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

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

Version: 02

Author: Dr. Akanksha Tiwari

Assistant Professor

Signature with date Atiwari 27/12/2024

Reviewer: Dr. Mahesh Belhekar

Associate Professor

Dr. Mahesh N. Belhekar
Associate Professor
Department of Clinical Pharmacology
New MS Building, First Floor,
Seth GS Medical College and KEM Hospital
Acharya Donde Marg, Parel,
Mumbai - 400 012. India

Signature with date 28-Dec-2024

Approved by: Dr. Nithya Gogtay

Professor & Head

Signature with date 28/12/24

Dr. Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.

TABLE OF CONTENTS:

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

6. Detailed instructions

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

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

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

Reviewer: Dr. Mahesh Belhekar

Associate Professor

Dr. Mahesh N. Belhekar
Associate Professor
Department of Clinical Pharmacology
New MS Building, First Floor,
Seth GS Medical College and KEM Hospital
Acharya Donde Marg, Parel,
Mumbai - 400 012. India

Signature with date 28.Dec.2024

Approved by: Dr. Nithya Gogtay

Professor & Head

Signature with date 28.12.24

Dr. Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.

Study Title:	
Site Name :	**Site Number :**
Sponsor :	
Principal Investigator :	
Investigational Product:	**Lot No :**

APPENDIX 1

Sr. No	Date	Randomi-sation No	Dose	Time of administration	No of IP used	No: of IP dam-aged	No: of IP remain-ning	Signature with date

PI's signature _____ **Date** _____/_____/_____