Version 2.0 dated 1st January2026
Effective date: 3rd January2026
Revision due date: 31st of December 2026

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

Version:2.0 dated 1st January2026

Effective date: 3rd January 2026

Revision due date: 31st of December 2026

Prepared by: Dr. Shiva Krishna Rao.T
DM Resident

Shiva
1) Jan/2026

Dr. Shital Bendkhale
Project Scientist- II

Bendkhale
1/JAN/2026

Signature with date

Reviewed by: Dr Roopa Parida
Assistant Professor

Signature with date

Roopa
01/Jan/2026

Authorized by: Dr Nithya Gogtay
Professor and Head of the Department

Signature with date

1.1.26

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

Version 2.0 dated 1st January2026
Effective date: 3rd January2026
Revision due date: 31st of December 2026

TABLE OF CONTENTS:

Version 2.0 dated 1st January2026
Effective date: 3rd January2026
Revision due date: 31st of December 2026

Ph.1 SOP B17: 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:	Pharmacist / Study co-ordinator

	• 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	
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	Pharmacist / Study co-

	clinical trials which may be on-going at that time	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

Reviewed by: Dr Roopa Parida

Assistant Professor

Signature with date 01/Jan/2026

Authorized by: Dr Nithya Gogtay

Professor and Head of the Department

Signature with date 1.1.26

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 adminis-tration	No of IP used	No: of IP dam-aged	No: of IP remain-ning	Signature with date

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