PERFORMANCE QUALIFICATION FOR LYOPHILIZER

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EXECUTION APPROVAL SIGNATURES

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.

Performance Qualification （PQ）

Type of equipment	Lyophilizer
Customer	
MODEL	FNLY-30SCP
Revision	The First Edition
Department	Quality Assurance
Page	10

PQ protocol approval/PQ

	Name	**Department**	**Date and signature**
Prepared by		Quality Assurance	
Reviewed by		Quality Assurance	
Approved by		Technology Management	

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1. SCOPE:

This Performance Qualification (PQ) study will be performed on the Lyophilizer.

This protocol describes the equipment, test procedures, specifications, and documents used to establish that the Lyophilizer, performs in accordance with the manufacturer's design specifications. The factory will be referred to as …… throughout the rest of this document.

This documentation package has been prepared by personnel. This document will provide for the delineation of responsibilities of …….. and ……, 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 Lyophilizer performs according to the manufacturer's specifications and …… requirements.

3. BACKGROUND:

The Freeze Dryer is a new system purchased specifically for use at the new …….

4. INTRODUCTION:

This Performance Qualification (PQ) protocol is specific for the Lyophilizer located.

Testing will be performed to verify and document that the equipment is performing as required to meet 'In Process" and 'Final Product' requirements specified.

Testing will be performed to verify and document that the system performs in accordance with the manufacturer's specifications, and ……. requirements.

5. SYSTEMDESCRIPTION:

The Lyophilizer System, Model No. FNLY-30SCP 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 11 units (available) + 1 （thermalbalance） 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 –55ºC to +70ºC. 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 –75ºC (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 25P 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. TESTINGPROCEDURES:

The Performance Qualification will be performed using the protocol attachments. All pertinent information will be recorded on these forms. Copies of the 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 the protocol.

NOTE: Any exceptions to this protocol must be fully investigated and documented. This PQ 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. ACCEPTANCECRITERIA:

- The Installation and Operational Qualification will be completed prior to starting this document.

- All data forms required for execution of the protocol must be completely, accurately, and properly filled out.

- The lyophilization cycles utilize actual product will be performed by approved operation manual and meet the following criteria:

  - Freeze-drying curve parameters are set as required.

  - Temperature difference between product T C is less than ±1°C.

- All criteria specified on the data sheets must be met.

- All validation tests outlined in the protocol attachments must be successfully executed with the results noted on the appropriate pages. All verifications must be answered “yes” or a protocol deviation must be documented. Re-testing must be described and justified.

◦

Attachment 1–Lyophilizer Loading Test

TEST OBJECTIVE: To demonstrate the lyophilizer performs as required by …… for successful run with loads of water. The testing will verify product is uniformly lyophilized throughout the chamber by monitoring water temperature and performing testing on samples. This document recorded and proved the lyophilizer is capable of performing the activities of the process it is required to perform , according to the user's requirements.

TESTMETHOD:

1. **Load Preparation:** According to normal production, load the products for freeze on the shelves.

2. Ready the lyophilizer for operation. Verify the correct parameters for each cycle run.

3. All runs will be performed with lyophilizer cycle parameters.

4. Start the lyophilizer. Record the time and date when initiated.

Post-Testing:

4. Evaluate the in-process and final product testing results. Determine if all results meet product specifications.

TESTR ESULTS:

Print the data, curve and recipe. Attach the data printout of full cycle run to this section of the protocol.

Refer to the Attachments for test results. Generate a narrative summary as part of the Summary Report.

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Attachment 2-Data Summary Work Sheet

Date of Testing		Run Number	
Number of TCs used			
Minimum/Maximum product TC temperature reached during freezing hold		°C	°C
Minimum/Maximum product TC temperature reached during drying hold above 30°C		°C	°C
Each product temperatures reach 30°C		( ) Yes ( ) No	

ACCEPTANCE CRITERIA:

- All criteria specified on the data sheets must be met.

- All validation tests outlined in the protocol attachments must be successfully executed with the results noted on the appropriate pages. All verifications must be answered "yes" or a protocol deviation must be documented. Re-testing must be described and justified.

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

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

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Attachment 3–Freeze-Drying Curve Verification Data Sheet

Record the freeze-drying curve parameters for each run performed below:

	Step	Set point
1.	Freezing	Set point of temperature: 40˚C
		Time of decline of temperature: 90 min
		The duration of temperature control: 60 min
2.	Condenser preparation	Temperature :<-45˚C
3.	Chamber vacuum	Vacuum<0.3mbar
4.	First sublimation	Set point of Temperature:0˚C
		Time of rise of temperature:60 min
		The duration of temperature control: 90 min
		Temperature control deviation ±1.0˚C
		Vacuum: <0.3 mbar
		Set point of Temperature:30˚C
		Time of rise of temperature:60 min
		The duration of temperature control：90 min
		Temperature control deviation ±1.0˚C
		Vacuum: <0. 3mbar
5	Pressure rise test	Pressure gap:<0.1mbar
		Interval time:5 min
6		Set point of Temperature:40˚C
		Time of rise of temperature: 30 min

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	Step	Set point
	Secondary Drying	The duration of temperature control：60min
		Temperaturecontroldeviation±1.0˚C
		Vacuum:<0.1mbar
		Set point of Temperature:50˚C
		Vacuum:<0.1mbar
		Time : 30 min
		Temperature control deviation ±1.0˚C
		Set point of Temperature: 60˚C
		Time of rise of temperature:30 min
		The duration of temperature control：60min
		Temperature control deviation ± 1.0˚C
		Vacuum:<0.1mbar
7	Pressure rise test	Pressure gap:<0.08mbar
		Interval time:5 min
8	Dry air in	Dry air in and reach 1000 mbar
9	End	

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Comments:

Acceptance Criteria: All above cycle parameters have been verified and all Yes/No questions must be answered "Yes" or explained indicating acceptance for intended use.

Meets operational requirements **( )Yes** **( )No**

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Checked by	Quality Assurance	
Reviewed by	Quality Assurance	

Attachment 4-Data Plots Data Sheet

Record and print data and curve.

Create the graphs and data of lyophilizing:
1. All TCs vs. time for the full cycle.
2. All data for the full cycle.
3. The recipe of the cycle.

NOTE: If, in any of the preceding function tests, the equipment fails to perform as specified, a Deviation will exist. All Deviations from this testing protocol must be explained.

Acceptance Criteria: Did the Lyophilizer recipe perform as specified

( ) YES **( ) NO**

Summary:

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