

DEPARTMENT OF CLINICAL PHARMACOLOGY
SETH GSMC AND KEMH, MUMBAI – 400012

DCP/Ph1/016: Managing a pharmacy for storage of investigational products for clinical trials

Version 1.3

Effective date: 1st of January 2024

Revision due date: 31st of December 2024

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1. Purpose: The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for the proper management and storage of investigational products in a pharmacy for use in clinical trials.

2. Scope: This SOP applies to the pharmacy department responsible for receiving, storing, and dispensing investigational products in a clinical trial setting.

3. Responsibilities: The Principal investigator, Co-investigator, Pharmacist, Study Nurse, Study Coordinator or any other appropriately qualified staff in the team, as delegated by the Principal Investigator for implementation of this SOP.

4. Applicable rules, regulations and guidelines:

- Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR (2017)
- ICH E6 (R3) Integrated Addendum to ICH E6 (R1), Current Step 4 version dated May 2023
- Medical Devices Rules, 2019
- New Drugs and Clinical Trials Rules, 2019

5. References (to other SOPs)

- Ph1 SOP No. 17/45: Management of investigational products for a Phase I clinical trial

6. Detailed instructions

| S.No | Task | Person responsible |
|------|---|--------------------|
| 1 | Instructions regarding receipt and placement of | |

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| | <p>IPs in the refrigerator:</p> <ul style="list-style-type: none">• Record temperature of the refrigerators twice every day (excluding Sunday and any public/bank holidays as per local policy)• Store study IPs in the main body of the refrigerator, allowing air to circulate around the packages and ensuring there is no obstruction to the refrigerator fan.• Do not keep the IPs in the door of the refrigerator or in the bottom drawers or adjacent to the freezer plate.• Protect IPs from light.• Place IPs in the refrigerator in such a way that the vent or fan meant for circulation of air is not blocked.• When 2 or more different IPs are simultaneously administered in a single study, place each IP on a separate rack and label it accordingly. | <p>Pharmacist, Study Nurse, study co-ordinator under the supervision of PI and CO-I</p> |
| 2 | <p>Maintenance of IP Refrigerators Required.</p> <ul style="list-style-type: none">• Defrost refrigerators once a week.• Keep the refrigerators away from radiator or other heat source.• Cover the refrigerator plugs and sockets with tape which reads “DO NOT UNPLUG”• Lock the refrigerators once used and use it exclusively for medicines.• Avoid unnecessarily opening of the door of the | <p>Pharmacist, Study Nurse under the supervision of PI and CO-I</p> |

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| | <p>refrigerator.</p> <ul style="list-style-type: none"> • Arrange for back up facilities in the event of the refrigerator failing or breaking down. • Calibrate the refrigerator annually. | |
| 3 | <p>Instructions regarding the data logger or temperature recording device</p> <ul style="list-style-type: none"> • Go through the operations manual for handling of the data logger. • If the instructions are not clear, then contact the sponsor /CRO for the operational details. • Ensure that the data logger is calibrated and battery is not in a drained state at the time of receipt. • Position the probe of the data logger in the center of the storing device. • 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. | Pharmacist, Study Nurse under the supervision of PI and CO-I |
| 4 | <p>Instructions regarding recording of temperature</p> <ul style="list-style-type: none"> • Record the temperature of the refrigerator in °C/°F as per protocol requirements twice a day (in the morning and evening or at times specified by the protocol) by the study pharmacist. • Record the minimum, maximum and actual temperature. • The recorded readings of the temperature log and should be signed and dated by allotted study | Pharmacist, Study Nurse under the supervision of PI and CO-I |

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| | <p>staffs and reviewed by the PI.</p> <ul style="list-style-type: none"> • Reconfigure the data logger at least once a week to capture the true maximum and minimum temperature. • Download data from the logger (if downloadable) at least once a week and saved into a secure computer by the Pharmacist. • 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. • In case the temperature of the room/ refrigerator exceeds the given limit, immediately transfer the IP with the help of Cryobox (if IP requires low temperature) to another room/ refrigerator that can maintain the required temperature. • Inform the same immediately to the Principal Investigator and the sponsor/CRO <i>via</i> email. • Ensure that the temperature log is sent to the Sponsor/CRO at regular intervals as specified in the protocol. | |
| 5 | <p>Instructions regarding handling of temperature excursions</p> <ul style="list-style-type: none"> • In case of deviation from the specified temperature range, inform the PI and the sponsor via email immediately. • Download the data from the data logger and identify the date and time at which the excursion | Pharmacist, Study Nurse under the supervision of PI and CO-I |

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| | <p>occurred.</p> <ul style="list-style-type: none"> • Notify the Institutional Ethics Committee (IEC) at the earliest with the corrective measures taken • Identify the reason for the excursion and take appropriate measures to avoid a repeat of the same. | |
| 6 | <p>Instructions to avoid temperature excursion</p> <ul style="list-style-type: none"> • Avoid opening the refrigerator frequently for the purpose of storing and retrieving the IPs. | Pharmacist, Study Nurse under the supervision of PI and CO-I |
| 7 | <p>Ordering and Monitoring of Stock</p> <ul style="list-style-type: none"> • Order IPs by the designated/delegated person(s) • Avoid over ordering or stock piling IPs. No more than 2-4 weeks stock should be maintained. • Ensure IPs with shorter dates are used first, (i.e. stock rotate). • Check regular weekly or monthly for removal of time expired IPs | Pharmacist, Study Nurse under the supervision of PI and CO-I |
| 8 | <p>Disposal of Unused and Expired IP</p> <ul style="list-style-type: none"> • Use of all reconstituted IPs and opened single and multi-dose vials within the period recommended by the manufacturer and disposed of at the end of a session • Dispose the expired and partly used IPs in a bin for incineration, together with used ampoules and vials. • If site has no facility for proper destruction of expired and partly used IPs then return the same | Pharmacist, Study Nurse under the supervision of PI and CO-I |

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| | for destruction to manufacturer or sponsor. | |
| 9 | IP Removed from The Refrigerator For Use <ul style="list-style-type: none"> Remove IPs from the refrigerator, only prior to immediate use Only one box should be removed at a time. 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. Marked IPs must be used at the session (if allowed) or appropriately destroyed. | Pharmacist, Study Nurse under the supervision of PI and CO-I |
| 10 | IP Spillage <ul style="list-style-type: none"> Clear IP spillage up quickly. Wear gloves, mop up with paper towels. Avoid skin puncture from glass or needles. Discard soiled paper towels, gloves and vials in a bin for incineration. Clean surface with Lysol Disinfectant. Wash with soap and water in case of splashes on the skin. Wash eyes with copious amounts of 0.9% sodium chloride and medical advice sought | Pharmacist, Study Nurse under the supervision of PI and CO-I |
| 11 | Use of Insulated Cool Boxes <ul style="list-style-type: none"> Use designated cool boxes Monitor the cool boxes with a thermometer. | Pharmacist, Study Nurse under the supervision of PI |

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| 12 | Treatment and Final Disposal <ul style="list-style-type: none">Will be carried as per Departmental SOP 24 (Waste Management) | Pharmacist, Study Nurse under the supervision of PI and CO-I. |
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7. Abbreviations

| | |
|------|---|
| Co-I | Co-investigator |
| ICH | International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use |
| ICMR | Indian Council of Medical Research |
| ID | Identity number |
| SOP | Standard Operating Procedure |
| PI | Principal Investigator |

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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: