
Back		R <sub>1</sub> = ___ R <sub>2</sub> =___ R <sub>3</sub> =__ R <sub>4</sub> =___ R <sub>5</sub> =___
Bottom		R <sub>1</sub> = ___ R <sub>2</sub> =___ R <sub>3</sub> =__ R <sub>4</sub> =___ R <sub>5</sub> =___
Left		R <sub>1</sub> = ___ R <sub>2</sub> =___ R <sub>3</sub> =__ R <sub>4</sub> =___ R <sub>5</sub> =___
Right		R <sub>1</sub> = ___ R <sub>2</sub> =___ R <sub>3</sub> =__ R <sub>4</sub> =___ R <sub>5</sub> =___

**Methods:**

Inspect if there is obvious defect of internal surface visually.

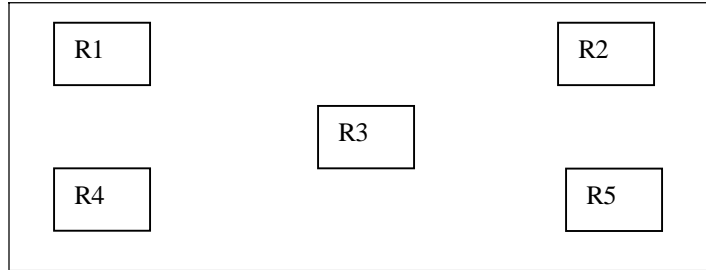
b. Choice five points at door every surface and test surface roughness (see chart 2)

2) Record test value of all of points.



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Figure 2**



**Comments:**

**Acceptance Criteria:** The maximum test value should be less than 0.4 μm

**Meets Acceptance Criteria:**

**Yes ( ) No ( )**

**E. Automatic slot door**

Item	Expected Result	Actual Result
Height	0.95 m	Yes ( ) No ( )
Sealing	Double seal	Yes ( ) No ( )
Open way	Move up and down	Yes ( ) No ( )
Driving way	Motor drive electric push rod	Yes ( ) No ( )
Insulation	Aluminum silicate and poly iso cyanurate foam	Yes ( ) No ( )
External material	304	Yes ( ) No ( )

**F. Connection Port**

Item	Expected Result	Actual Result
Ballspray	DN40	Yes ( ) No ( )
Test temperature	DN40	Yes ( ) No ( )
Small door clean water inlet	DN40	Yes ( ) No ( )
Fluid outlet	DN65	Yes ( ) No ( )
Oil inlet	DN65	Yes ( ) No ( )
View port	Φ150	Yes ( ) No ( )
Jacket water inlet	DN32	Yes ( ) No ( )
Jacket water outlet	DN32	Yes ( ) No ( )
Jacket air outlet	DN20	Yes ( ) No ( )
Chamber drain	DN65	Yes ( ) No ( )



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION FOR LYOPHILIZER

**Comments:**

**Acceptance Criteria:** All actual results will be the same as the expected results

**Meets Acceptance Criteria:** Yes ( ) No ( )

	Department	Sign. & Date
Checked by	Quality Assurance	
Reviewed by	Quality Assurance	



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Attachment 2–Product Shelves Data sheet**

**Purpose:** Verify system components are as specified by the manufacturer.

**Dimension and Material**

Item	Expected Result	Actual Result
Material	316 L	Yes ( ) No ( )
Dimension	1500 × 1800 × 24	Yes ( ) No ( )
Number of shelves	11 (available shelves)+1(thermal balance shelf)	Yes ( ) No ( )
Spacing	100 mm	Yes ( ) No ( )
Surface state	Mirror polish	Yes ( ) No ( )

**Shelf Pressure Test**

Item	Expected Result	Actual Result
PressTest	The pressure should not decline during pressure test.	Test time: _____h Initial pressure: _____MPa Final pressure: _____MPa

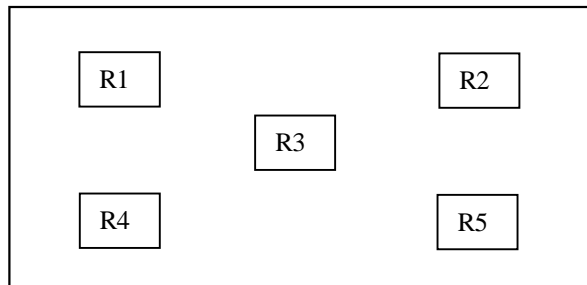
**Surface Roughness**

**Methods:**

Inspect if there is obvious defect of internal surface visually.

b. Choice five points according to chart 3 and test surface roughness.

2) Record test value of all of points.



**Figure 3**



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Comments:**

**Acceptance Criteria:** The surface of every shelf should be less than 0.4µm.

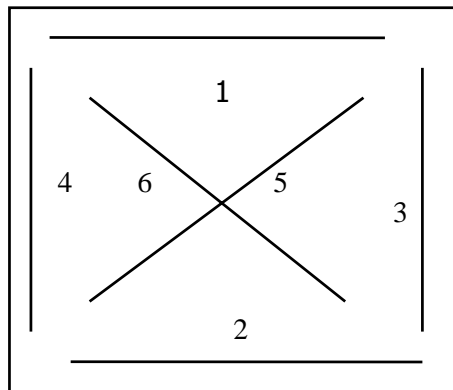
Item	Actual Result
Radiantshelf (bottom)	R <sub>1</sub> = _____ R <sub>2</sub> = _____ R <sub>3</sub> = _____ R <sub>4</sub> = _____ R <sub>5</sub> = _____
Shelf 1	R <sub>1</sub> = _____ R <sub>2</sub> = _____ R <sub>3</sub> = _____ R <sub>4</sub> = _____ R <sub>5</sub> = _____
Shelf 2	R <sub>1</sub> = _____ R <sub>2</sub> = _____ R <sub>3</sub> = _____ R <sub>4</sub> = _____ R <sub>5</sub> = _____
Shelf 3	R <sub>1</sub> = _____ R <sub>2</sub> = _____ R <sub>3</sub> = _____ R <sub>4</sub> = _____ R <sub>5</sub> = _____
Shelf 4	R <sub>1</sub> = _____ R <sub>2</sub> = _____ R <sub>3</sub> = _____ R <sub>4</sub> = _____ R <sub>5</sub> = _____
Shelf 5	R <sub>1</sub> = _____ R <sub>2</sub> = _____ R <sub>3</sub> = _____ R <sub>4</sub> = _____ R <sub>5</sub> = _____
Shelf 6	R <sub>1</sub> = _____ R <sub>2</sub> = _____ R <sub>3</sub> = _____ R <sub>4</sub> = _____ R <sub>5</sub> = _____
Shelf 7	R <sub>1</sub> = _____ R <sub>2</sub> = _____ R <sub>3</sub> = _____ R <sub>4</sub> = _____ R <sub>5</sub> = _____
Shelf 8	R <sub>1</sub> = _____ R <sub>2</sub> = _____ R <sub>3</sub> = _____ R <sub>4</sub> = _____ R <sub>5</sub> = _____
Shelf 9	R <sub>1</sub> = _____ R <sub>2</sub> = _____ R <sub>3</sub> = _____ R <sub>4</sub> = _____ R <sub>5</sub> = _____
Shelf 10	R <sub>1</sub> = _____ R <sub>2</sub> = _____ R <sub>3</sub> = _____ R <sub>4</sub> = _____ R <sub>5</sub> = _____
Shelf 11	R <sub>1</sub> = _____ R <sub>2</sub> = _____ R <sub>3</sub> = _____ R <sub>4</sub> = _____ R <sub>5</sub> = _____

**Meets Acceptance Criteria:** Yes () No ()

**Flatness**

**Methods:**

Put a steel ruler at shelf surface and test maxuim clearance between ruler and shelf surface with gap gauge  
According to chart 4



**Figure4**



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION FOR LYOPHILIZER

The flatness of every shelf should be less than  $\pm 0.5$  mm/m.

Item	Actual Result
Radiantshelf (bottom)	R <sub>1</sub> =_____ R <sub>2</sub> =_____ R <sub>3</sub> =_____ R <sub>4</sub> =_____ R <sub>5</sub> =_____ R <sub>6</sub> =_____
Shelf 1	R <sub>1</sub> =_____ R <sub>2</sub> =_____ R <sub>3</sub> =_____ R <sub>4</sub> =_____ R <sub>5</sub> =_____ R <sub>6</sub> =_____
Shelf 2	R <sub>1</sub> =_____ R <sub>2</sub> =_____ R <sub>3</sub> =_____ R <sub>4</sub> =_____ R <sub>5</sub> =_____ R <sub>6</sub> =_____
Shelf 3	R <sub>1</sub> =_____ R <sub>2</sub> =_____ R <sub>3</sub> =_____ R <sub>4</sub> =_____ R <sub>5</sub> =_____ R <sub>6</sub> =_____
Shelf 4	R <sub>1</sub> =_____ R <sub>2</sub> =_____ R <sub>3</sub> =_____ R <sub>4</sub> =_____ R <sub>5</sub> =_____ R <sub>6</sub> =_____
Shelf 5	R <sub>1</sub> =_____ R <sub>2</sub> =_____ R <sub>3</sub> =_____ R <sub>4</sub> =_____ R <sub>5</sub> =_____ R <sub>6</sub> =_____
Shelf 6	R <sub>1</sub> =_____ R <sub>2</sub> =_____ R <sub>3</sub> =_____ R <sub>4</sub> =_____ R <sub>5</sub> =_____ R <sub>6</sub> =_____
Shelf 7	R <sub>1</sub> =_____ R <sub>2</sub> =_____ R <sub>3</sub> =_____ R <sub>4</sub> =_____ R <sub>5</sub> =_____ R <sub>6</sub> =_____
Shelf 8	R <sub>1</sub> =_____ R <sub>2</sub> =_____ R <sub>3</sub> =_____ R <sub>4</sub> =_____ R <sub>5</sub> =_____ R <sub>6</sub> =_____
Shelf 9	R <sub>1</sub> =_____ R <sub>2</sub> =_____ R <sub>3</sub> =_____ R <sub>4</sub> =_____ R <sub>5</sub> =_____ R <sub>6</sub> =_____
Shelf 10	R <sub>1</sub> =_____ R <sub>2</sub> =_____ R <sub>3</sub> =_____ R <sub>4</sub> =_____ R <sub>5</sub> =_____ R <sub>6</sub> =_____
Shelf 11	R <sub>1</sub> =_____ R <sub>2</sub> =_____ R <sub>3</sub> =_____ R <sub>4</sub> =_____ R <sub>5</sub> =_____ R <sub>6</sub> =_____

Meets Acceptance Criteria:

Yes ( ) No ( )

	Department	Sign. & Date
Checked by	Quality Assurance	
Reviewed by	Quality Assurance	



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Attachment 3 – Ice Condenser Data sheet**

**Purpose:** Verify system components are as specified by the manufacturer.

**A. Dimension and Material**

Item	Expected Result	Actual Result
Internal Material	316L	Yes ( ) No ( )
Shape	Cylindrical	Yes ( ) No ( )
View Port	With an illumination lamp	Yes ( ) No ( )
Coil Material	316L	Yes ( ) No ( )
External Decorated Board	Stainless steel	Yes ( ) No ( )

**B. Connection Port**

Item	Expected Result	Actual Result
Water inlet	DN50	Yes ( ) No ( )
Coiltemperature test	DN40	Yes ( ) No ( )
Maintenance	DN40	Yes ( ) No ( )
Vacuum	DN100	Yes ( ) No ( )
Steam defrost	DN20	Yes ( ) No ( )
View port	Φ150	Yes ( ) No ( )
Drain port	DN65	Yes ( ) No ( )
Test temperature	DN40	Yes ( ) No ( )
Jacket venting	DN20	Yes ( ) No ( )
Jacket water inlet	DN20	Yes ( ) No ( )
Jacket overfall	DN20	Yes ( ) No ( )

**Comments:**

**Acceptance Criteria:** All actual results will be the same as the expected results.

**Meets Acceptance Criteria:**

**Yes ( ) No ( )**

	Department	Sign. & Date
Checkedby	QualityAssurance	
Reviewedby	QualityAssurance	





**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Attachment 4 – Refrigeration Data sheet**

**Purpose:** Verify system components are as specified by the manufacturer.

There are four independent sets for refrigerating system. Verify main components as shown below.

**A. Compressor**

Item	Expected Result	Actual Result
Brand	Bitzer	Yes ( ) No ( )
Model	S6Gg-25.2Y	Yes ( ) No ( )
Number	4	Yes ( ) No ( )
Serial No.	.....	Yes ( ) No ( )

**B. Water-cooling condenser**

Item	Expected Result	Actual Result
<b>Water cooling condenser</b>		
Brand	Jiangsuxuemei	Yes ( ) No ( )
Mode	WN-25	Yes ( ) No ( )
Number	4	Yes ( ) No ( )
SerialNo.	.....	Yes ( ) No ( )
<b>Safety valve</b>		
Brand	CASTEL	Yes ( ) No ( )
Model	.....	Yes ( ) No ( )
Number	4	Yes ( ) No ( )



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**C. Oil separator**

Item	Expected Result	Actual Result
Brand	Alco	Yes ( ) No ( )
Model	AW569011	Yes ( ) No ( )
Number	4	Yes ( ) No ( )

**D. Gas-liquid**

Item	Expected Result	Actual Result
Brand	Honoco	Yes ( ) No ( )
Model	SAV-2415	Yes ( ) No ( )
Number	4	Yes ( ) No ( )

**E. Filter**

Item	Expected Result	Actual Result
<b>Gas filter cartridge</b>		
Brand	Honoco	Yes ( ) No ( )
Model	CD-2205	Yes ( ) No ( )
Number	4	Yes ( ) No ( )
<b>Gas filter core</b>		
Brand	Alco	Yes ( ) No ( )
Model	D-48	Yes ( ) No ( )
Number	8	Yes ( ) No ( )
<b>Liquid filter cartridge</b>		
Brand	Hono	Yes ( ) No ( )
Model	CD-1102	Yes ( ) No ( )
Number	4	Yes ( ) No ( )
<b>Liquid filter core</b>		
Brand	Alco	Yes ( ) No ( )
Model	H-48	Yes ( ) No ( )
Number	4	Yes ( ) No ( )

**F. Thermo static expansion valve**

Item	Expected Result	Actual Result
<b>Expansion valve of condenser</b>		
Brand	Danfoss	Yes ( ) No ( )
Model	TE5	Yes ( ) No ( )
Number	4	Yes ( ) No ( )



## INSTALLATION QUALIFICATION FOR LYOPHILIZER

Expansion valve of shelves		
Brand	Danfoss	Yes ( ) No ( )
Model	TE5	Yes ( ) No ( )
Number	4	Yes ( ) No ( )
Expansion valve for adjusting shelves temperature		
Brand	Danfoss	Yes ( ) No ( )
Model	TES2	Yes ( ) No ( )
Number	2	Yes ( ) No ( )

### G. Pressure meter

Item	Expected Result	ActualResult
High pressure meter		
Brand	REFCO	Yes ( ) No ( )
Model	-1~35Bar	Yes ( ) No ( )
Number	4	Yes ( ) No ( )
Medium pressure meter		
Brand	REFCO	Yes ( ) No ( )
Model	-1~16Bar	Yes ( ) No ( )
Number	4	Yes ( ) No ( )
Low pressure meter		
Brand	REFCO	Yes ( ) No ( )
Model	-1~16Bar	Yes ( ) No ( )
Number	4	Yes ( ) No ( )
Oilpressure meter		
Brand	REFCO	Yes ( ) No ( )
Model	-1~16Bar	Yes ( ) No ( )
Number	4	Yes ( ) No ( )
Water pressure meter		
Brand	REFCO	Yes ( ) No ( )
Model	-1~16Bar	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
Pressure relay	Expected Result	Actual Result
High pressure relay		
Brand	Danfoss	Yes ( ) No ( )
Model	KP5	Yes ( ) No ( )
Number	4	Yes ( ) No ( )
Low pressure relay		



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

Brand	Danfoss	Yes ( ) No ( )
Model	KP2	Yes ( ) No ( )
Number	4	Yes ( ) No ( )
<b>Low pressure relay</b>		
Brand	Danfoss	Yes ( ) No ( )
Model	KP1	Yes ( ) No ( )
Number	4	Yes ( ) No ( )
<b>Difference of oil pressure relay</b>		
Brand	Danfoss	Yes ( ) No ( )
Model	MP54	Yes ( ) No ( )
Number	4	Yes ( ) No ( )
<b>Water pressure relays</b>		
Brand	Danfoss	Yes ( ) No ( )
Model	KP2	Yes ( ) No ( )
Number	1	Yes ( ) No ( )

**H. Sight glass**

Item	ExpectedResult	Actual Result
Brand	Danfoss	Yes ( ) No ( )
Model	SGN6s	Yes ( ) No ( )
Number	4	Yes ( ) No ( )
Model	SGN12s	Yes ( ) No ( )
Number	4	Yes ( ) No ( )

**I. Solenoid valve**

Item	ExpectedResult	Actual Result
Brand	Danfoss	Yes ( ) No ( )
<b>Solenoid valve of condenser</b>		
Model	EVR6	Yes ( ) No ( )
Number	4	Yes ( ) No ( )
<b>Solenoid valve of shelves</b>		
Model	EVR6	Yes ( ) No ( )
Number	4	Yes ( ) No ( )
<b>Solenoid valve of adjusting shelves temperature</b>		
Model	EVR6	Yes ( ) No ( )
Number	2	Yes ( ) No ( )
<b>Solenoid valve of adjusting pressure</b>		
Model	EVR6	Yes ( ) No ( )
Number	4	Yes ( ) No ( )



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**J. Other valves:**

Item	Expected Result	Actual Result
<b>Maintenance valve of expansion valve (Receive valve)</b>		
Brand	Castel	Yes ( ) No ( )
Model	6420	Yes ( ) No ( )
Number	18	Yes ( ) No ( )

**Comments:**

**Acceptance Criteria:** All actual results will be the same as the expected results.

**MeetsAcceptanceCriteria:** Yes ( ) No ( )

	Department	Sign. &Date
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## INSTALLATION QUALIFICATION FOR LYOPHILIZER

### Attachment 5–Vacuum Data sheet

**Purpose:** Verify system components are as specified by the manufacturer.

#### A. Vacuum pump:

Item	Expected Result	ActualResult
Brand	Leybold	Yes ( ) No ( )
Model	D65B	Yes ( ) No ( )
Number	2	Yes ( ) No ( )
Serial No.	.....	Yes ( ) No ( )

#### B. Booster pump:

Item	ExpectedResult	ActualResult
Brand	Leybold	Yes ( ) No ( )
Model	WAU1001	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
SerialNo.	911	Yes ( ) No ( )

#### C. Valves:

Item	Expected Result	Actual Result
<b>Chamber – Condenser isolation valve</b>		
Brand	Tiansheng	Yes ( ) No ( )
Dimension	φ700	Yes ( ) No ( )
<b>Little butter fly valve</b>		
Brand	Dendyi	Yes ( ) No ( )
Model	DN100	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
<b>Electromagnetic baffle valve</b>		
Brand	Siegind	Yes ( ) No ( )
Model	GDC-8/S	Yes ( ) No ( )
Number	2	Yes ( ) No ( )



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Comments:**

**Acceptance Criteria:** All actual results will be the same as the expected results.

**Meets Acceptance Criteria:**

**Yes ( ) No ( )**

	<b>Department</b>	<b>Sign. &amp; Date</b>
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**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Attachment 6 – Hydraulic System Data Sheet**

**Purpose:** Verify system components areas specified by the manufacturer.

**A. Hydraulic pump:**

Item	ExpectedResult	ActualResult
Brand	BREVINI	Yes ( ) No ( )
Model	MC44KW	Yes ( ) No ( )
Number	1	Yes ( ) No ( )

**B. Mushroom valve cylinder parameters:**

Item	Expected Result	Actual Result
Stroke	320 mm	Yes ( ) No ( )
Diameter of piston rod	70 mm	Yes ( ) No ( )
Diameter of cylinder	125 mm	Yes ( ) No ( )

**C. Stoppering cylinder parameters:**

Item	Expected Result	Actual Result
Stroke	1380 mm	Yes ( ) No ( )
Diameter of piston rod	90 mm	Yes ( ) No ( )
Diameter of cylinder	180 mm	Yes ( ) No ( )

**D. Pressure relay:**

Item	ExpectedResult	ActualResult
Brand	ISO	Yes ( ) No ( )
Model	C54110038	Yes ( ) No ( )
Number	2	Yes ( ) No ( )





**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**E. Valves:**

Item	Expected Result	Actual Result
<b>Electromagnetic shuttle valve</b>		
Brand	Aron/Brevini	Yes ( ) No ( )
Model	AD3E03CM003/XDC3C03N 2F002	Yes ( ) No ( )
Number	1/1	Yes ( ) No ( )
<b>Orifice check valve</b>		
Brand	Aron/Brevini	Yes ( ) No ( )
Model	AM3QFABC004	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
<b>Over fall valve</b>		
Brand	Aron/Brevini	Yes ( ) No ( )
Model	AM3RDP1C2004	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
<b>Guide non return</b>		
Brand	Aron/Brevini	Yes ( ) No ( )
Model	AM3UPAB1003	Yes ( ) No ( )
Number	1	Yes ( ) No ( )

**Comments:**

**AcceptanceCriteria:** All actual results will be the same as the expected results.

**Meets Acceptance Criteria:** Yes ( ) No ( )

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**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Attachment 7–Pneumatic System Data sheet**

**Purpose:** Verify system components are as specified by the manufacturer.

**A. Pneumatic units:**

Item	Expected Result	Actual Result
<b>Pneumatic triple units</b>		
Brand	Zemai	Yes ( ) No ( )
Model	3/8"	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
<b>Inlet valve of compressed air</b>		
Brand	Zemai	Yes ( ) No ( )
Model	3/8"	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
<b>Pneumatic board</b>		
Brand	Mindman	Yes ( ) No ( )
Model	G1/4"	Yes ( ) No ( )
Number	1	Yes ( ) No ( )

**B. Air pressure relay**

Item	Expected Result	Actual Result
Brand	SMC	Yes ( ) No ( )
Model	1/8"	Yes ( ) No ( )
Number	1	Yes ( ) No ( )

**C. Solinoid**

Item	Expected Result	Actual Result
<b>Two-position and five-way valve</b>		
Brand	Mindman	Yes ( ) No ( )
Model	MVSC-220-4E1	Yes ( ) No ( )
Number	25	Yes ( ) No ( )
<b>Two-position and five-way valve</b>		
Brand	Mindman	Yes ( ) No ( )
Model	MVSC-220-4E2	Yes ( ) No ( )
Number	2	Yes ( ) No ( )

**Comments:**

**AcceptanceCriteria:** All actual results will be the same as the expected results.

**Meets Acceptance Criteria:** Yes ( ) No ( )



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

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**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Attachment 8–Circulation System Data sheet**

**Purpose:** Verify system components areas specified by the manufacturer.

**A. Circulation Pipeline**

Item	Expected Result	Actual Result
Pipe dimension	Φ76	Yes ( ) No ( )
Pipe material	304	Yes ( ) No ( )

**B. Plate heat exchange**

Item	Expected Result	Actual Result
Brand	Alfalaval	Yes ( ) No ( )
Model	AC120-60EQ	Yes ( ) No ( )
Number	4	Yes ( ) No ( )
Serial No.		Yes ( ) No ( )

**C. Circulation pump**

Item	Expected Result	Actual Result
Brand	Hermetic	Yes ( ) No ( )
Model	CNF50-160	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
SerialNo.	DH26578	Yes ( ) No ( )

**D. Pressure controller**

Item	Expected Result	Actual Result
Brand	Danfoss	Yes ( ) No ( )
Model	KP2	Yes ( ) No ( )
Number	1	Yes ( ) No ( )



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**E. Electric heater:**

Item	Expected Result	Actual Result
<b>Electric heater</b>		
Brand	Syfdroq	Yes ( ) No ( )
Power	24KW	Yes ( ) No ( )
Number	2	Yes ( ) No ( )
<b>Temperature controller</b>		
Brand	Danfoss	Yes ( ) No ( )
Model	KP79	Yes ( ) No ( )
Numbe	1	Yes ( ) No ( )
<b>Circulation pressure meter</b>		
Brand	Z.Y	Yes ( ) No ( )
Model	YTN-63	Yes ( ) No ( )
Number	1	Yes ( ) No ( )

**F. Insulating resistance for electric heater:**

Item	Actual Result	Actual Result
1#	Insulating resistance = MΩ	MΩ
2#	Insulating resistance = MΩ	MΩ
3#	Insulating resistance = MΩ	MΩ

**Methods**

- Adjust meg ohm meter range to 500V/200MΩ
- Connect positive meter pen with a terminal for electric heater tube and connect negative meter pen with cartridge.
- Press test button and record value.
- Repeat above steps for every electric heater tube.



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Comments:**

**Acceptancecriteria: All of test values should be mort than 10MΩ.**

**Meets Acceptance Criteria: Yes ( ) No ( )**

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**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Attachment 9–CIP/SIP System Data sheet**

**Purpose:** Verify system components areas specified by the manufacturer.

**A. CIP/SIP Inlet Pipeline**

Item	Expected Result	Actual Result
Pipe dimension	φ38	Yes ( ) No ( )
Pipe material	316L	Yes ( ) No ( )

**B. CIP/SIP Drain Pipeline**

Item	Expected Result	Actual Result
Pipe dimension	φ76	Yes ( ) No ( )
Pipe material	304	Yes ( ) No ( )

**C. Water-ring pump**

Item	Expected Result	Actual Result
<b>Water-ring pump</b>		
Brand	SIHI	Yes ( ) No ( )
Model	LEMC150	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
Serial No.	10252LJJ	Yes ( ) No ( )
<b>Water ring pump isolation valves</b>		
Brand	Dengyi	Yes ( ) No ( )
Model	DN40	Yes ( ) No ( )
Number	1	Yes ( ) No ( )

**D. Steamtrap**

Item	Expected Result	Actual Result
Brand	MIYAWAKI	Yes ( ) No ( )
Model	SU2N3/4"/ SD11/2"	Yes ( ) No ( )
Number	2	Yes ( ) No ( )



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**E. Safety valve**

Item	Expected Result	Actual Result
<b>Safety valve</b>		
Brand	Tengen	Yes ( ) No ( )
Model	DN20	Yes ( ) No ( )
Number	1	Yes ( ) No ( )

**F. Pneumatic valve**

Item	Expected Result	Actual Result
<b>Drain valve of chamber (Pneumatic butterfly valve)</b>		
Brand	Dengyi	Yes ( ) No ( )
Model	DN65	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
<b>Drain valve of condenser (Pneumatic butterfly valve)</b>		
Brand	Dengyi	Yes ( ) No ( )
Model	DN65	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
<b>Steam drain valve</b>		
Brand	Dengyi	Yes ( ) No ( )
Model	DN25	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
<b>Water drain valve (Pneumatic butterfly valve)</b>		
Brand	Dengyi	Yes ( ) No ( )
Model	DN65	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
<b>Main steam valve</b>		
Brand	Burkert	Yes ( ) No ( )
Model	DN25	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
<b>Cleaning</b>		
Brand	Burkert	Yes ( ) No ( )
Model	DN40	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
<b>Water/steam inlet valve of chamber</b>		
Brand	Burkert	Yes ( ) No ( )
Model	DN40	Yes ( ) No ( )
Number	3	Yes ( ) No ( )
<b>Water/Steam inlet valve of Condenser</b>		
Brand	Burkert	Yes ( ) No ( )
Model	DN40	Yes ( ) No ( )
Number	1	Yes ( ) No ( )





# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION FOR LYOPHILIZER

### G. Nozzle

Item	ExpectedResult	Actual Result
<b>Noozle</b>		
Model	1/4HH-SS6.5	Yes ( ) No ( )
Number	42	Yes ( ) No ( )
<b>Ballsprayer</b>		
Model	Φ38	Yes ( ) No ( )
Number	2	Yes ( ) No ( )

### Comments:

**Acceptance Criteria:** All actual results will be the same as the expected results.

**Meets Acceptance Criteria:**

Yes ( ) No ( )

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**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Attachment 10–Venting System Data sheet**

**A. Venting pipeline**

Item	Expected Result	Actual Result
Pipe dimension	φ25	Yes ( ) No ( )
Pipe material	316L	Yes ( ) No ( )

**B. Pneumatic valve**

Item	Expected Result	Actual Result
<b>Main air inlet valve</b>		
Brand	Burkert	Yes ( ) No ( )
Model	DN25	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
<b>Chamber air inlet valve</b>		
Brand	Burkert	Yes ( ) No ( )
Model	DN40	Yes ( ) No ( )
Number	3	Yes ( ) No ( )
<b>Condenser air inlet valve</b>		
Brand	Burkert	Yes ( ) No ( )
Model	DN40	Yes ( ) No ( )
Number	1	Yes ( ) No ( )

**Comments:**

**Acceptance Criteria:** All actual results will be the same as the expected results.

**Meets Acceptance Criteria:**

**Yes ( ) No ( )**

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**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Attachment 11–Electrical System Data sheet**

**Purpose:** Verify system components are as specified by the manufacturer.

**A. Main Components:**

Name	Brand	Model	QTY	Result
<b>Connector Schneider</b>				
Compressor	SCHNEIDER		4	Yes ( ) No ( )
Circulation pump	SCHNEIDER		1	Yes ( ) No ( )
Vacuum pump	SCHNEIDER		2	Yes ( ) No ( )
Hydraulic units	SCHNEIDER		1	Yes ( ) No ( )
Water-ring pump	SCHNEIDER		1	Yes ( ) No ( )
Electric heater	SCHNEIDER		2	Yes ( ) No ( )
Booster pump	SCHNEIDER		1	Yes ( ) No ( )
Little door motor	SCHNEIDER		2	Yes ( ) No ( )
<b>Air breaker</b>				
Main power	SCHNEIDER		1	Yes ( ) No ( )
Compressor	SCHNEIDER		2	Yes ( ) No ( )
Circulation pump	SCHNEIDER		2	Yes ( ) No ( )
Vacuum pump	SCHNEIDER		2	Yes ( ) No ( )
Hydraulic units	SCHNEIDER		1	Yes ( ) No ( )
Waterring pump	SCHNEIDER		1	Yes ( ) No ( )
Electric heater	SCHNEIDER		2	Yes ( ) No ( )
Boosterpump	SCHNEIDER		1	Yes ( ) No ( )
Littledoormotor	SCHNEIDER		1	Yes ( ) No ( )
<b>Littleairbreaker</b>				
ACcontrol loop (220V)	SCHNEIDER	OSMC32N2C16	1	Yes ( ) No ( )
Controlpower	SCHNEIDER	OSMC32N2C10	1	Yes ( ) No ( )



## INSTALLATION QUALIFICATION FOR LYOPHILIZER

Solenoid power	SCHNEIDER		1	Yes ( ) No ( )
Aassistantpower	SCHNEIDER		1	Yes ( ) No ( )
PLC output	SCHNEIDER		1	Yes ( ) No ( )
Compressor 1 electric heat protection	SCHNEIDER		1	Yes ( ) No ( )
Compressor 2 electric heat protection	SCHNEIDER		1	Yes ( ) No ( )
Compressor 3 electric heat protection	SCHNEIDER		1	Yes ( ) No ( )
Compressor 4 electric heat protection	SCHNEIDER		1	Yes ( ) No ( )
Compressor 1 electric heater	SCHNEIDER		1	Yes ( ) No ( )
Compressor 2 electric heater	SCHNEIDER		1	Yes ( ) No ( )
Compressor 3 electric heater	SCHNEIDER		1	Yes ( ) No ( )
Compressor4electric heater	SCHNEIDER		1	Yes ( ) No ( )
Vacuumgauge for chamber	SCHNEIDER		1	Yes ( ) No ( )
Vacuumgauge for condenser	SCHNEIDER		1	Yes ( ) No ( )
<b>Switchpower</b>				
Power supply DC1	MIWE	24V/20A	1	Yes ( ) No ( )
Power supply DC2	MIWE	5V/3A	1	Yes ( ) No ( )
<b>Solid relay</b>				
Heater	SHIMADEN		2	Yes ( ) No ( )
<b>UPS</b>				
UPS	SANTAK		1	Yes ( ) No ( )
<b>PLC</b>				
Power module	OMRON		2	Yes ( ) No ( )
CPU module	OMRON		1	Yes ( ) No ( )
Analog input module	OMRON		3	Yes ( ) No ( )
Analog output module	OMRON		1	Yes ( ) No ( )
Digital input module	OMRON		4	Yes ( ) No ( )
Digital output module	OMRON		6	Yes ( ) No ( )
Communication module	OMRON		1	Yes ( ) No ( )
Temperature control module	OMRON		1	Yes ( ) No ( )



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**B Insulating resistance**

Item	Earth L1	Earth L2	Earth L3
Whole equipment insulating resistance			

**Methods:** Adjust insulating meter to 500V/200 M $\Omega$ . Clamp cathode in earth terminal and connect anode with three terminal of main switch. Press test button and read values.

**Comments:**

Acceptance Criteria: Test values are more than or equal 10M $\Omega$ .

**Meets Acceptance Criteria:**

Yes ( ) No ( )

**C Whole Equipment Creepage Current**

Item	Earth L1	Earth L2	Earth L3
Whole equipment creepage			

**Methods:** Adjust tester to 1000V/1s and set creepage current to 15mA. Clamp cathode in earth terminal and connect anode with three terminal of main switch. Press test button and read values.

**Comments:**

**Acceptance Criteria:** Test values are less than 15mA.

**Meets Acceptance Criteria:**

Yes ( ) No ( )



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**D AC Voltage**

Element	MeasurePosition	Rating volage±10%	L1-L2 voltage L1-L2	L2-L3 voltage L2-L3	L1-L3 voltage L1-L3
DC power voltage	Main power inlet	380-440 V AC 3PH /50Hz / 60Hz			

**DC Voltage**

Element	Measurespot	Ratingvolage±10%	Measuredvalue
Sight glass lamp	Sight glass lamp	DC5V	
ControlDC power	Sensor	DC24V	
	PLC input		
	Touch screen		

**Comments:**

**Acceptance Criteria:** Test values are equal rating value.

**Meets Acceptance Criteria:**

Yes ( ) No ( )

**E Motor Rotation:**

Electrify momentarily and in spectmotor rotation. If motor rotation is reverse, correct it and fill in table.

Component	Motor rotation is normal or not
Circulation pump	Yes ( ) No ( )
Booster pump	Yes ( ) No ( )
Vacuum pump 1	Yes ( ) No ( )
Vacuum pump 2	Yes ( ) No ( )
Hydraulic pump	Yes ( ) No ( )
Waterring pump	Yes ( ) No ( )



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Comments:**

**AcceptanceCriteria:** All actual results will be the same as the expected results.

**Meets Acceptance Criteria:**

Yes ( ) No ( )

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**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Attachment12–ControllSystem Datasheet**

**Purpose:** Verify system components are as specified by the manufacturer.

**A. Computer Hardware**

Item	Supplier	Model	ActualResult
Host Computer	DELL	Inspiron 570	Yes ( ) No ( )
Display	DELL	E 1912 H	Yes ( ) No ( )

**B. Computer software**

Item	Supplier	Model	Revision	Actual Result
Operation system	Microsoft	WINDOWSXP		Yes ( ) No ( )
Configuration software	Hite	NetSCADA0103SC/E -1000	V5.0	Yes ( ) No ( )

**C. Touch Screen:**

Item	Expected Result	Actual Result
Brand	OMRON	Yes ( ) No ( )
Model	NB10W-TW00B-Z	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
Brand	OMRON	Yes ( ) No ( )
Model	NB5Q-TW00B	Yes ( ) No ( )
Number	1	Yes ( ) No ( )

**D. Control Panel:**

Accessorial control panel is remote control unit. It is installed at decorated board that is at asepsis room. There are switches and buttons.

Item	Result
Shelf up	Yes ( ) No ( )
Shelf down	Yes ( ) No ( )
Chamber air inlet	Yes ( ) No ( )

**Comments:**

**Acceptance Criteria:** All actual results will be the same as the expected results.

**Meets Acceptance Criteria:** Yes ( ) No ( )





# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION FOR LYOPHILIZER

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**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Attachment 13–Measure Instruments**

**Purpose:** To demonstrate that all hardware items are well identified and the installation has been made following the instructions of the system manufacturer.

**A. Temperature probe:**

Item	Expected Result	Actual Result
<b>Product</b>		
Brand	KAIXIN	Yes ( ) No ( )
Model	PT100	Yes ( ) No ( )
Precision grade	B	Yes ( ) No ( )
Number	11	Yes ( ) No ( )
<b>Shelf oil inlet or outlet</b>		
Brand	KAIXIN	Yes ( ) No ( )
Model	PT100	Yes ( ) No ( )
Precision grade	B	Yes ( ) No ( )
Number	2	Yes ( ) No ( )
<b>Condenser temperature</b>		
Brand	KAIXIN	Yes ( ) No ( )
Model	PT100	Yes ( ) No ( )
Precision grade	B	Yes ( ) No ( )
Number	4	Yes ( ) No ( )
<b>Chamber steam temperature</b>		
Brand	KAIXIN	Yes ( ) No ( )
Model	PT100	Yes ( ) No ( )
Precision grade	B	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
<b>Condenser steam temperature</b>		
Brand	KAIXIN	Yes ( ) No ( )
Model	PT100	Yes ( ) No ( )
Precision grade	B	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
<b>Shelf temperature</b>		
Brand	KAIXIN	Yes ( ) No ( )
Model	PT100	Yes ( ) No ( )
Precision grade	B	Yes ( ) No ( )
Number	6	Yes ( ) No ( )

**B. Electric-contact pressure gauge**

Item	Expected Result	Actual Result
Brand	Z.Y上	Yes ( ) No ( )
Model	-0.1~+0.3MPa	Yes ( ) No ( )
Number	1	Yes ( ) No ( )



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**C. Pressure transducer:**

Item	Expected Result	Actual Result
Brand	Ideas	Yes ( ) No ( )
Model	1200BG4A002A3UA	Yes ( ) No ( )
Number	3	Yes ( ) No ( )

**D. Proximity sensor:**

Item	Expected Result	Actual Result
Brand	OMRON	Yes ( ) No ( )
Model	E2E-X3D1-N-Z2MBY OMS	Yes ( ) No ( )
Number	1	Yes ( ) No ( )

**E. Vacuum gauge**

Item	Expected Result	Actual Result
Brand	EDWARDS	Yes ( ) No ( )
Model	APG-MP/NW16ST/ST	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
Serial No.	116800489	Yes ( ) No ( )
Brand	EDWARDS	Yes ( ) No ( )
Model	APG-MP/NW16ST/ST	Yes ( ) No ( )
Number	1	Yes ( ) No ( )
Serial No.	126072298	Yes ( ) No ( )

**Comments:**

**Acceptance criteria:**

All hardware items are well identified with the manufacturer and model.  
All hardware components are correctly installed.

**Meets Acceptance Criteria:**

Yes ( ) No ( )

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**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Attachment 14 - PLC Input/Output Test**

Verify these veral inputs/outputs of the system, checking the connections to the cards of the PLC.

**A. Analog Input:**

Address	Description	PLCNo.	Expected Result	Actual Result
2001	Product temperature 1	12	Adjust analog resistance potentiometer and the data for 2001 address change in normal range.	Yes ( ) No ( )
2003	Product temperature 2	12	Adjust analog resistance potentiometer and the data for 2003 address change in normal range.	Yes ( ) No ( )
2005	Product temperature 3	12	Adjust analog resistance potentiometer and the datafor 2005 address change in normal range.	Yes ( ) No ( )
2007	Product temperature 4	12	Adjust analog resistance potentiometer and the data for 2007 address change in normal range.	Yes ( ) No ( )
2002	Product temperature 5	12	Adjust analog resistance potentiometer and the datafor 2002 address change in normal range.	Yes ( ) No ( )
2004	Product temperature 6	12	Adjust analog resistance potentiometer and the data for 2004 address change in normal range.	Yes ( ) No ( )
2031	Product temperature 7	13	Adjust analog resistance potentiometer and the data for 2031 address change in normal range.	Yes ( ) No ( )
2033	Product temperature 8	13	Adjust analog resistance potentiometer and the data for 2033 address change in normal range.	Yes ( ) No ( )
2035	Product temperature 9	13	Adjust analog resistance potentiometer and the data for 2035 address change in normal range.	Yes ( ) No ( )
2037	Product temperature 10	13	Adjust analog resistance potentiometer and the data for 2037 address change in normal range.	Yes ( ) No ( )



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION FOR LYOPHILIZER

2032	Condenser temperature 2	13	Adjust analog resistance potentiometer and the data for 2032 address change in normal range.	Yes ( ) No ( )
2034	Condenser temperature 3	13	Adjust analog resistance potentiometer and the data for 2034 address change in normal range.	Yes ( ) No ( )
2036	Condenser temperature 4	13	Adjust analog resistance potentiometer and the data for 2036 address change in normal range.	Yes ( ) No ( )
2038	Condenser coldspot temperature	13	Adjust analog resistance potentiometer and the data for 2038 address change in normal range.	Yes ( ) No ( )
2045	Chamber pressure	14	Adjust analog resistance potentiometer and the data for 2045 address change in normal range.	Yes ( ) No ( )
2046	Condenser pressure	14	Adjust analog resistance potentiometer and the data for 2046 address change in normal range.	Yes ( ) No ( )
2047	Little pressure	14	Adjust analog resistance potentiometer and the data for 2047 address change in normal range.	Yes ( ) No ( )
2048	Steam sterilizing cold spot temperature	14	Adjust analog resistance potentiometer and the data for 2048 address change in normal range.	Yes ( ) No ( )
2051	Product temperature 11	15	Adjust analog resistance potentiometer and the data for 2051 address change in normal range.	Yes ( ) No ( )
2053	Shelf temperature 1	15	Adjust analog resistance potentiometer and the data for 2053 address change in normal range.	Yes ( ) No ( )
2055	Shelf temperature 2	15	Adjust analog resistance potentiometer and the data for 2055 address change in normal range.	Yes ( ) No ( )
2057	Shelf temperature 3	15	Adjust analog resistance potentiometer and the data for 2057 address change in normal range.	Yes ( ) No ( )
2052	Shelf temperature 4	15	Adjust analog resistance potentiometer and the data for 2052 address change in normal range.	Yes ( ) No ( )



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION FOR LYOPHILIZER

2054	Shelf temperature 5	15	Adjust analog resistance potentiometer and the data for 2054 address change in normal range.	Yes ( ) No ( )
2056	Shelf temperature 6	15	Adjust analog resistance potentiometer and the data for 2056 address change in normal range.	Yes ( ) No ( )
2013	Oil inlet temperature	11	Adjust analog resistance potentiometer and the data for 2013 address change in normal range.	Yes ( ) No ( )
2014	Oil outlet temperature	11	Adjust analog resistance potentiometer and the data for 2014 address change in normal range.	Yes ( ) No ( )
2023	Chamber cold spot temperature	11	Adjust analog resistance potentiometer and the data for 2023 address change in normal range.	Yes ( ) No ( )
2024	Condenser 1 temperature	11	Adjust analog resistance potentiometer and the data for 2024 address change in normal range.	Yes ( ) No ( )

### B. Digital Input:

Address	Description	PLC No.	Expected Result	Actual Result
00000	Power detector	1	Enforce input set. The 00 lamp of No.1 PLC is on.	Yes ( ) No ( )
00001	Water pressure relay	1	Enforce input set. The 01 lamp of No.1 PLC is on.	Yes ( ) No ( )
00002	Compressed air pressure relay	1	Enforce input set. The 02 lamp of No.1 PLC is on.	Yes ( ) No ( )
00003	Compressor 1 high temperature temperature signal	1	Enforce input set. The 03 lamp of No.1 PLC is on.	Yes ( ) No ( )
00004	Compressor 2 high temperature temperature signal	1	Enforce input set. The 04 lamp of No.1 PLC is on.	Yes ( ) No ( )
00005	Circulation pump pressure signal	1	Enforce input set. The 05 lamp of No.1 PLC is on.	Yes ( ) No ( )



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

00006	Electric heater over temperature signal	1	Enforce input set. The 06 lamp of No.1 PLC is on.	Yes ( ) No ( )
00007	Chamber-condenser isolation valve open signal	1	Enforce input set. The 07 lamp of No.1 PLC is on.	Yes ( ) No ( )
00008	Chamber-condenser isolation valve close signal	1	Enforce input set. The 08 lamp of No.1 PLC is on.	Yes ( ) No ( )
00009	Hydraulic units pressure signal	1	Enforce input set. The 09 lamp of No.1 PLC is on.	Yes ( ) No ( )
00010	Shelf pressure switch	1	Enforce input set. The 10 lamp of No.1 PLC is on.	Yes ( ) No ( )
00011	Main steam valve open signal	1	Enforce input set. The 11 lamp of No.1 PLC is on.	Yes ( ) No ( )
00012	Cylinder feed back signal	1	Enforce input set. The 12 lamp of No.1 PLC is on.	Yes ( ) No ( )
00013	Safety isolation valve open signal	1	Enforce input set. The 13 lamp of No.1 PLC is on.	Yes ( ) No ( )
00014	Safety raster signal	1	Enforce input set. The 14 lamp of No.1 PLC is on.	Yes ( ) No ( )
00015	Vacuum-condenser isolation valve open signal	1	Enforce input set. The 15 lamp of No.1 PLC is on.	Yes ( ) No ( )
00100	Vacuum-condenser isolation valve close signal	2	Enforce input set. The 00 lamp of No.2 PLC is on.	Yes ( ) No ( )
00101	Mid – pressure relay 1	2	Enforce input set. The 01 lamp of No.2 PLC is on.	Yes ( ) No ( )
00102	Mid-pressure relay 2	2	Enforce input set. The 02 lamp of No.2 PLC is on.	Yes ( ) No ( )



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

00103	Low-presssure relay1	2	Enforce input set. The 03 lamp of No.2 PLC is on.	Yes ( ) No ( )
00104	High-presssure relay1	2	Enforce input set. The 04 lamp of No. 2 PLC is on.	Yes ( ) No ( )
00105	Electric heat-protector1	2	Enforce input set. The 05 lamp of No.2 PLC is on.	Yes ( ) No ( )
00106	Difference foil pressure relay 1	2	Enforce input set. The 06 lamp of No2 PLC is on.	Yes ( ) No( )
00107	Low-presssure relay 2	2	Enforce input set. The 07 lamp of No.2 PLC is on.	Yes ( ) No ( )
00108	High-presssure relay 2	2	Enforce input set. The 08 lamp of No.2 PLC is on.	Yes ( ) No ( )
00109	Electricheat-protector 2	2	Enforce input set. The 09 lamp of No.2 PLC is on.	Yes ( ) No ( )
00110	Difference foil pressure relay 2	2	Enforce input set. The 10 lamp of No.2 PLC is on.	Yes ( ) No ( )
00111	Chamber sight glass lamp	2	Enforce input set. The 11 lamp of No.2 PLC is on.	Yes ( ) No ( )
00112	Condenser sight glass lamp	2	Enforce input set. The 12 lamp of No.2 PLC is on.	Yes ( ) No ( )
00113	Local/remote control	2	Enforce input set. The 12 lamp of No.2 PLC is on.	Yes ( ) No ( )
00114	Door close signal	2	Enforce input set. The 14 lamp of No.2 PLC is on.	Yes ( ) No ( )
00115	Compressor over load protector 1	2	Enforce input set. The15 lamp of No.2 PLC is on.	Yes ( ) No ( )





**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

00200	Compressor overload protector 2	3	Enforce input set. The 00 lamp of No.3 PLC is on.	Yes( ) No( )
00201	Vacuum pump overload protector 1	3	Enforce input set. The 01 lamp of No.3 PLC is on.	Yes( ) No( )
00202	Vacuum pump overload protector 2	3	Enforce input set. The 02 lamp of No.3 PLC is on.	Yes( ) No( )
00203	Fluid pump overload protector 1	3	Enforce input set. The 03 lamp of No.3 PLC is on.	Yes( ) No( )
00204	Spare	3	Enforce input set. The 04 lamp of No.3 PLC is on.	Yes( ) No( )
00205	Hydraulic pump overload protector	3	Enforce input set. The 05 lamp of No.3 PLC is on.	Yes( ) No( )
00206	Water ring pump overload protector	3	Enforce input set. The 06 lamp of No.3 PLC is on.	Yes( ) No( )
00207	Booster pump overload protector	3	Enforce input set. The 07 lamp of No.3 PLC is on.	Yes( ) No( )
00208	Little door motor overload protector	3	Enforce input set. The 08 lamp of No.3 PLC is on.	Yes( ) No( )
00209	Little door work upper limit protector	3	Enforce input set. The 09 lamp of No.3 PLC is on.	Yes( ) No( )
00210	Little door work lower limit protector	3	Enforce input set. The 10 lamp of No.3 PLC is on.	Yes( ) No( )
00211	Little door protector	3	Enforce input set. The 11 lamp of No.3 PLC is on.	Yes( ) No( )
00212	Electric-contact pressure gauge	3	Enforce input set. The 12 lamp of No.3 PLC is on.	Yes( ) No( )



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION FOR LYOPHILIZER

00213	Small door scram signal	3	Enforce input set. The 13 lamp of No.3 PLC is on.	Yes( ) No( )
00214	Hydraumatic scram button	3	Enforce input set. The 14 lamp of No.3 PLC is on.	Yes( ) No( )
00215	System scram button	3	Enforce input set. The 15 lamp of No.3 PLC is on.	Yes( ) No( )
00300	Compressor 3 high temperature temperature signal	4	Enforce input set. The 00 lamp of No4 PLC is on.	Yes( ) No( )
00301	Compressor 4 high temperature temperature signal	4	Enforce input set. The 01 lamp of No4 PLC is on.	Yes( ) No( )
00302	Mid-presssure relay 3	4	Enforce input set. The 02 lamp of No.4 PLC is on.	Yes( ) No( )
00303	Mid-presssure relay 4	4	Enforce input set. The 03 lamp of No4 PLC is on.	Yes( ) No( )
00304	Low-presssure relay 3	4	Enforce input set. The 04 lamp of No.4 PLC is on.	Yes( ) No( )
00305	High-presssure relay 3	4	Enforce input set. The 05 lamp of No4 PLC is on.	Yes( ) No( )
00306	Electric heat-protector 3	4	Enforce input set. The 06 lamp of No.4 PLC is on.	Yes( ) No( )
00307	Difference of oil pressure relay 3	4	Enforce input set. The 07 lamp of No.4 PLC is on.	Yes( ) No( )
00308	Low-presssure relay 4	4	Enforce input set. The 08 lamp of No.4 PLC is on.	Yes( ) No( )
00309	High-presssure relay 4	4	Enforce input set. The 09 lamp of No4 PLC is on.	Yes( ) No( )



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION FOR LYOPHILIZER

00310	Electricheat-protector 4	4	Enforce input set. The 10 lamp of No.4 PLC is on.	Yes( ) No( )
00311	Difference of oil pressure relay 4	4	Enforce input set. The 11 lamp of No.4 PLC is on.	Yes( ) No( )
00312	Compressor overload protector 3	4	Enforce input set. The 12 lamp of No.4 PLC is on.	Yes( ) No( )
00313	Compressor overload protecor 4	4	Enforce input set. The 13 lamp of No.4 PLC is on.	Yes( ) No( )
00314	Door bolt enter	4	Enforce input set. The 14 lamp of No.4 PLC is on.	Yes( ) No( )
00315	Door bolt out	4	Enforce input set. The 15 lamp of No.4 PLC is on.	Yes( ) No( )

### C. Digital Input:

Address	Description	PLC No. PLC	ExpectedResult	ActualResult
	Compressor 1	5	Enforce output set. The 00 lamp of No.5 PLC is on.	Yes( ) No( )
	Compressor 2	5	Enforce output set.The 01 lamp of No.5 PLC is on.	Yes( ) No( )
	Vacuum pump 1	5	Enforce output set. The 02 lamp of No.5 PLC is on.	Yes( ) No( )
	Vacuum pump 2	5	Enforce output set.The 03 lamp of No.5 PLC is on.	Yes( ) No( )
	Fluid pump	5	Enforce output set.The 04 lamp of No.5 PLC is on.	Yes( ) No( )
	Spare	5	Enforce output set. The 05 lamp of No.5 PLC is on.	Yes( ) No( )



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION FOR LYOPHILIZER

	Hydraulic pump	5	Enforce output set.The 06 lamp of No.5 PLC is on.	Yes ( ) No ( )
	Water ring pump	5	Enforce output set.The 07 lamp of No.5 PLC is on.	Yes ( ) No ( )
	Booster pump	5	Enforce output set.The 08 lamp of No.5 PLC is on.	Yes ( ) No ( )
	Heat power 1	5	Enforce output set.The 09 lamp of No.5 PLC is on.	Yes ( ) No ( )
	Heat power 2	5	Enforce output set.The 10 lamp of No.5 PLC is on.	Yes ( ) No ( )
	Little door rise	5	Enforce output set.The 11 lamp of No.5 PLC is on.	Yes ( ) No ( )
	Little door fall	5	Enforce output set.The 12 lamp of No.5 PLC is on.	Yes ( ) No ( )
	Touch screen switch	5	Enforce output set.The 13 lamp of No.5 PLC is on.	Yes ( ) No ( )
	Heater control	5	Enforce output set.The 14 lamp of No.5 PLC is on.	Yes ( ) No ( )
	Shelf temperature regulate valve 1	5	Enforce output set.The 15 lamp of No.5 PLC is on.	Yes ( ) No ( )
	Shelve cooling valve 1	6	Enforce output set.The 00 lamp of No.6 PLC is on.	Yes ( ) No ( )
	Shelve cooling valve 2	6	Enforce output set.The 01 lamp of No.6 PLC is on.	Yes ( ) No ( )
	Condenser cooling valve 1	6	Enforce output set.The 02 lamp of No.6 PLC is on.	Yes ( ) No ( )



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION FOR LYOPHILIZER

	Condenser cooling valve 2	6	Enforce output set.The 03 lamp of No.6 PLC is on.	Yes ( ) No ( )
	Shelf temperature regulate valve 2	6	Enforce output set.The 04 lamp of No.6 PLC is on.	Yes ( ) No ( )
	Bellows respirator valve	6	Enforce output set.The 05 lamp of No.6 PLC is on.	Yes ( ) No ( )
	Bellows validation vacuum valve	6	Enforce output set.The 06 lamp of No.6 PLC is on.	Yes ( ) No ( )
	Chamber condenser isolation valve open	6	Enforce output set.The 07 lamp of No.6 PLC is on.	Yes ( ) No ( )
	Chamber condenser isolation valve close	6	Enforce output set.The 08 lamp of No.6 PLC is on.	Yes ( ) No ( )
	Mid-pressure adjust valve 3	6	Enforce output set.The 09 lamp of No.6 PLC is on.	Yes ( ) No ( )
	Mid-pressure adjust valve 4	6	Enforce output set.The 10 lamp of No.6 PLC is on.	Yes ( ) No ( )
	Small butterfly valve	6	Enforce output set.The 11 lamp of No.6 PLC is on.	Yes ( ) No ( )
	Air outlet valve	6	Enforce output set.The 12 lamp of No.6 PLC is on.	Yes ( ) No ( )
	Sterilization isolation valve	6	Enforce output set.The 13 lamp of No.6 PLC is on.	Yes ( ) No ( )
	Filter isolation valve 1	6	Enforce output set.The 14 lamp of No.6 PLC is on.	Yes ( ) No ( )
	Filter isolation valve 2	6	Enforce output set.The 15 lamp of No.6 PLC is on.	Yes ( ) No ( )



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

	Safety isolation valve	7	Enforce output set. The 00 lamp of No.7 PLC is on.	Yes ( ) No ( )
	Main steam inlet valve	7	Enforce output set. The 01 lamp of No.7 PLC is on.	Yes ( ) No ( )
	Main cleaning valve	7	Enforce output set. The 02 lamp of No.7 PLC is on.	Yes ( ) No ( )
	Chamber cleaning valve	7	Enforce output set. The 03 lamp of No.7 PLC is on.	Yes ( ) No ( )
	Shelf board cleaning valve	7	Enforce output set. The 04 lamp of No.7 PLC is on.	Yes ( ) No ( )
	Condenser cleaning valve	7	Enforce output set. The 05 lamp of No.7 PLC is on.	Yes ( ) No ( )
	Little door cleaning valve	7	Enforce output set. The 06 lamp of No.7 PLC is on.	Yes ( ) No ( )
	Chamber water/steam outlet valve	7	Enforce output set. The 07 lamp of No.7 PLC is on.	Yes ( ) No ( )
	Condenser water/steam outlet valve	7	Enforce output set. The 08 lamp of No.7 PLC is on.	Yes ( ) No ( )
	Main water drain valve	7	Enforce output set. The 09 lamp of No.7 PLC is on.	Yes ( ) No ( )
	Steam outlet valve	7	Enforce output set. The 10 lamp of No.7 PLC is on.	Yes ( ) No ( )
	Trap valve	7	Enforce output set. The 11 lamp of No.7 PLC is on.	Yes ( ) No ( )
	Water-ring pump water pump water inlet valve	7	Enforce output set. The 12 lamp of No.7 PLC is on.	Yes ( ) No ( )



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION FOR LYOPHILIZER

	Water-ring pump isolation valve	7	Enforce output set.The 13 lamp of No.7 PLC is on.	Yes ( ) No ( )
	Little door validation vacuum valve	7	Enforce output set.The 14 lamp of No.7 PLC is on.	Yes ( ) No ( )
	Little door compressed air valve	7	Enforce output set.The 15 lamp of No.7 PLC is on.	Yes ( ) No ( )
	Mid-pressure adjust valve 1	8	Enforce output set. The 00 lamp of No.8 PLC is on.	Yes ( ) No ( )
	Mid-pressure adjust valve 2	8	Enforce output set.The 01 lamp of No.8 PLC is on.	Yes ( ) No ( )
	Moter cooling solenoid valve 2	8	Enforce output set. The 02 lamp of No.8 PLC is on.	Yes ( ) No ( )
	Moter cooling solenoid valve 2	8	Enforce output set.The 03 lamp of No.8 PLC is on.	Yes ( ) No ( )
	Chamber filter isolation valve	8	Enforce output set.The 04 lamp of No.8 PLC is on.	Yes ( ) No ( )
	Filter drain valve	8	Enforce output set.The 05 lamp of No.8 PLC is on.	Yes ( ) No ( )
	Filter intermitten valve	8	Enforce output set.The 06 lamp of No.8 PLC is on.	Yes ( ) No ( )
	Filter trap valve 1	8	Enforce output set. The 07 lamp of No.8 PLC is on.	Yes ( ) No ( )
	Filter trap valve 2	8	Enforce output set.The 08 lamp of No.8 PLC is on.	Yes ( ) No ( )
	Filter trap valve 3	8	Enforce output set.The 09 lamp of No.8 PLC is on.	Yes ( ) No ( )



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION FOR LYOPHILIZER

	Chamber clip set of water inlet valve 1	8	Enforce output set.The 10 lamp of No.8 PLC is on.	Yes ( ) No ( )
	Chamber clip set of water drain valve	8	Enforce output set. The 11 lamp of No.8 PLC is on.	Yes ( ) No ( )
	Chamber clip set of water respirator valve	8	Enforce output set. The 12 lamp of No.8 PLC is on.	Yes ( ) No ( )
	Defrosting valve	8	Enforce output set.The 13 lamp of No.8 PLC is on.	Yes ( ) No ( )
	Moter cooling solenoid valve 3	8	Enforce output set.The 14 lamp of No.8 PLC is on.	Yes ( ) No ( )
	Moter cooling solenoid valve 4	8	Enforce output set.The 15 lamp of No.8 PLC is on.	Yes ( ) No ( )
	Condenser clip set of water inlet valve 1	9	Enforce output set.The 00 lamp of No.9 PLC is on.	Yes ( ) No ( )
	Condenser clip set of water drain valve	9	Enforce output set.The 01 lamp of No.9 PLC is on.	Yes ( ) No ( )
	Condenser clip set of water respirator valve	9	Enforce output set.The 02 lamp of No.9 PLC is on.	Yes ( ) No ( )
	Chamber vacuum guage isolation	9	Enforce output set.The 03 lamp of No.9 PLC is on.	Yes ( ) No ( )
	Alarm lamp	9	Enforce output set.The 04 lamp of No.9 PLC is on.	Yes ( ) No ( )
	Alarm speaker	9	Enforce output set.The 05 lamp of No.9 PLC is on.	Yes ( ) No ( )
	End lamp	9	Enforce output set.The 06 lamp of No.9 PLC is on.	Yes ( ) No ( )





# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION FOR LYOPHILIZER

	Spare	9	Enforce output set.The 07 lamp of No.9 PLC is on.	Yes ( ) No ( )
	Spare	9	Enforce output set.The 08 lamp of No.9 PLC is on.	Yes ( ) No ( )
	Spare	9	Enforce output set.The 09 lamp of No.9 PLC is on.	Yes ( ) No ( )
	Spare	9	Enforce output set.The 10 lamp of No.9 PLC is on.	Yes ( ) No ( )
	Spare	9	Enforce output set.The 11 lamp of No.9 PLC is on.	Yes ( ) No ( )
	Spare	9	Enforce output set.The 12 lamp of No.9 PLC is on.	Yes ( ) No ( )
	Spare	9	Enforce output set.The 13 lamp of No.9 PLC is on.	Yes ( ) No ( )
	Spare	9	Enforce input set. The 14 lamp of No.9 PLC is on.	Yes ( ) No ( )
	Spare	9	Enforce output set.The 15 lamp of No.9 PLC is on.	Yes ( ) No ( )
	Compressor 3	10	Enforce output set.The 00 lamp of No.10 PLC is on.	Yes ( ) No ( )
	Compressor 4	10	Enforce output set.The 01 lamp of No.10 PLC is on.	Yes ( ) No ( )
	Shelve cooling valve 3	10	Enforce output set.The 02 lamp of No.10 PLC is on.	Yes ( ) No ( )
	Shelve cooling valve 4	10	Enforce output set.The 03 lamp of No.10 PLC is on.	Yes ( ) No ( )



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION FOR LYOPHILIZER

	Condenser cooling valve 3	10	Enforce output set. The 04 lamp of No.10 PLC is on.	Yes ( ) No ( )
	Condenser cooling valve 4	10	Enforce output set. The 05 lamp of No.10 PLC is on.	Yes ( ) No ( )
	Door bolt enter	10	Enforce output set. The 06 lamp of No.10 PLC is on.	Yes ( ) No ( )
	Door bolt out	10	Enforce output set. The 07 lamp of No.10 PLC is on.	Yes ( ) No ( )
	Cooling water main valve	10	Enforce output set. The 08 lamp of No.10 PLC is on.	Yes ( ) No ( )
	Cooling water drain valve	10	Enforce output set. The 09 lamp of No.10 PLC is on.	Yes ( ) No ( )
	Chamber sight glass lamp	10	Enforce output set. The 10 lamp of No.10 PLC is on.	Yes ( ) No ( )
	Condenser sight glass lamp	10	Enforce output set. The 11 lamp of No.10 PLC is on.	Yes ( ) No ( )
	Spare solenoid valve	10	Enforce output set. The 12 lamp of No.10 PLC is on.	Yes ( ) No ( )
	Spare solenoid valve	10	Enforce output set. The 13 lamp of No.10 PLC is on.	Yes ( ) No ( )
	Spare	10	Enforce output set. The 14 lamp of No.10 PLC is on.	Yes ( ) No ( )
	Spare	10	Enforce output set. The 15 lamp of No.10 PLC is on.	Yes ( ) No ( )



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Comments:**

**Acceptance criteria:**

Every input/output defined in the supplier documentation is in the PLC.

Every PLC input/output must be represented in the supplier documentation.

It should not remain in any input/output connection deviation.

All hardware items are well identified with their/n, manufacturer and model. All hardware components are correctly installed.

**Meets Acceptance Criteria:**

**Yes ( ) No ( )**

	<b>Department</b>	<b>Sign. &amp; Date</b>
Checked by	Quality Assurance	
Reviewed by	Quality Assurance	



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Attachment 15 – Utility Data Sheet**

**A. Electrical**

Equipment : \_\_\_\_\_ Lyophilizer \_\_\_\_\_

Equipment No.: \_\_\_\_\_

Location: \_\_\_\_\_

**Circuit Attribute**

Item	Circuit Rating	Equipment Rating	Field Measurement
Volts	380V	380 V	
Power	146KW	146 KW	
Phase	3	3	

**Electrical Protection**

Item	Actual Result
Source:	( ) SwitchGear ( ) Panel
Equipment power	( ) Hard-wired ( ) Corded with appropriate plug
Local disconnect safety over ride switch?	( ) Yes ( ) No
Overload Protection	( ) Main breaker ( ) Circuit Breaker
Overload Protection Rating	( ) Yes ( ) No
Ground wire connected ?	( ) Yes ( ) No

**B. Compressed Air**

Compressed Air Source:

DRY AIR Pressure

Reducing Valve Installed ?

(√) Yes ( ) No

If installed location in \_\_\_\_\_ Pneumatic triple-units \_\_\_\_\_



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

Connection Line Size: 3/8"

Air Pressure 5bar ≤ P ≤ 8bar

Field Notes:

**C. Cooling Water**

Connection Line Size: 3"

Inlet Pressure 1.5bar ≤ P ≤ 2bar

Inlet Water Temperature T ≤ 25°C

Inlet Water Pipe Connection type 3" threaded/G3"

Field Notes:

**D. Water for Injection**

Inlet Pressure ≥ 5 bar

Connection Line Size: 1-1/2"

Inlet Water Pipe Connection type

Clamp Field Notes:

**E. Water drain:**

Size of Line: DN65 Pipe Material: 304

Drains to:  Floor drain



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

- Drain piping
- Building drain
- Acid drain
- Other \_\_\_\_\_

Pre-treatment before drain?  Yes  No  N/A

Describe: \_\_\_\_\_  
\_\_\_\_\_

Field Notes:

**F. Steam discharge**

Size of Line: \_\_\_\_\_ DN65 \_\_\_\_\_ Pipe Material: \_\_\_\_\_ 304 \_\_\_\_\_

- Drains to:
- Floor drain
  - Drain piping
  - Building drain
  - Acid drain
  - Other \_\_\_\_\_

Pre-treatment before drain?  Yes  No  N/A



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

Describe: \_\_\_\_\_  
\_\_\_\_\_

Field Notes:

**Comments:**

**Acceptance Criteria:** All utilities must be verified to meet the attached manufacturer's specifications.

**Meets Acceptance Criteria:** Yes ( ) No ( )

	Department	Sign. & Date
Checked by	Quality Assurance	
Reviewed by	Quality Assurance	



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Attachment 16-Engineering Drawing List**

Copies of the latest revisions are attached to the Protocol.

Drawing No.	Title	Verifiedby/Date
	Pipe and instrument drawing	
	Layout arrangement	
	Wiring drawing	

**Acceptance Criteria:**

All drawing must be current.

The equipment assembly conforms to the latest version of the drawings.

All installed components,instrumentation and valves are correctly and clearly tagged.

All installed components,instrumentation and valves are the same as the design specifications.

All relief devices are installed in the correct locations and orientations,and will relieve safely.

All pipe work is correctly supported/bracketed.

All instruments are fitted in correct locations.All of them are accessible and readable.

**Meets Acceptance Criteria:**

**Yes ( ) No ( )**

	Department	Sign. & Date
Checked by	Quality Assurance	
Reviewed by	Quality Assurance	





# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION FOR LYOPHILIZER

### Attachment 17-Lubricant List

List the lubricants used in the system. Verify that the lubricants are compatible for their intended use. The list will contain product contact or potential product contact as well as non-product contact lubricants. Document the results below.

Lubricated Part	Lubricant	Do Products isolate from Lubricant (Yes, No, Potential)
Compressor	Compressor oil	Yes ( ) No ( )
Vacuum pump	Vacuum pump oil	Yes ( ) No ( )
Hydraulic pump	Hydraulic oil:46#	Yes ( ) No ( )
Circulation piping	Silicon oil	Yes ( ) No ( )

**Comments:**

**Acceptance Criteria:** All blanks must be completed and all yes/no questions must be answered with “yes” or explained.

**Meets Acceptance Criteria:** Yes ( ) No ( )

	Department	Sign. & Date
Checked by	Quality Assurance	
Reviewed by	Quality Assurance	



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

**Attachment 18-Major Component Labeling List**

All major components, sensors, transmitters, gauges, valves and controlled devices must be listed.

NO.	Component Requiring Labeling	Correctly Labeled
<b>Refrigerant System:</b>		
	Compressor 1	Yes ( ) No ( )
	Compressor 2	Yes ( ) No ( )
	Compressor 3	Yes ( ) No ( )
	Compressor 4	Yes ( ) No ( )
	Oil separator 1	Yes ( ) No ( )
	Oil separator 2	Yes ( ) No ( )
	Oil separator 3	Yes ( ) No ( )
	Oil separator 4	Yes ( ) No ( )
	Water cooling condenser 1	Yes ( ) No ( )
	Water cooling condenser 2	Yes ( ) No ( )
	Water cooling condenser 3	Yes ( ) No ( )
	Water cooling condenser 4	Yes ( ) No ( )
	Liquid filter 1	Yes ( ) No ( )
	Liquid filter 2	Yes ( ) No ( )
	Liquid filter 3	Yes ( ) No ( )
	Liquid filter 4	Yes ( ) No ( )
	Shelves cooling valve 1	Yes ( ) No ( )
	Shelves cooling valve 2	Yes ( ) No ( )
	Shelves cooling valve 3	Yes ( ) No ( )
	Shelves cooling valve 4	Yes ( ) No ( )



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

NO.	Component Requiring Labeling	Correctly Labeled
	Ice condenser cooling valve 1	Yes ( ) No ( )
	Ice condenser cooling valve 2	Yes ( ) No ( )
	Ice condenser cooling valve 3	Yes ( ) No ( )
	Ice condenser cooling valve 4	Yes ( ) No ( )
	Shelves temperature regulation valve 1	Yes ( ) No ( )
	Shelves temperature regulation valve 2	Yes ( ) No ( )
	Expansion valve of shelves-1	Yes ( ) No ( )
	Expansion valve of shelves-2	Yes ( ) No ( )
	Expansion valve of shelves-3	Yes ( ) No ( )
	Expansion valve of shelves-4	Yes ( ) No ( )
	Expansion valve of temperature regulation 1	Yes ( ) No ( )
	Expansion valve of temperature regulation 2	Yes ( ) No ( )
	Expansion valve of condenser-1	Yes ( ) No ( )
	Expansion valve of condenser-2	Yes ( ) No ( )
	Expansion valve of condenser-3	Yes ( ) No ( )
	Expansion valve of condenser-4	Yes ( ) No ( )
	Electromagnetic valve of shelves-1	Yes ( ) No ( )
	Electromagnetic valve of shelves-2	Yes ( ) No ( )
	Electromagnetic valve of shelves-3	Yes ( ) No ( )
	Electromagnetic valve of shelves-4	Yes ( ) No ( )
	Electromagnetic valve of temperature regulation 1	Yes ( ) No ( )
	Electromagnetic valve of temperature regulation 2	Yes ( ) No ( )
	Electromagnetic valve of condenser-1	Yes ( ) No ( )
	Electromagnetic valve of condenser-2	Yes ( ) No ( )
	Electromagnetic valve of condenser-3	Yes ( ) No ( )
	Electromagnetic valve of condenser-4	Yes ( ) No ( )



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

NO.	Component Requiring Labeling	Correctly Labeled
	Plate heat exchanger-1	Yes ( ) No ( )
	Plate heat exchanger-2	Yes ( ) No ( )
	Plate heat exchanger-3	Yes ( ) No ( )
	Plate heat exchanger-4	Yes ( ) No ( )
	Gas-liquid filter-1	Yes ( ) No ( )
	Gas-liquid filter-2	Yes ( ) No ( )
	Gas-liquid filter-3	Yes ( ) No ( )
	Gas-liquid filter-4	Yes ( ) No ( )
	Gas filter-1	Yes ( ) No ( )
	Gas filter-2	Yes ( ) No ( )
	Gas filter-3	Yes ( ) No ( )
	Gas filter-4	Yes ( ) No ( )
	Low pressure meter 1	Yes ( ) No ( )
	Low pressure meter 2	Yes ( ) No ( )
	Low pressure meter 3	Yes ( ) No ( )
	Low pressure meter 4	Yes ( ) No ( )
	Middle pressure meter 1	Yes ( ) No ( )
	Middle pressure meter 2	Yes ( ) No ( )
	Middle pressure meter 3	Yes ( ) No ( )
	Middle pressure meter 4	Yes ( ) No ( )
	High pressure meter 1	Yes ( ) No ( )
	High pressure meter 2	Yes ( ) No ( )
	High pressure meter 3	Yes ( ) No ( )
	High pressure meter 4	Yes ( ) No ( )
	Oil pressure meter 2	Yes ( ) No ( )



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

NO.	Component Requiring Labeling	Correctly Labeled
	Oil pressure meter 2	Yes ( ) No ( )
	Oil pressure meter 3	Yes ( ) No ( )
	Oil pressure meter 4	Yes ( ) No ( )
	Low pressure relay 1	Yes ( ) No ( )
	Low pressure relay 2	Yes ( ) No ( )
	Low pressure relay 3	Yes ( ) No ( )
	Low pressure relay 4	Yes ( ) No ( )
	Middle pressure relay 1	Yes ( ) No ( )
	Middle pressure relay 2	Yes ( ) No ( )
	Middle pressure relay 3	Yes ( ) No ( )
	Middle pressure relay 4	Yes ( ) No ( )
	High pressure relay 1	Yes ( ) No ( )
	High pressure relay 2	Yes ( ) No ( )
	High pressure relay 3	Yes ( ) No ( )
	High pressure relay 4	Yes ( ) No ( )
	Difference of oil pressure relay 1	Yes ( ) No ( )
	Difference of oil pressure relay 2	Yes ( ) No ( )
	Difference of oil pressure relay 3	Yes ( ) No ( )
	Difference of oil pressure relay 4	Yes ( ) No ( )
<b>Vacuum System:</b>		
	Vacuum pump_1	Yes ( ) No ( )
	Vacuum pump_2	Yes ( ) No ( )
	Booster pump	Yes ( ) No ( )
	Pump isolation valve-1	Yes ( ) No ( )
	Pump isolation valve-2	Yes ( ) No ( )
	Vacuum gauge check valve	Yes ( ) No ( )



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

NO.	Component Requiring Labeling	Correctly Labeled
	Vacuum gauge 1	Yes ( ) No ( )
	Vacuum gauge 2	Yes ( ) No ( )
	Condenser-pump isolation valve	Yes ( ) No ( )
<b>Circulation System:</b>		
	Fluid pump	Yes ( ) No ( )
	Circulation pump pressure meter	Yes ( ) No ( )
	Pressure controller	Yes ( ) No ( )
	Electric heater	Yes ( ) No ( )
	Temperature controller	Yes ( ) No ( )
	Expansion tank	Yes ( ) No ( )
<b>SIP &amp; CIP system: SIP &amp; CIP</b>		
	Water-ring pump	Yes ( ) No ( )
	Chamber drain valve	Yes ( ) No ( )
	Condenser drain valve	Yes ( ) No ( )
	Water-ring pump isolation valve	Yes ( ) No ( )
	Main drain valve	Yes ( ) No ( )
	Main steam exhaust valve	Yes ( ) No ( )
	Water-ring pump water inlet valve	Yes ( ) No ( )
	Water-ring pump drain valve	Yes ( ) No ( )
	Sub-drain valve	Yes ( ) No ( )
	Steam trap 1	Yes ( ) No ( )
	Steam trap 2	Yes ( ) No ( )
	Electric-contact pressure gauge	Yes ( ) No ( )
	Main Clean water inlet valve	Yes ( ) No ( )
	Condensor water/steam inlet valve	Yes ( ) No ( )



**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

NO.	Component Requiring Labeling	Correctly Labeled
	Chamber water/steam inlet valve 1	Yes ( ) No ( )
	Chamber water/steam inlet valve 2	Yes ( ) No ( )
	Chamber water/steam inlet valve 3	Yes ( ) No ( )
	Safety valve	Yes ( ) No ( )
	Main steam inlet valve	Yes ( ) No ( )
<b>Hydraulic System:</b>		
	Hydraulic units	Yes ( ) No ( )
	Shelf hydraulic cylinder	Yes ( ) No ( )
	Mushroom hydraulic cylinder	Yes ( ) No ( )
<b>Pneumatic System:</b>		
	Pneumatic triple units	Yes ( ) No ( )
	Air pressure relay	Yes ( ) No ( )
	24-way pneumatic unit	Yes ( ) No ( )

**Comments:**

**Acceptance Criteria:** All major components must be identified.

**Meets Acceptance Criteria:** Yes ( ) No ( )

	Department	Sign. & Date
Checked by	Quality Assurance	
Reviewed by	Quality Assurance	



## INSTALLATION QUALIFICATION FOR LYOPHILIZER

### Attachment 19- Spare Parts List

Generate or attach an itemized list of the manufacturer recommended spare parts. Attachments may be copies of spare parts lists provided in individual equipment operation or maintenance manuals. Spare parts are items used to replace worn-out or broken items.

If a manufacturer recommended spare parts listing is available it may be attached to this data sheet.

S.No.	Name	Model	Quantity	Brand
1.	Vacuum pump oil		8L	
2.	Sight glass	SGN12s	1	DANFOSS
3.	Refrigerant	R404A	10.9 Kg	
4.	Compressor oil	BSE32	10 L	
5.	Product temperature probe	PT-100 (single head)	2	
6.	Product temperature probe	PT-100 (double head)	5	
7.	Steam temperature probe	PT-100	2	
8.	High pressure meter	-1~35Bar	1	REFCO
9.	Low pressure meter	-1~16Bar	1	REFCO
10.	Cooling solenoid valve winding	EVR6(NC)	2	DANFOSS
11.	Cooling solenoid valve	EVR6	1	DANFOSS
12.	Pneumatic solenoid valve winding		5	
13.	Solid-state relay		1	
14.	Compressor AC contactor		1	
15.	Middle contactor		1	
16.	Temperature transmitter		2	
17.	Vacuum grease box		1	
18.	Anti siphon plate valve	GYC-JQ40	1	Siegind
19.	Heat temperature elements	TES5	1	DANFOSS





**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

20.	Outlet sub assembly	TES5-7.2	2	DANFOSS
21.	Liquid filter core	H48	2	
22.	Gas filter core	D48	4	
23.	High pressure relay	KP5	1	DANFOSS
24.	Low pressure relay	KP1	1	DANFOSS
25.	Heat insulating material	20 mm thickness	2m <sup>2</sup>	
26.	Heat insulating material	5mm thickness	2m <sup>2</sup>	
27.	Mucilage		0.7Kg	
28.	Siliconoil		5L	
29.	Low pressure relay	KP2	1	DANFOSS
30.	Pressure meter	YTN-63	1	Z.Y
31.	Heat transfer oil flange gasket		2	
32.	Two-position and five-way valve (Single electronic)	MVSC-220-4EI	1	Mindman
33.	Airtube		20m	
34.	Connector	1/4"×φ6 mm 1/4"×φ8 mm φ6×φ6×φ6 mm		
35.	Doorseal article	Silicone rubber	1	
36.	Endoscopic glass		2	
37.	Sight glass seal article	EPDM	2	
38.	Sight glass lamp		2	
39.	hydro-cylinder seal article		1	
40.	Bellow seal article	EPDM	2	
41.	Hydraulic unit seal article		1	
42.	Flaring kit		1	
43.	Connector	ISO40×KF16	1	
44.	Adapter connector	ISO40	2	
45.	Lathedog	ISO40	2	



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION FOR LYOPHILIZER**

46.	Fluorine pad	ISO40	10	
47.	Nausea board	ISO40	2	
48.	Connector	KF16	2	
49.	Lathedog	KF16	2	
50.	Fluorine pad	KF16	5	
51.	Blank flange	KF16	2	
52.	Ratch wrench		1	
53.	Refrigerant filling pipe	Homemade	1	

**Comments:**

**Acceptance Criteria:** A spare parts list must be available for the system and its associated pieces of equipment.

**Meets Acceptance Criteria:** Yes ( ) No ( )

	Department	Sign. & Date
Checked by	Quality Assurance	
Reviewed by	Quality Assurance	