Category: Study conduct
Title: Return /Destruction of Investigational product
SOP No.: D 23/07
Date first effective: 1 Jan 2025 **Review date:** 31 Dec 2025

Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

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Author: Dr. Rupali Mishra
DM Resident

Signature with date 30/Dec/2024

Reviewer: Dr. Mahesh Belhekar
Associate Professor

30.12.2024.

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

Signature with date

Approved by: Dr. Nithya Gogtay
Professor and Head

Signature with date 30/12/24

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

Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

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1. Purpose

This standard operating procedure (SOP) describes the requirements for the return or destruction of Investigational Product [IP].

2. Scope

This SOP applies to all procedures related to the return or destruction of IP.

3. Responsibilities

Principal investigator (PI), Co-investigator (Co-I), Study Coordinator, Pharmacist or any other appropriately qualified staff in the team, as delegated by the Principal Investigator, will be responsible for the return/destruction of IP in connection with all clinical studies.

4. Applicable rules, regulations and guidelines

1. 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
2. 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)
3. 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)
4. 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)

5. References to other applicable SOPs:

- SOP No. 18/09: Archiving documents.
- SOP No. 22/07 Storage, safe handling of Investigational Product (IP) and Maintaining it's Temperature Log
- SOP No. 11/07 Dispensing Investigational Product (IP)

6. Detailed Instructions

1. The study participant will return all study-related supplies to authorized study personnel (the study coordinator or pharmacist) as per protocol and also all unused medication/s at the subsequent visit or at end of the study.
2. The Study pharmacist will count the returned drug and compare this with the amount of drug expected to have been used since the previous study visit.
3. For IP administered at the site, the study pharmacist should do a real time check on the accountability
4. He/she will update the appropriate sections of the IP dispensing and IP accountability log, including an explanation of discrepancies, if applicable. The appropriate data will also be entered into the CRF.
5. The Study pharmacist will keep the Drug Dispensing log and the IP accountability CRF pages updated, regardless of when the monitor performs final accountability log review.
6. The Study pharmacist will store the returned drug in a secure area until it is verified by the monitor.
7. Whether the drug is returned to the sponsor or destroyed on-site will be determined by the instructions in the study protocol.

A. Return of IP to Sponsor

1. Depending on the protocol, the study drug will be returned to the sponsor at the end of the trial or at intervals specified by the sponsor.
2. The Study Coordinator will follow the protocol or other instructions from the sponsor or CRO to decide whether empty containers must be returned.
3. The Study Coordinator/Pharmacist will coordinate with the Monitor to determine which carrier is preferred for the shipment, mode of transfer, transport conditions and if the monitor needs to complete an independent drug accountability review before it is shipped back to the sponsor.
4. Unless instructed otherwise by the monitor, the Study Coordinator will:

- Perform an inventory of the drug supplies (Refer to SOP No. 22/07 Storage, safe handling of Investigational Product (IP) and Maintaining it's Temperature Log, Also SOP No. 11/07 Dispensing Investigational Product (IP)
- Compare this with the study medication records
- Document discrepancies in the CRF
- Complete the Drug Return/Destruction Form (if provided by the sponsor or CRO)
- Include a copy of the signed and completed Drug Return Form with the drug shipment and place the original in the trial master file

B. <u>On-Site Destruction of Study Drug</u>

1. If the sponsor or CRO requires on-site destruction of the study drug, the Study Coordinator should:

- Obtain written confirmation from the monitor identifying the specific study drug that can be destroyed.
- Obtain appropriate paperwork concerning destruction of the drug that is required in the site's SOPs (e.g., signed incineration records) and place a copy in the study file.
- Provide the monitor with written proof of study drug destruction from the site.
- Complete the Drug Return/Destruction Form or similar form provided by the sponsor or CRO.
- Provide a signed copy of the form to the monitor and retain the original in the trial master file.

C. <u>Study Drug Record Retention</u>

At study completion, the Study Coordinator will file all drug records with other regulatory documents in accordance with the record retention policy for the study. (Refer to SOP No. 18/9: Archiving documents).

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

Belle
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Professor and Head

Signature with date

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

30/12/24