**Category** : Pre study procedures and Study conduct
**Title** : Receipt,storage and inventory management of Investigational Product (IP)

**SOP No/ Version No :** DCP 13/08
**Date first effective:** 01 Jan 2026 **Review date:** 31 Dec 2026
Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

**Category:** Pre study procedures and Study conduct

**Title:** Receipt, storage and inventory management of Investigational Product (IP)

**SOP No/ Version No:** 13/08 **Total pages:** 08

**Date first effective:** 01 Jan 2026 **Next Review date:** 31 Dec 2026

**Version:** 08

**Author:** 1) Dr.Shiva Krishna Rao.T
1st Year DM Resident
Shiva Krishna RT 1 Jan 2026

2) Dr. Shital Bendkhale
Project Scientist- II
11 JAN 2026

Signature with date

**Reviewer:** Dr. Roopa Parida
Assistant Professor

Signature with date
Rparida 01/Jan/26
Dr. ROOPA PARIDA
Department of Clinical Pharmacology
Seth GS Medical College & KEM Hospital,
Parel, Mumbai-400 012.

**Approved by:** Dr. Nithya Gogtay
Professor and Head

Signature with date
1/Jan/26
Dr Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building
Seth GS Medical College & KEM Hospital
Parel, Mumbai 400 012

**Category** : Pre study procedures and Study conduct
**Title** : Receipt,storage and inventory management of Investigational Product (IP)

**SOP No/ Version No :** DCP 13/08
**Date first effective:** 01 Jan 2026 **Review date:** 31 Dec 2026
Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

## Table of Contents



Dr Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building
Seth GS Medical College & KEM Hospital
Parel, Mumbai 400 012

**Category** : Pre study procedures and Study conduct
**Title** : Receipt,storage and inventory management of Investigational Product (IP)

**SOP No/ Version No :** DCP 13/08
**Date first effective:** 01 Jan 2026 **Review date:** 31 Dec 2026
Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

## 1. Purpose

This SOP describes the procedures study personnel will use to fulfill the regulatory and ethical responsibilities for receipt, storage and inventory management of Investigational Product (IP) used in clinical studies.

## 2. Scope

The SOP is limited to receipt, storage and inventory management of Investigational Product (IP) used in clinical studies.

## 3. Responsibilities

Study pharmacist, Co-investigator and Principal Investigator or any other appropriately qualified member of staff in the team, as delegated by the Principal Investigator, will be responsible for receipt, inventory and storage of IPs.

## 4. Applicable rules, regulations and guidelines

- National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017), https://ethics.ncdirindia.org/ICMR_Ethical_Guidelines.aspx, last accessed on 23rd Mach 2026.
- New Drugs and Clinical Trials Rules (2019), https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/New-Drugs/, last accessed on 23rd March 2026.
- ICH HARMONISED GUIDELINE GOOD CLINICAL PRACTICE (GCP) E6(R3), https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf, last accessed on 23rd March 2026.
- India GCP guidelines (Draft, September 2024), https://ethics.ncdirindia.org/asset/pdf/Indian_GCP_guideline.pdf, last accessed on 23rd March 2026.
- National Ethical Guidelines for Biomedical Research Involving Children.https://ethics.ncdirindia.org//asset/pdf/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children.pdf last accessed on 23rd March 2026.



Dr Nithya Gogtay 1.1.26
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building
Seth GS Medical College & KEM Hospital
Parel, Mumbai 400 012

- Standard-Operating-Procedures of Institutional Ethics Committee, Seth GS Medical College and KEM Hospital, Mumbai https://www.kem.edu/wpcontent/uploads/2025/03/SOPs_V7_effective_from_9th_Dec_2024_Seth_GSMC_&_KEMH_Mumbai.pdf V7-effective-from-9th-Dec-2024_.pdf (last accessed 23rd March, 2026)

5. **References to other applicable SOPs:**

SOP No/ Version No11/08 Dispensing Investigational Product (IP)
SOP No/ Version No22/08 Storage of IP and Maintaining its Temperature Log
SOP No/ Version No23/08 Destruction/return of Investigational product

1-1-26
Dr Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building
Seth GS Medical College & KEM Hospital
Parel, Mumbai 400 012

## 6. Detailed Instructions

1. Upon receipt of the investigational product (IP) (from sponsor or any appropriate organization), the shipment should be inventoried, verifying that the receipt date, lot number, drug type, batch number, temperature if appropriate (for Example Vaccines) and quantity on the packing slips are the same as what was actually received.
2. Check the temperature on receiving the shipment from the sponsor for Investigational Product that require a specific temperature range.
3. Promptly bring any discrepancies to the attention of the Sponsor/supplier of the drug.
4. Retain a copy of the shipping inventory, packing slips and document inventory in the trial master file.
5. Receipt of investigational product (IP) should be acknowledged and the copy of the same should be kept in the Trial Master File.
6. The investigational product (IP) should be stored in a restricted access environment according to requirements listed in the protocol or the investigator's brochure (Refer to SOP No 22/07 Storage of IP and Maintaining temperature log).
7. The expiry date of the Investigational Product(IP) should be noted, and the Investigational Product(IP) should be returned, disposed of, in accordance with the approved protocol when the drug is outdated. (Refer to SOP No/ Version No 23/08 Destruction/return of Investigational product).
8. Investigational Product IP should be distributed uniformly across the racks in the refrigerator where it is stored.
9. The Investigational Product (IP) should be dispensed by the designee according to the SOP No/ Version No11/08: Dispensing Investigational Product (IP).
10. Drug accountability documentation should be completed on arrival of supplies, each time Investigational Product (IP) is dispensed, and when Investigational



01.01.26
Dr Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building
Seth GS Medical College & KEM Hospital
Parel, Mumbai 400 012

Product (IP) is returned to the sponsor. (Refer to SOP No/ Version No 23/08 Destruction/return of Investigational product)

11. Compliance by the participant with the procedures described in the protocol should be verified. Discrepancies between amount of the The investigational product (IP) used by the participants and amount returned and the reasons underlying any discrepancies should be documented. If the participant has not taken the drug as required by the protocol, the PI should determine whether the participant may remain in the study or be withdrawn.
12. When all participants have completed the study medication, the records should be checked for accuracy and should be signed and dated by the PI.
13. During the course of the study, partially used doses, used containers and tubing should be disposed of in the manner described in the protocol, and, if they are biohazards, in accordance with the institution's biohazard policies.
14. At the conclusion of the study, the study drug should be inventoried and prepared to be returned to the sponsor in accordance with the requirements of the sponsor or the manufacturer (SOP No/ Version No 23/08 Destruction/return of Investigational product).
15. All documentation regarding receipt, storage, dispensing, and return of used containers must be complete and accurate.
16. A copy of all accountability documents should be maintained in the Trial Master File.

3/1/26

Dr Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building
Seth GS Medical College & KEM Hospital
Parel, Mumbai 400 012

| Study Title: | |
|---|---|
| **Site Name :** | **Site Number :** |
| **Sponsor :** | |
| **Principal Investigator :** | |
| **Investigational Product:** | **Lot No :** |

7. **Appendix: IP Accountability Log**

| SI No: | Date | Randomisation No: | Dose | Time of administration | No: of IP used | No: of IP damaged | No: of IP remaining | Signature |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

**Investigator's signature** _____ **Date** ____/____/____

1-1-26

Dr Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building
Seth GS Medical College & KEM Hospital
Parel, Mumbai 400 012

## 8. Glossary

**Investigational Product:**

- A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. [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 ,Last accessed on 23rd March, Adopted on 06 January 2025].

**Reviewer as appropriate:**

Signature with date 01/Jan/26

Dr. ROOPA PARIDA
Department of Clinical Pharmacology
Seth GS Medical College & KEM Hospital,
Parel, Mumbai-400 012.

**Approved by Head of Department:** Dr. Nithya Gogtay
Professor and Head

Signature with date 01/Jan/26

Dr Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building
Seth GS Medical College & KEM Hospital
Parel, Mumbai 400 012