

FAT PROTOCOL

Equipment	Vacuum Freezing Dryer
Manufacturer	Shanghai China Sun Far-east Pharmaceutical Machinery Co., Ltd
Customer	OAO GEROPHARM-Bio
Model	GZLYZ15
Document version	1.00

1. Introduction

1.1 Purpose

This protocol describes the activities for FAT of **GZLYZ15**

The objective target of this protocol is to establish documented evidence that all key aspects of the equipment installation adhere to the approved criteria.

1.2 Facility

The FAT will take place at Manufacture's factory

1.3 Responsibilities

This protocol can be executed before deliver of the machine by engineer nominated by both customer and manufacturer

1.4 Skills Requirement

The FAT shall be performed by trained and instructed skilled personnel only. If there is any deviation caused by a negligent use or inexperience of the operators, the sellers take no responsibility.

2. Approval of FAT

FAT is approved for execution. Any change to this section must be approved according to the change control procedure

	Company	Name	Date	Sign
created	OOO GEROPHARM	Dmitry Kolobovnikov	03.09.2013.	
reviewed	-	-	-	-
approved				
approved				

3. FAT tests

General inspection of the machine documentation in accordance with the Contract	Yes	Yes with remarks	No	Value/Remark	PL
Acceptance criteria: <ul style="list-style-type: none"> - A final version of the documentation is present - All necessary chapters are present, readable and complete 					
Checked by:		Date:			

General inspection of the machine in accordance with the Contract (the technical specification checking)	Yes	Yes with remarks	No	Value/Remark	PL
Acceptance criteria: <ul style="list-style-type: none"> - Technical machine characteristics are in accordance with the specification - All equipment is installed at the machine in accordance with the specification - The machine functions are in accordance with the specification 					
Checked by:		Date:			

Comparing the machine layout drawing with the machine	Yes	Yes with remarks	No	Value/Remark	PL
Acceptance criteria: <ul style="list-style-type: none"> - The machine layout drawing is readable and complete - The drawing includes a unique document name, a version and a date - The machine design is in accordance with the drawing 					
Checked by:		Date:			

Verification of the media connections positions with the machine layout drawing	Yes	Yes with remarks	No	Value/Remark	PL
Acceptance criteria: <ul style="list-style-type: none"> - All media connection are indicated in the accordance with the drawing - All media connection are located in the accordance with the drawing $\pm 50\text{mm}$ 					
Checked by:		Date:			

Dimensional inspection	Yes	Yes with remarks	No	Value/Remark	PL
Acceptance criteria: <ul style="list-style-type: none"> - Measures must be correspond with a $\pm 50\text{mm}$ precision to the drawing dimensions 					
Checked by:		Date:			

Verification of the PLC program	Yes	Yes with remarks	No	Value/Remark	PL
Procedure: - Note the actual program version and name of the author				Program version: _____ Author: _____	
Checked by:		Date:			

Cooling rate and lowest temperature of shelves	Yes	Yes with remarks	No	Value/Remark	PL
Procedure - check the cooling water, temperature $\leq 20^{\circ}\text{C}$ and amount $\geq 20\text{t}$ - Start the machine cooling $+25^{\circ}\text{C}\sim-55^{\circ}\text{C}$ (no load) Acceptance criteria: - cooling time $+25^{\circ}\text{C}\sim-40^{\circ}\text{C}$ is less than 60 min. - the lowest temperature is -55°C (no load and time requirement)				Actual cooling time $+25^{\circ}\text{C}\sim-40^{\circ}\text{C}$: _____ Actual lowest temperature: _____	
Checked by:		Date:			

Cooling rate and lowest temperature of condenser	Yes	Yes with remarks	No	Value/Remark	PL
<p>Procedure</p> <ul style="list-style-type: none"> - Confirm condenser temperature is about +25°C - Set up the condenser temperature is -75°C and start cooling. - When the temperature cool down to -40°C, write down the time. - Continue cooling the condenser - When it reaches the lowest temperature, write down the time and temperature. <p>Acceptance criteria:</p> <ul style="list-style-type: none"> - Cooling time from +25°C to -40°C is less than 30 min. - Max. low temperature $\leq -75^\circ\text{C}$ 				<p>Actual cooling time +25°C~-40°C:</p> <hr/> <p>Actual lowest temperature:</p> <hr/>	
Checked by:		Date:			

Test of control system	Yes	Yes with remarks	No	Value/Remark	PL
<p>Procedure</p> <ul style="list-style-type: none"> - switch on the machine, trans the control panel to debugging - check the function of every button 					
Checked by:		Date:			

Cooling jacket checking	Yes	Yes with remarks	No	Value/Remark	PL
<p>Procedure</p> <ul style="list-style-type: none"> - After SIP cool down the chamber up to +60°C - Connect cooling water +10°C÷+17°C to the inlet on the chamber and the door - Cool down the chamber and the door during 25 min - Stop cooling, open the door. Make visual inspection of the chamber inside. <p>Acceptance criteria:</p> <ul style="list-style-type: none"> - On the inside of chamber and the door straight condensate roads in accordions with cooling jacket design are visible 					
Checked by:		Date:			

Machine cooling down test	Yes	Yes with remarks	No	Value/Remark	PL
<p>Procedure</p> <ul style="list-style-type: none"> - Install at least 3 temperature sensors in 3 different places inside the chamber directly under the chamber sealing without contact with metal parts. - Make complete SIP cycle with sterilization temperature +123°C and sterilization time 30 min. - Start cooling down the chamber with cooling water inlet to the chamber and the door. - Start cooling down of the shelves up to +27°C when the silicon oil temperature will be $\leq 65^{\circ}\text{C}$ - Do not open the chamber door. - After finishing SIP 4 hours later check the temperature of the 3 sensors - Wait 30 minutes more and check the temperature of the 3 sensors again <p>Acceptance criteria:</p> <ul style="list-style-type: none"> - after finishing SIP 4 hours later the temperature inside the chamber is not higher the room temperature 				<p>Actual temperature measurements 4 hours later finishing SIP:</p> <p>1. _____ 2. _____ 3. _____</p> <p>Actual temperature measurements 4 hours 30 minutes later finishing SIP:</p> <p>1. _____ 2. _____ 3. _____</p>	
Checked by:		Date:			

Full lyo cycle	Yes	Yes with remarks	No	Value/Remark	PL
<p>Procedure</p> <ul style="list-style-type: none"> - fill trays with water not more than 10mm and load it to the chamber - do the vacuum freezing of water - check the whole running of machine <p>Acceptance criteria:</p> <ul style="list-style-type: none"> - Trays are empty - Full cycle finished successfully 					
Checked by:		Date:			

Machine overpressure test	Yes	Yes with remarks	No	Value/Remark	PL
<p>Procedure</p> <ul style="list-style-type: none"> - Create inside the chamber and the condenser the overpressure 1,3bar with compressed air. - Close the mushroom-valve. - Right down the pressure inside the machine - After 30 min check the overpressure again. <p>Acceptance criteria:</p> <ul style="list-style-type: none"> - After 30 min the overpressure change is not more 0,01bar. 				<p>Actual overpressure change after 30 min:</p> <hr/>	
Checked by:		Date:			

Shelves temperature distribution uniformity and temperature control ability	Yes	Yes with remarks	No	Value/Remark	PL
<p>Procedure</p> <ul style="list-style-type: none"> - Put 2-3 pcs temperature sensors on each shelve in three positions: conduction oil inlet port, conduction oil out port, middle of shelves. The temperature sensor needs to contact with shelve fully - Run the machine with shelves temperatures: -30°C、0°C、+30°C - Record the temperature 30 minutes later reaching the set points <p>Acceptance criteria:</p> <ul style="list-style-type: none"> - Temperature different between each point of shelves $\leq \pm 1^\circ\text{C}$ from average value; - Temperature different between shelves $\leq \pm 1^\circ\text{C}$ from average value; 				Fill down the table below	
Checked by:		Date:			

Shelf	Set T	+30°C			0°C			-30°C		
	Real T (°C)	left	right	center	left	right	center	left	right	center
1										
2										
3										
4										
5										
6										
7										
8										
Data analysis		Average shelves temperature		Max. deviation between each point of shelfe (\pm)			Max. deviation between shelves (\pm)			
+30°C(°C)										
0°C(°C)										
-30°C(°C)										

4. FAT Punch List (PL)

5. FAT final result

The factory acceptance test (FAT) is:

- Accepted without remarks
- Accepted with remarks (see the Punch List)
- Not accepted. The equipment is subject to modifications and retest.

Customer			
Company	Name	Date	Signature

Manufacturer			
Company	Name	Date	Signature

Manufacturer's representative			
Company	Name	Date	Signature