

Category : Pre study procedures and Study conduct
Title : Receipt, Inventory, and storage of Investigational Product (IP)
SOP No. : D 13/06
Date first effective: 01 Jan 2024 **Review date:** 31 Dec 2024
Department of Clinical Pharmacology, First Floor, New MS Building, Seth GS Medical
College & KEM Hospital, Parel, Mumbai 400012.

Category: Pre study procedures and Study conduct
Title: Receipt, Inventory, and storage of Investigational Product (IP)
SOP No.: D 13/06 **Total pages:** 07
Date first effective: 01 Jan 2024 **Next Review date:** 31 Dec 2024
Version: 06

SOP Team:

Author: Dr. Roopa Parida
DM Resident

Signature with date

Parida
26/Dec/2023

Reviewer: Dr. Mahesh Belhekar
Associate Professor

Signature with date

Bel
27/Dec/2023

Dr. Mahesh N. Belhekar
Associate Professor
Department of Clinical Pharmacology
New MS Building, First Floor,
Seth GS Medical College and KEM Hospital
Acyarya Donde Marg, Parel,
Mumbai- 400 012, India.

Approved by: Dr. Nithya Gogtay
Professor and Head

Signature with date

u *31.12.23*
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, Inventory, and storage of Investigational Product (IP)
SOP No. : D 13/06
Date first effective: 01 Jan 2024 **Review date:** 31 Dec 2024
Department of Clinical Pharmacology, First Floor, New MS Building, Seth GS Medical
College & KEM Hospital, Parel, Mumbai 400012.

Table of Contents

No.	Contents	Page No.
1	Purpose	3
2	Scope	3
3	Responsibility	3
4	Applicable rules/guidelines	3
5	References to other applicable SOPs	3
6	Detailed instructions	4
7	Appendix	6
8	Glossary	7
9	Abbreviations	7

Category : Pre study procedures and Study conduct
Title : Receipt, Inventory, and storage of Investigational Product (IP)
SOP No. : D 13/06
Date first effective: 01 Jan 2024 **Review date:** 31 Dec 2024
Department of Clinical Pharmacology, First Floor, New MS Building, Seth GS Medical
College & KEM Hospital, Parel, Mumbai 400012.

1. **Purpose**

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

2. **Scope**

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

3. **Responsibilities**

Principal Investigator (PI), Co-investigator (Co-I), study pharmacist 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**

- New Drugs and Clinical Trials Rules 2019
https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf (last accessed 20th Dec, 2023)
- ICMR Guidelines for Biomedical and Health Research involving Human Participants 2017
http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
(last accessed 20 Dec 2023)
- ICH-GCP E6 (R3) Draft Guidelines dated 19th May 2023
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf

Category : Pre study procedures and Study conduct
Title : Receipt, Inventory, and storage of Investigational Product (IP)
SOP No. : D 13/06
Date first effective: 01 Jan 2024 **Review date:** 31 Dec 2024
Department of Clinical Pharmacology, First Floor, New MS Building, Seth GS Medical
College & KEM Hospital, Parel, Mumbai 400012.

5. References to other applicable SOPs:

- SOP No. D 11/06 Dispensing Investigational Product (IP)
- SOP No. D 22/06 Storage of IP and Maintaining its Temperature Log
- SOP No. D 23/06 Destruction/return of Investigational product

6. Detailed Instructions

1. Upon receipt of the investigational product (IP), the shipment should be inventoried, verifying that the receipt date, lot number, drug type, batch number 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.
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 IP should be acknowledged and the copy of the same should be kept in the trial master file [if appropriate]
6. The IP should be stored in a secure environment according to requirements listed in the protocol or the investigator's brochure (Refer to SOP No D 22/06 Storage of IP and Maintaining temperature log).
7. The expiry date of the drug should be noted, and the drug should be returned, disposed of, in accordance with the approved protocol when the drug is outdated. (Refer to SOP No. D 23/06 Destruction/return of Investigational product).
8. IP should be distributed uniformly across the racks in the refrigerator where it is stored.
9. The IP should be dispensed by the designee according to the SOP No. D 11/06: Dispensing Investigational Product (IP).
10. Drug accountability documentation should be completed on arrival of supplies, each time IP is dispensed, and when IP is returned to the sponsor. (Refer to SOP No. D 23/06 Destruction/return of Investigational product)

Category : Pre study procedures and Study conduct
Title : Receipt, Inventory, and storage of Investigational Product (IP)
SOP No. : D 13/06
Date first effective: 01 Jan 2024 **Review date:** 31 Dec 2024
Department of Clinical Pharmacology, First Floor, New MS Building, Seth GS Medical
College & KEM Hospital, Parel, Mumbai 400012.

11. Compliance by the participant with the procedures described in the protocol should be verified. Discrepancies between amount of the drug 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. D 23/06 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 (TMF).

Category : Pre study procedures and Study conduct
Title : Receipt, Inventory, and storage of Investigational Product (IP)
SOP No. : D 13/06
Date first effective: 01 Jan 2024 **Review date:** 31 Dec 2024
 Department of Clinical Pharmacology, First Floor, New MS Building, Seth GS Medical
 College & KEM Hospital, Parel, Mumbai 400012.

7. Appendix: IP Accountability Log

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

SI No:	Date	Randomization No:	Dose	Time of administration	No: of IP used	No: of IP damaged	No: of IP remaining	Signature

Investigator's signature _____

Date ____/____/____

Category : Pre study procedures and Study conduct
Title : Receipt, Inventory, and storage of Investigational Product (IP)
SOP No. : D 13/06
Date first effective: 01 Jan 2024 **Review date:** 31 Dec 2024
Department of Clinical Pharmacology, First Floor, New MS Building, Seth GS Medical
College & KEM Hospital, Parel, Mumbai 400012.

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. [ICH E6 (R3), www.ich.org, accessed on 20th Dec 2023].

9. Abbreviations:

- Co-I:** Co-investigator
- IP:** Investigational Product
- PI:** Principal investigator
- SOP:** Standard Operating Procedure
- TMF:** Trial Master File

Reviewer: Dr. Mahesh Belhekar
Associate Professor

Signature with date

M
27/DEC/2023

Dr. Mahesh N. Belhekar
Associate Professor
Department of Clinical Pharmacology
New MS Building, First Floor,
Seth GS Medical College and KEM Hospital,
Acyarya Donde Marg, Parel,
Mumbai- 400 012, India.

Approved by: Dr.Nithya Gogtay
Professor and Head

Signature with date

NG 31-12-23
Dr. Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.