Title Management of investigational products for a Phase I clinical trial

SOP No. : DCP/Ph1/017

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.

Category: Study conduct

Title: DCP/Ph1/017: Management of investigational products for a Phase I clinical trial

SOP No.: DCP/Ph1/017 **Total pages: 07**

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DCP/Ph1/017: Management of investigational products for a Phase I clinical trial

- **1. Purpose**: The purpose of this SOP is to describe the process for the receipt, storage (including temperature monitoring) and disposal of the investigational product (IP) in a Phase I clinical trial
- **2. Scope**: This SOP is limited to receipt, storage (including temperature monitoring) and disposal of the 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)

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 B16: Managing a pharmacy for storage of investigational products for clinical trials

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6. Detailed instructions

S.No	Task	Person responsible			
1	Ensure all the facilities in the pharmacy as per Ph. 1	PI / Co-I / Pharmacist /			
	SOP B16 are in place	Study co-ordinator			
2	Upon receipt of the investigational product (IP),	Pharmacist / Study co-			
	check for the following:	ordinator			
	Name of the IP	Countries have self-request			
	Receipt date and time,				
	Batch number				
	• Lot number,	reorgen seit untäblienngen Z			
	Manufacturing date	(11) magazaval laquami s			
	Expiry date				
	Temperature at the point of dispatch				
	• Temperature at the point of receipt at the	Ref alministration in the second			
	trial site	THE SHEET AMOUNT OF THE			
	Formulation and	o hageod fanalmeant			
	• Quantity				
3	Confirm that the above are the same on the packing	Pharmacist / Study co-			
	slips as what is actually received.	ordinator			
4	Check the temperature of the IP on receipt of	Pharmacist / Study co-			
	shipment	ordinator			
5	Inspect the IP for any damage, leakage, spillage, or	PI / Co-I / Pharmacist /			
	any form of destruction, or expiry.	Study co-ordinator			
	If any form of damage, promptly bring this to the				
	notice of the sender				
6	Prepare the IP log as given in Appendix 1	Pharmacist / Study co-			

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	golds - Resolution Egolds and the St. Decome	ordinator			
7	Attach the copies of packing slips to the IP log	Pharmacist / Study co-			
		ordinator			
8	File the drug receipt and the packing slips in the	Pharmacist / Study co-			
	Trial Master File (TMF)	ordinator			
9	Acknowledge the receipt of the IP to the sender via	PI / Co-I / Pharmacist /			
	e-mail	Study co-ordinator			
10	Store the IP as per conditions specified in the	Pharmacist / Study co-			
	protocol and / or the Investigator's Brochure	ordinator			
11	Ensure storage of IP separately from the IP of other	Pharmacist / Study co-			
	clinical trials which may be on-going at that time	ordinator			
12	Label the box containing the IP appropriately (if not	Pharmacist / Study co-			
	already labelled)	ordinator			
13	Distribute the IP uniformly across the racks where it	Pharmacist / Study co-			
	is stored	ordinator			
14	Update the IP log every time an IP is dispensed, and	Pharmacist / Study co-			
	when used / unused IP is / are returned	ordinator			
15	Check for any discrepancy in the quantity of IP used	Pharmacist / Study co-			
	by the participant and the IP returned.	ordinator			
	If any discrepancy, document this in the IP log	4			
	along with reasons for the same				
16	Dispose of all used IP as per the protocol and / or	PI / Co-I / Pharmacist /			
	instructions by the Sponsor / as per hospital	Study co-ordinator			
	procedures	Anglik of Belowing			
17	Document the disposal of used IP in the IP log	Pharmacist / Study co-			
	Mary 1981	ordinator			
18	If any unused IP is remaining, dispose of the same /	PI / Co-I / Pharmacist /			
	return to the Sponsor as per the protocol and / or as	Study co-ordinator			
	per instructions by the Sponsor	Departir			

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19	Document the disposal of unused IP in the IP log	Pharmacist	/	Study	co-
	and keep a copy in the TMF	ordinator			
20	Get the IP log signed by PI after each dispensing /	Pharmacist	/	Study	co-
- 00	return if IP	ordinator			

7. Abbreviations

Co-I	Co-Investigator
IB	Investigator's Brochure
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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	te Name	•					Site	Number :
AF	PPENDI	X 1						
AH	PPENDI	X 1 Randomisation No	Dose	Time of administrat	No of IP used	No: of IP dam- aged	No: of IP remain-ning	Signature with date

PI's signature	Date	/	/

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