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Title : Dispensing Investigational Product (IP)
SOP No. : D 11/07
Date first effective: 01 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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1. Purpose

This standard operating procedure (SOP) describes the processes for the dispensing of the investigational product (IP).

2. Scope

This SOP applies to all procedures related to the IP dispensing in clinical studies.

3. Responsibilities

This SOP applies to those members of the clinical research team involved in dispensing of the IP including the Principal Investigator, Co-investigator, Study Coordinator and the Pharmacist.

4. Applicable rules, regulations and guidelines

- 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
- 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)
- 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)
- New Drugs and Clinical Trials 2019 https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf documents/NewDrugs_CTRules_2019.pdf (Last accessed 20 Dec 2024)

5. References to other applicable SOPs:

SOP No.03/07 Responsibilities of the study team.

SOP No.20/07 Receipt, Inventory and storage of Investigational Product (IP)

SOP No.22/07 Storage of IP and Maintaining its Temperature Log

SOP No.23/07 Destruction/ return of Investigational product

6. Detailed Instructions

1. Principal Investigator, Study Coordinator/ Pharmacist or designee will dispense study medication as instructed in the protocol.
2. The PI should ensure before the initiation of the trial that the designated study team member is trained about
    a. Storage and dispensing of the IP
    b. Accounting for dispensed IP (including return of unused IP by participant to the site)
    c. Site SOPs for management of the IP and IP management guidelines mentioned in the protocol
3. The designated study team member should ensure that sufficient and timely supplies of the IP are available during the study.
4. Each time the study drug is dispensed to a participant at the study site, it should be appropriately recorded in the IP dispensing log.
5. Documentation should include the following (Appendix of SOP 20/07: Receipt, Inventory and storage of Investigational Product (IP)
    - Participant's ID and/or initials
    - Amount dispensed (batch and lot number, if appropriate)
    - Date of dispensing (and time, if appropriate)
    - Anatomical site of administration in case of injectable IP (if appropriate)
    - Dose calculation sheet, if appropriate
    - Number of vials / tablets left
    - Name and dated signature of individual dispensing the IP
    - In case of damage, a 'note to file' should be generated and this is to be intimated to the sponsor
6. Note the batch or serial number, expiry date and the dose of the medication when it is dispensed to the participant.
7. The personnel designated by the PI to dispense the IP must ensure that the participant understands when and how to take the medication (if applicable). When

the protocol requires the participant to record the date, time, and methods of taking the study drug, the researcher must make sure that the participant understands how to fulfill the responsibility.

8. Ensure that each time study medication is dispensed, the drug accountability form is completed [Appendix: IP Accountability Form, Refer to SOP No.20/07 Receipt, Inventory and storage of Investigational Product (IP)]
9. Depending on the design of the Case Report Form (CRF), the tear-off portion of the drug's label, containing the blinded information (if applicable), may be attached to the Drug Dispensing Log, to the CRF, or to another form provided by the sponsor.
10. Document any problems encountered with a participant's compliance in line with study protocol, if specified in the study protocol.
11. After use by the study participant, return all used and unused containers/units, if appropriate, to the study Coordinator and update the accountability log accordingly. If any containers/units are missing or unused, document the reasons for the same. [Appendix: IP Accountability Form, Refer to SOP No.20/07 Receipt, Inventory and storage of Investigational Product (IP)
12. Receipt, Storage and destruction/ return of unused IP(s) to the Sponsor should be done as per SOP No.20/07 (Receipt, Inventory and storage of Investigational Product (IP)), SOP No.22/07 (Storage of IP and maintaining its Temperature Log) and SOP No.23/07 (Destruction / return of Investigational product).
13. The study Coordinator/pharmacist will:
    - Perform periodic inventory of study drug supplies to ensure that supplies are adequate and within the appropriate expiration date.
    - Alert the appropriate contact person when additional supplies are required.
    - If emergency (life-threatening condition) unblinding of the study drug is medically necessary, document all circumstances appropriately and notify sponsor as soon as possible. Only the PI can open the code, if required medically.

14. A copy of all accountability documents will be maintained in the Trial Master File (TMF).

7. Glossary

- 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)

1. **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.

2. **Blinding**

   A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single blinding usually refers to the subject(s) being unaware, and double blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

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