

**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, 1<sup>st</sup> floor, New MS building Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

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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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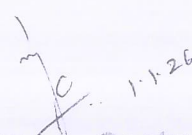
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- Use temperature-controlled containers if specified in the protocol.
- Only authorized personnel may transport the IP.
- Transport should be direct with no intermediate stops, logged with time out and time received, and conducted under appropriate 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
  - o Inspect prepared IP
  - o Verify label and participant details
  - o Record time of receipt
  - o 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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