

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

Ph.1 SOP B16: Managing a pharmacy for storage of investigational products for clinical trials

Version 2.0 dated 1st January 2026
Effective date: 3rd January 2026
Revision due date: 31st of December 2026

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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

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6. Detailed instructions

S.No	Task	Person responsible
1	<p>Instructions regarding receipt and placement of IPs in the refrigerator:</p> <ul style="list-style-type: none"> • Record temperature of the refrigerator 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” 	<p>Pharmacist, Study Nurse under the supervision of PI and CO-I</p>

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	<ul style="list-style-type: none"> • Lock therefrigeratorsonce used and useit exclusively for medicines. • Avoid unnecessarily opening of the door of the refrigerator. • 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 PIand CO-I
4	<p>Instructions regarding recording of temperature</p> <ul style="list-style-type: none"> • Record the temperature of the refrigerator in ^oC/ ^oF 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 	Pharmacist, Study Nurse under the supervision of PIand CO-I

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	<p>temperature.</p> <ul style="list-style-type: none"> • The recorded readings of the temperature log and should be signed and dated by allotted study staffs and reviewed by the PI. • 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 	Pharmacist, Study Nurse under the supervision of PI and CO-I

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	<p>via email immediately.</p> <ul style="list-style-type: none"> • Download the data from the data logger and identify the date and time at which the excursion occurred. • 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 	Pharmacist, Study Nurse under the supervision of PI and CO-I

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	<p>and vials.</p> <ul style="list-style-type: none"> • If site has no facility for proper destruction of expired and partly used IPs then return the same for destruction to manufacturer or sponsor. 	
9	<p>IP Removed from The Refrigerator For Use</p> <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	<p>IP Spillage</p> <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

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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
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.

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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Assistant Professor

Signature with date

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01/Jan/2026

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Professor and Head of the Department

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