Category: Departmental SOP
Title: Transport of Investigational Product(IP) from Pharmacy and/or preparation area to the area where it will be actually administered
SOP No/Version No.: DCP 30/08
Date first effective: 1 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.

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SOP No/Version No.: DCP 30/08 **Total pages**: 8

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Version: 08

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Table of Contents

1.1.26
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1) Purpose:

To ensure standardized and secure transport of Investigational Product(IP) from pharmacy and/or preparation area to the area where it will actually be administered/given

3) Scope:

This SOP applies to ALL personnel involved in the handling, dispensing, preparation, and intra-facility transport of IP for clinical trial participants.

This SOP is equally applicable for both academic and sponsored studies.

3) Responsibilities:

*Pharmacist-Dispense and prepare IP as per protocol and handover to authorised personnel.

*May or may not be blinded based on the blinded based on the study protocol

Authorized Staff: Receive, inspect, and verify the IP before administration.

6) Detailed Instructions:

- The IP is prepared by pharmacist (e.g., dilution, reconstitution) as per protocol in a designated preparation room.
- The pharmacist dispenses the IP and logs it in the accountability record.
- Labelling will include as per requirement of study protocol: (eg.)
    - Protocol number
    - Participant ID
    - Dose and route
    - Preparation date/time
    - Manufacturing date of Investigational Product
    - Expiry date of Investigational Product
    - "For Clinical Trial Use Only"

After preparation, the IP must be placed in a clean, sealed secondary sterile container or tray.

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-Use temperature-controlled containers if specified in the protocol.

-Only authorized personnel may transport the IP.

-Transport should be direct with no intermediate stops, logged with time out and time received, and conducted under appropriate environmental conditions as specified in the protocol.

-The IP must never be left unattended during transport.

-Upon arrival at the administration room. The team will

- Inspect prepared IP
- Verify label and participant details
- Record time of receipt
- Note any issues or temperature deviations

-Any deviation (eg., delay, breakage, temperature excursion) must be recorded and reported to IEC/Sponsor as per protocol requirements.

-If necessary, IP MAY NOT be administered to the clinical trial participant.

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Reviewer as appropriate:

Signature with date

01/Jan/2026

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