

Cleaning of Clinical Trials Storage Locations

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

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This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reviewers	Details of significant changes
1.0	13 th March 2020		
2.0	21 st February 2024	Rachel Spooner	Addition of Ultra Low Freezer instructions. Change of author and SOP title. Addition of cleaning of clinical trials IMP shelving in the clinical trials dispensary. Addition of more related Pharmacy SOPs/Forms

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1 Introduction, Background and Purpose

The function of the clinical trials refrigerators and freezers is to ensure that the physical, and chemical stability of pharmaceutical products stored within them are maintained in agreement with manufacturer and sponsor storage requirements.

Regular cleaning and temperature monitoring of storage areas forms part of the Quality Management System (QMS) and allows the Quality Assurance (QA) team to provide documented evidence to show that manufacturers storage requirements have been satisfied and the quality of the pharmaceutical products stored within the refrigerators and freezers can be assured.

Temperatures of all storage locations within pharmacy clinical trials are monitored in accordance with Pharm/S48 - Temperature Monitoring (Clinical Trials)

2 Who Should Use This SOP

This SOP should be used by any member of the Clinical Trials team undertaking the cleaning of any of the storage locations used by Clinical Trials.

3 When this SOP Should be Used

This SOP should be used when conducting the cleaning of any of the Clinical Trial fridges, freezers, ultra-low freezer or shelving.

Clinical Trial Refrigerators and shelving are to be cleaned once every quarter, totalling four instances in a calendar year. Freezers are to be cleaned twice per calendar year, 6 months apart, and ultra-low freezers must be cleaned once a year when defrosted.

4 Procedure(s)

Before this procedure is carried out ensure the daily workload is considered. Plan cleaning around prescriptions and orders that may be due in and schedule the most appropriate time. For example, when a fridge or freezer has low stock levels and is waiting for new supplies to arrive from the sponsors this would be the most suitable time to clean a fridge/freezer to minimise the amount of stock which could be affected by the cleaning process.

As per Pharm/S70 (stock management of IMP in Pharmacy), upon completion of the Clinical Trials monthly stock check, 2 IMP storage locations must be chosen each month to clean as per the Clinical Trials IMP storage location cleaning schedule (Pharm/F40) to ensure locations are cleaned and maintained appropriately throughout the year.

Empty the Refrigerator/Freezer:

1. Proceed to the refrigerator or freezer; complete the details necessary on **Pharm/F40** (stored in the 'temperature monitoring file' in the Clinical Trials office), including the time cleaning began and the location any stock was kept

- during the cleaning. Identify a suitable temporary storage area, another fridge or freezer as required, to transfer the stock into for the duration of cleaning; making sure it is within temperature range. Keep the doors of all **fridges** closed as much as possible for the duration of the process to try and prevent temperature excursions.
2. Transfer the items into the alternative fridge or freezer as appropriate, ensuring the Denward logger that is inside the fridge or freezer (which is to be cleaned) is transferred with the stock. This is to show a continuation of temperature recording during the cleaning process.
 3. For refrigerator cleaning, now proceed to step 8 (Cleaning internal surfaces)

Defrost Freezer:

Check if the freezer is “self-defrosting”. If so, and there is no ice build-up, it will not be required to be defrosted.

Sponsor supplied ultra-low freezers will have their own procedures for defrosting and cleaning. Refer to the Ultra Low Freezer section below.

4. Turn off and unplug freezer at the wall.
5. Open door and leave ajar, place wet floor sign outside of freezer in case of spillage.
6. Leave until all ice has completely melted.
7. Mop up all water inside the freezer with paper towels and any water on the floor with a mop from the cleaner’s cupboard within the pharmacy department.

Clean internal surfaces:

8. Remove any shelving and place on a safe flat surface.
9. Collect the Clinell wipes found in the clinical trials dispensary or obtain a new pack from pharmacy stores if required.
10. Using a wipe, working from top to bottom, wipe all internal surfaces of the fridge or freezer.
11. Using a Clinell wipe, wipe the shelving. Replace them in their original position in the refrigerator or freezer (be careful not to damage the refrigerator or freezer).
12. Turn the refrigerator or freezer back on at the wall.
13. Close the refrigerator or freezer door to allow the unit to return to temperature.

Cleaning refrigerator/freezer external surfaces and components:

14. Using Clinell wipes, wipe the exterior panels of the refrigerator or freezer. Do not wipe directly onto working electrical parts; extra care must be taken to avoid contact with the LED display, to ensure accidental temperature adjustment or power interruption is avoided.
15. Once cleaning has been completed, log the finish time on **Pharm/F40**.
16. Ensure that EMS is reading at the required temperature before any stock is transferred back to the original location. The Denward logger that was transferred with the stock to the temporary location should be checked for any excursions before returning to the original location.
17. Once the temperature of the fridge/freezer is verified as being in range using EMS, place all stock back in the cleaned refrigerator or freezer.
 - Fridge temperature range: 2°C to 8°C
 - Freezer: -15°C to -25°C

If a temperature excursion is recorded on the accompanying Denward logger or in the temporary location, then a file note must be produced to document the occurrence. The temperature excursion will then need to be handled in the usual manner.

A file note will be required to accompany the monthly saved graph produced from EMS for the original (cleaned location) to show why the records show an excursion.

Ensure that the Denward logger data is produced and saved for this month to show a continuation of temperature recording.

The times provided on **Pharm/F40** will provide evidence of stock being located elsewhere at the time of excursion.

Cleaning Ultra Low Freezer

- Before cleaning ensure that unit has fully defrosted.
- To do so, ensure the unit is empty and disconnect the power.
- Leave for 24 hours to defrost.
- Once the ice has melted, thoroughly dry the inside of the freezer with paper towels. **Do not use clinell wipes or any solvents.**
- Pay particular attention to the door seal and remove any excess water before switching back on.

Cleaning IMP Shelving in the Clinical Trials Dispensary

1. Remove all stock from the shelves. Ensure shelving is cleaned one bay at a time to avoid any confusion regarding the storage of different IMP.
2. Wipe the shelves from top to bottom, back to front, with a Clinell wipe which can be found in the Clinical Trials Dispensary.
3. Allow the shelves to air dry before placing the stock back onto the shelves.
4. IMP removed from the shelves must remain in the Clinical Trials dispensary for the duration of the cleaning to ensure temperature monitoring is maintained. As a result, a Denward logger is not required to monitor the movement from ambient stock.

Upon completion of cleaning, ensure all details on **Pharm/F40** are completed and return the form to the designated section of the Temperature Monitoring File in the clinical trials office.

As per the monthly stock check process in Pharm/S70, the chosen locations for cleaning must also be documented and ticked on Pharm/F63 (monthly stock check form) upon completion of cleaning.

5 Related SOPs and Documents

Pharm/F40 - Clinical Trials Fridge/Freezer Cleaning Schedule

Pharm/S48 - Temperature Monitoring (Clinical Trials)

Pharm/S70 – Stock Management of IMP in Pharmacy

Pharm/F63 – Monthly Stock Check Form