

Revision: ----	Document Code: WI- ML-6431	Standard Operating Procedure (SOP) for Christ-C150 Freeze Dryer	 دانشگاه علوم پزشکی و خدمات بهداشتی و درمانی آستان قدس عالمی
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Standard Operating Procedure (SOP): Christ-C150 Freeze Dryer (Lyophilizer)

1. Objective

To define the standard operating procedure for the safe and effective operation of the German-made Christ-C150 Freeze Dryer for the lyophilization of sensitive biological, pharmaceutical, and chemical samples.

2. Scope

Freeze-drying (lyophilization) is a process that removes water through sublimation—transitioning ice directly into vapor by reducing system pressure. This SOP covers the three-stage process: Primary Freezing, Primary Drying (Vacuum Sublimation), and Secondary Drying (Vacuum Evaporation). This method is intended for materials sensitive to heat or those requiring long-term storage and easier transport.

3. Responsibility

The responsibility for implementing this procedure lies with the designated laboratory experts.

4. Operating Procedure

Preparation

- Power Up:** Turn the Christ-C150 device to the **ON** position using the switch on the left side.
- Sample Loading:** Open the sample chamber cover, place the prepared samples into the chamber, and secure them. Adjust the sample container position to ensure optimal exposure and efficiency.
- Closing:** Securely close the sample chamber cover.

Setting Parameters (Easy Keys & Navigation)

Use the navigation keys (▲/▼) and the **ENTER/OK** keys to configure the cycle phases:

- Freezing Phase:**
- Navigate to **Menu** → **Change set values** → **Enter** → **Freezing** → **Enter**.
- Select **Edit**, adjust the time using ▲/▼, and confirm with **OK**.
- Vacuum/Heating Phase:**
- Navigate to **Menu** → **Options** → **Enter** → **Settings** → **Edit**.
- Select **Heat** → **Edit**, set the duration with ▲/▼, and confirm with **OK**.
- Primary Drying Phase:**

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- Navigate to **Menu** → **Change set values** → **Enter** → **Main Drying** → **Enter**.
- Select **Edit**, adjust the time using ▲/▼, and confirm with **OK**.

Starting the Process

1. Use the **Back** key to return to the main menu.
2. Select **Mode** to choose the starting phase.
3. **Recommended Sequence:** Initiate the process in the following order for optimal results: **Freezing** → **Vacuum/Heating Pump** → **Main Drying**.

5. Safety and Maintenance Notes

- **Sample Integrity:** Ensure samples are properly contained to prevent spilling within the vacuum chamber.
- **Vacuum Safety:** Always ensure the chamber seal is clean and undamaged before starting to maintain the necessary vacuum levels.
- **System Integrity:** Do not attempt to open the chamber while the vacuum pump is engaged.
- **Cleaning:** After completing the cycle, allow the condenser to defrost fully and clean the chamber thoroughly to prevent cross-contamination for future batches.
- **Troubleshooting:** If the system fails to reach the target vacuum, inspect the gasket seals and the drain valve for potential leaks. Always refer to the manufacturer's manual for specific error codes or maintenance schedules.

5. Laboratory Safety Protocols

- **Personal Protective Equipment (PPE):** Always wear appropriate protective gear, including safety goggles, gloves, and a laboratory coat.
- **Proper Training:** Operators must be fully trained on the device's operation, potential hazards, and safety protocols.
- **Avoid Flammable Materials:** Keep all flammable substances away from the freeze dryer.
- **Emergency Power Cut-off:** In case of any malfunction or emergency, immediately disconnect the device from the power supply.

Sample Submission and Handling Procedures

- **Sample Volume:** The maximum volume per sample is 10 mL.
- **Plate Usage:** Use plates with a large surface area. Do not exceed 10 mL of sample per plate.
- **Falcon Tubes:** Samples in 50 mL Falcon tubes should not exceed 10 mL. For 15 mL or 10 mL tubes, keep the volume below 5 mL.

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- **Vials:** Ensure the sample volume in vials is less than 1 mL.
- **Pre-freezing:** Before submission, ensure the sample is completely frozen at -20°C (standard freezer) and subsequently at -70°C. The sample must be thoroughly frozen again immediately before being placed in the freeze dryer.
- **Process Duration:** The standard freeze-drying cycle is 24 hours.
- **Sealing:** Cover the sample container securely with aluminum foil or Parafilm.

6. Maintenance and Operational Guidelines

- **Prevent Overheating:** Avoid overheating the product during the cycle to prevent melting or collapse of the sample structure.
- **Pressure Management:** Prevent excessive water vapor buildup in the chamber and condenser, as this can increase pressure and damage the unit.
- **Vapor Choking:** Ensure water vapor is evacuated efficiently through the vapor outlet to prevent pressure accumulation and vapor choking.
- **Regular Maintenance and Service:** The freeze dryer must undergo routine maintenance and professional servicing to ensure safe and optimal performance.
- **Pre-operational Inspection:** Inspect the device for any visible damage or technical defects before each use.
- **Manufacturer's Instructions:** Strictly follow all guidelines and instructions provided by the manufacturer.
- **Adequate Ventilation:** Ensure the workspace is well-ventilated to prevent the accumulation of potentially harmful vapors.
- **Temperature Control:** Maintain precise temperature control throughout the freeze-drying process to prevent product degradation.
- **Proper Packaging:** After the process is complete, package the product appropriately to protect it from damage and contamination.

Important Notice:

To prevent damage to the device and its chamber, samples must be free of flammable materials, acids, and organic solvents, including (but not limited to) alcohol, acetone, DMSO, ether, chloroform, xylene, and hexane. Failure to comply with these regulations will result in the user being held financially liable for any resulting damages.

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