Category : Study Procedures

Title : Dispensing of Investigational Products for a Phase I clinical trial

SOP No. : DCP/Ph1/018

Date first effective: 01 Jan 2025 Review date: 31 Dec 2025

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TABLE OF CONTENTS

S. No	Content	Page no
1	Purpose	3 of 6
2	Scope	3 of 6
3	Responsibilities	3 of 6
4	Applicable rules, regulations and guidelines	3 of 6
5	References (to other SOPs)	3 of 6
6	Detailed instructions	3-5 of 6
7	Abbreviations	6 of 6

DCP/Ph1/018: Dispensing of Investigation Products for a Phase I clinical trial

1. Purpose: The purpose of this SOP is to describe the process for the dispensing of any Investigational Product (IP) in a Phase I clinical trial

2. Scope: This SOP is limited to dispensing of an IP in a Phase I clinical trial at our institute

3. Responsibilities: The responsibilities for ensuring implementation of this SOP lies with the Principal Investigator (PI) and the Pharmacist

4. Applicable rules, regulations and guidelines:

- Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR, 2017
- International Council on Harmonization (ICH); Good Clinical Practice Draft Guidelines: (R3) dated 19th May, 2023
- Medical Devices Rules, India, 2017
- New Drugs and Clinical Trials 2019

5. References (to other SOPs)

- Ph. 1 SOP B17: Management of investigational products for a Phase I clinical trial

6. Detailed instructions

S.No	Task	Person responsible
1	Ensure that all study team members are trained in the management and dispensing of IP	PI
2	Confirm the identity of the participant by cross-checking with his / her participant ID	PI / Co-I / Study co-ordinator / Pharmacist
3	Confirm the correctness of the IP to be administered by cross-checking with the treatment arm allocation	PI / Co-I / Study co-ordinator / Pharmacist

	(if applicable)	
4	Confirm that the storage conditions of the IP have been appropriate (Refer Ph. 1 SOP B17: Management of investigational products for a Phase I clinical trial*	PI / Co-I / Study co-ordinator / Pharmacist
5	Check the IP for any form of damage or expiry. In case of any form of damage to the IP, avoid its administration. Generate a 'note to file' and intimate the sponsor	PI / Co-I / Study co-ordinator / Pharmacist
6	Check the data logger for any temperature or humidity deviations of the IP. If any temperature or humidity excursions are present, inform the sponsor and obtain sponsor authorization prior to dispensing the IP	PI / Co-I / Study co-ordinator / Pharmacist
7	Dispense the IP to the study participant as per the protocol**	PI / Co-I / Study co-ordinator / Pharmacist
8	Notify all temperature and humidity excursions to the IEC	PI / Co-I / Study co-ordinator / Pharmacist
9	Document the following in the IP dispensing log: • Participant's ID and / or initials • Date and time of dispensing • Amount of IP dispensed • Batch and lot number • Manufacturing date • Expiry date • Route of administration of IP • Anatomical site of administration (in case of injectable IP)	PI / Co-I / Study co-ordinator / Pharmacist

	• Dose administered • Dose calculation sheet (if applicable) • Number of vials / tablets of IP left after dispensing • Name and dated signature of individual dispensing the IP	
10	In case of dispensing the IP for use at home, instruct the participant how to use the IP properly. If the protocol requires the participant to record the date, time, and methods of taking the IP, instruct the participant clearly as to how to fulfil this responsibility	PI / Co-I / Study co-ordinator / Pharmacist
11	If the IP is to be reconstituted, (for e.g. in case of lyophilized vaccines), follow the protocol for reconstitution. Keep the tray with contents required for reconstitution ready	Study nurse
12	Attach the tear-off portion of the drug's label, containing the blinded information to the IP Dispensing Log, to the CRF, or to another form provided by the sponsor (if applicable)	Study co-ordinator / Pharmacist
13	Return the IP to the storage site	Study co-ordinator / Pharmacist
14	Complete the drug accountability form	Study co-ordinator / Pharmacist
15	Review and sign the drug accountability form	PI
16	File the drug accountability form in the Trial Master File (TMF)	Study co-ordinator / Pharmacist

* Also, the pharmacist should ensure that sufficient and timely supplies of the IP are available during the study and there is no shortage of IP at the time of dispensing

** Any injectable IP has to be administered ONLY by a medical person. Oral IPs may be dispensed by non-medical study co-ordinators / pharmacists after due authorization by the sponsor.

7. Abbreviations

Co-I	Co-Investigator
CRF	Case Record Form
ID	Identification number
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMR	Indian Council of Medical Research
IP	Investigational product
PI	Principal Investigator
SOP	Standard Operating Procedure
TMF	Trial Master File

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