**Category:** Study Procedures
**Title**: Storage, safe handling of IP and Maintaining its Temperature Log
**SOP No.: D** 22 /07
**Date first effective:** 1 Jan 2025 **Review date:** 31 Dec 2025

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**Table of Contents**

## 1. Purpose

This Standard Operating Procedure describes the procedure for storage, handling of investigational product (IP) and maintaining the Temperature Log of the trial medication during the study period.

## 2. Responsibilities & Scope

Principal investigator, Co-investigator, Pharmacist, Study Coordinator or any other appropriately qualified staff in the team, delegated by the Principal Investigator, will be responsible for storage, handling of IP and maintaining the Temperature log of the trial medication during the study period. Every designated staff will have a backup who will perform the duties in his/her absence.

This SOP is limited to describing the essential steps to be taken by the study staff for the safe handling of study IPs (IPs) in clinical trial and maintenance of temperature as advised by the sponsor during the trial.

## 3. Applicable rules, regulations and guidelines

- ICMR's Ethical Guidelines for Biomedical and Health research involving Human Participants, ICMR(2017)
  http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) ICH E6 (R3)
  https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf (Adopted on 06 January 2025)
- Indian GCP guidelines 2001
  https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzM5NQ (Last accessed 20 Dec 2024)
- New Drugs and Clinical Trials 2019
  https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdfdocuments/NewDrugs_CTRules_2019.pdf (Last accessed 20 Dec 2024)

## 4. Detailed Instructions

### Staff Training

- The temperatures recorded must be audited regularly at least annually
- Calibration of temperature monitoring device and refrigerator should be maintained & updated as per requirement, desired frequency
- The delegated study team member (preferably the pharmacist) should ascertain the temperature requirements of the IP as per the protocol provided by the sponsor.
- The pharmacist must ensure that the refrigerator for storing of IPs in the Pharmacy room of the ward no.24 of the Department of Clinical Pharmacology, is calibrated.
- Access to the refrigerator in which IP is stored should be restricted. The Pharmacist is responsible to ensure that this is followed. The PI should sign off the access register at least once a week
- If the IP is to be stored at room temperature, it should be stored in Pharmacy room located at ward no. 24 of Department of Clinical Pharmacology, or in Residents Room in Phase 1 unit, 2nd Floor, New MS Building, KEM Hospital depending on the temperature requirement.
- The refrigerator must be labeled with the name of the study, storage temperature for which the IPs are housed, with the date and due date of calibration.
- Data logger should always be kept with the IP to keep a track of temperature round the clock

### 4.1. Instructions regarding receipt and placement of IPs in the refrigerator:

1) On receipt of study IPs, check the IPs against the expiry date and discrepancies, order for leakage, damage, before signing for them on the receipt form.
2) IPs must be refrigerated immediately on receipt and not left out at room temperature.

3) Study IPs type, quantity, batch number and expiry date must be recorded together with the date and time received.
4) Manufacturers' recommendations on storage must be adhered to. The delegated study team member (preferably the pharmacist) should ascertain the temperature requirements of the IP as per the protocol provided by the sponsor.
5) Study IPs must be kept in their original containers issued by the manufacturer and stored as advised.
6) Temperatures reached within the refrigerator must be recorded twice every day (excluding Sunday and any public/bank holidays as per local policy)
7) Study IPs must be stored in the main body of the refrigerator, allowing air to circulate around the packages and ensuring there is no obstruction to the refrigerator fan.
8) Study IPs must not be stored in the door of the refrigerator or in the bottom drawers or adjacent to the freezer plate.
9) IPs must be protected from light.
10) IPs should be placed in the refrigerator such that the vent or fan meant for circulation of air is not blocked and should be evenly distributed across each rack.
11) When 2 or more different IPs are simultaneously administered in a single study, each should be placed on a separate rack and the rack should be labeled accordingly.

### 4.2 Maintenance of IP Refrigerators

1) Refrigerators must be defrosted once a week
2) Refrigerators must not be situated near a radiator or other heat source. They must also be appropriately ventilated
3) Refrigerator plugs and sockets must be covered with tape which reads "DO NOT UNPLUG"
4) Refrigerators used for IP storage should be lockable and used exclusively for medicines.

5) The door of the refrigerator must not be opened unnecessarily and should not be left open any longer than absolutely necessary.
6) Arrangements must be in place for back up facilities in the event of the refrigerator failing or breaking down.
7) Calibration of the refrigerator need to be done yearly

**4.3. Instructions regarding the data logger or temperature recording device**

1. Go through the operations manual for handling of the data logger.
2. If the instructions are not clear, then contact the sponsor /CRO for the operational details.
3. Ensure that the data logger is calibrated and battery is not in a drained state at the time of receipt.
4. Position the probe of the data logger in the center of the storing device.
5. Allow the data logger to get conditioned by placing it in the refrigerator for at least 2 hours before initiating the recording of the temperature.

**4.4. Instructions regarding recording of temperature**

1. The temperature of the refrigerator should be recorded in $^{O}C$/ $^{0}F$ as per protocol requirements twice a day (in the morning and evening or at times specified by the protocol) by the study pharmacist. The minimum, maximum and actual temperature at time of recording should be recorded.
2. If the readings are not measured in case of Sundays or public holidays, a comment must be provided stating the reason in the temperature log.
3. The readings should be entered in the temperature log and should be signed and dated by allotted staff and reviewed by the study coordinator.
4. The data logger should be reconfigured at least once a week to capture the true maximum and minimum temperature.
5. Data from the logger should be downloaded (if downloadable) at least once a week and saved into a secure computer by the Pharmacist.

6. In case the temperature of the room/ refrigerator exceeds the given limit, immediately transfer the IP with the help of Cryo box (if IP requires low temperature) to another room/ refrigerator that can maintain the required temperature.
7. Inform the same immediately to the Principal Investigator and the sponsor/CRO *via* email.
8. Ensure that the temperature log is sent to the Sponsor/CRO at regular intervals as specified in the protocol.

**4.5. Instructions regarding handling of temperature excursions**

1. In case of deviation from the specified temperature range, inform the PI and the sponsor via email.

2. Download the data from the data logger and identify the date and time at which the excursion occurred.

3. Notify the Institutional Ethics Committee (IEC) at the earliest with the corrective measures taken

4. Identify the reason for the excursion and take appropriate measures to avoid a repeat of the same.

**4.6. Instructions to avoid temperature excursion**

1. Avoid opening the refrigerator frequently for the purpose of storing and retrieving the IPs.

**4.7. Ordering And Monitoring of Stock**

1) IPs should be ordered by the designated/delegated person(s)
2) Care must be taken to avoid over ordering or stock piling IPs. No more than 2-4 weeks stock should be maintained.
3) IPs must be placed within the fridge to ensure IPs with shorter dates are used first, (i.e. stock rotate). Regular weekly or monthly checks must be made to remove time expired IPs.

**4.8. Disposal Of Unused and Expired Ip**

1) All reconstituted IPs and opened single and multi-dose vials must be used within the period recommended by the manufacturer and disposed of at the end of a session
2) Expired and partly used IPs must be disposed of in a bin for incineration, together with used ampoules and vials.
3) If site has no facility for proper destruction of expired and partly used IPs then they should return the same for destruction to manufacturer or sponsor.

### 4.9. Batch Number and Expiry Date

1) The name of the IP, batch number, the manufacturer used and the expiry date must be recorded.

### 4.10. IP Removed from the Refrigerator for Use

1) IPs must only be removed from the refrigerator immediately prior to use
2) Only one box should be removed at a time.
3) All unused IPs which have been out of the refrigerator must be marked with a cross and dated and then replaced immediately in the refrigerator, or appropriately destroyed, if the IP has been exposed to a higher-than-average room temperature or a long clinic session.
4) IPs that have been marked with a cross and dated must be used at the session (if allowed) or appropriately destroyed

### 4.11. IP Spillage

IP spillage must be cleared up as below

1) Spillages must be cleared quickly whilst wearing gloves, mop up excess with paper towels.
2) Avoid skin puncture from glass or needles.
3) Discard soiled paper towels, gloves and vials in a bin for incineration.
4) Clean surface with Lysol Disinfectant.
5) Splashes on the skin must be washed with soap and water.

6) Eyes must be washed with copious amounts of 0.9% sodium chloride and medical advice sought

### 4.12. Use Of Insulated Cool Boxes

1) Designated cool boxes should be used.
2) It is strongly recommended that the cool box is monitored with a thermometer.

### 4.13. Treatment And Final Disposal

Will be carried as per SOP 24/07 (Waste Management)

## Annexure 1: Template of temperature log

### TEMPERATURE LOG

**Protocol ID:**
**Protocol title:**

**Investigational Product:**
**Principal Investigator:**
**Person maintaining temperature log**
**Centre:**

| | | Morning Temp $^0$ C | | | | | Evening Temp $^0$C | | | | Monitor verification during site visit (Initials and date) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Date | Time | Max | Min | Actual | Sign | Time | Max | Min | Actual | Sign | |
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Signature of PI or designee:

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