

**Category:** Study procedures  
**Title:** Separation, Storage and Shipment of Blood samples.  
**SOP No.:** D 25/06  
**Date first effective:** 01 Jan 2024      **Review date:** 31 Dec 2024

Department of Clinical Pharmacology, First Floor, New MS Building,  
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

**Category:** Study procedures  
**Title:** Separation, Storage and Shipment of Blood samples.

**SOP No:** D 25 /06      **Total pages:** 07

**Date first effective:** 01 Jan 2024      **Next Review date:** 31 Dec 2024

**Version:** 06

**SOP Team**

**Author:** Dr. Rupali Mishra  
DM Resident

Signature with date

*Rupali*  
28/Dec/2023

**Reviewer:** Dr. Mahesh Belhekar  
Associate Professor

Signature with date

*Belhekar*  
29/Dec/2023 • **Dr. Mahesh N. Belhekar**  
Associate Professor  
Department of Clinical Pharmacology  
New MS Building, First Floor,  
Seth GS Medical College and KEM Hospital  
Acyarya Donda Marg, Parel,  
Mumbai- 400 012, India.

**Approved by:** Dr. Nithya Gogtay  
Professor and Head

Signature with date

*Nithya*  
31-12-23

Confidential

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

**Category:** Study procedures

**Title:** Separation, Storage and Shipment of Blood samples.

**SOP No.:** D 25/06

**Date first effective:** 01 Jan 2024

**Review date:** 31 Dec 2024

Department of Clinical Pharmacology, First Floor, New MS Building,  
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

### Table of Contents

<b>NO.</b>	<b>CONTENTS</b>	<b>Page No.</b>
<b>1</b>	<b>Purpose</b>	<b>3</b>
<b>2</b>	<b>Scope</b>	<b>3</b>
<b>3</b>	<b>Responsibility</b>	<b>3</b>
<b>4</b>	<b>Applicable rules, regulations and guidelines</b>	<b>3</b>
<b>5</b>	<b>Reference to other applicable SOPs</b>	<b>3</b>
<b>6</b>	<b>Detailed Instructions</b>	<b>4</b>
<b>7</b>	<b>Annexures</b>	<b>6</b>
<b>8</b>	<b>Abbreviation</b>	<b>6</b>

**Category:** Study procedures

**Title:** Separation, Storage and Shipment of Blood samples.

**SOP No.:** D 25/06

**Date first effective:** 01 Jan 2024

**Review date:** 31 Dec 2024

Department of Clinical Pharmacology, First Floor, New MS Building,  
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

### **1. Purpose**

This standard operating procedure (SOP) describes the procedure for separation, storage and shipment of samples.

### **2. Scope**

This SOP is limited to procedures of Separation, Storage and Shipment of Blood samples.

### **3. Responsibility**

The Principal Investigator (PI) will allocate the task of performing separation, storage and shipment of samples to appropriate trained personnel who will be identified at the beginning of the trial.

### **4. Applicable rules and regulation**

- ICMR Good Clinical Laboratory Practices Guidelines 2008  
<http://icmr.nic.in/guidelines/GCLP.pdf> accessed on 20<sup>th</sup> Dec 2023  
[Last accessed on 20 Dec]
- Guidelines for the shipment and receipt of infectious specimens  
[http://hiv.neuro.jhmi.edu/nead/resources/NEAD\\_protocol\\_5-10-06.doc](http://hiv.neuro.jhmi.edu/nead/resources/NEAD_protocol_5-10-06.doc)  
[Last accessed on 20 Dec 2023]
- New Drugs and Clinical Trials Rules 2019  
[https://cdsco.gov.in/opencms/export/sites/CDSCO\\_WEB/Pdf-documents/NewDrugs\\_CTRules\\_2019.pdf](https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf) [Last accessed on 20Dec]
- ICH-GCP E6 (R3) Draft Guidelines dated 19th May 2023  
[https://database.ich.org/sites/default/files/ICH\\_E6%28R3%29\\_DraftGuideline\\_2023\\_0519.pdf](https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf)]

**Category:** Study procedures

**Title:** Separation, Storage and Shipment of Blood samples.

**SOP No.:** D 25/06

**Date first effective:** 01 Jan 2024

**Review date:** 31 Dec 2024

Department of Clinical Pharmacology, First Floor, New MS Building,  
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

#### **5. Reference to other applicable SOPs**

- SOP No. D03/06: Responsibilities of the study team
- SOP No. D10/06: Procedure for collection of blood samples of trial subjects.
- SOP No. D24/06: Waste Management.

#### **6. Detailed instructions**

1. The procedures described in this SOP begin once the blood is collected. Blood samples are collected in glass bulbs/ Vacutainers (Refer SOP No. D10/06: Procedure for collection of blood samples of trial subjects).
2. After collection of blood samples, the serum or plasma is to be separated in calibrated centrifuge machine as soon as possible or as mentioned in the protocol.
3. The concerned personnel should wear a pair of gloves throughout the procedure till the time the sample is being handled. Universal precautions should be exercised while processing blood sample.
4. Separation of Serum/ Plasma:
  - For Serum sample: Allow the sample to clot at room temperature till complete clot formation. This usually takes five to 15 minutes
  - After clotting of sample, at room temperature and prior to centrifugation, run a glass rod / stick along the interior wall of the bulb to disrupt clot adhesion to the tube wall.
  - For Plasma sample: Invert the Vacutainer (eight times) or shake the test tube to mix the sample well with anticoagulant.
  - Centrifuge the sample at 2500/3000 rpm for 10-15 minutes at room temperature.

**Category:** Study procedures

**Title:** Separation, Storage and Shipment of Blood samples.

**SOP No.:** D 25/06

**Date first effective:** 01 Jan 2024

**Review date:** 31 Dec 2024

Department of Clinical Pharmacology, First Floor, New MS Building,  
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

- After centrifugation, separate the serum / plasma sample with a pipette into small storage vials.
- Label the serum / plasma sample tube / vials.
- Be careful not to transfer the red cells along with the plasma / serum.

5. Storage:

Depending upon the intended laboratory analysis and stability of the sample, blood may be stored under a variety of conditions and for variable time. Protocol specific SOP should be followed.

- After processing the sample discard it (Refer SOP No. D 24/06 Waste Management).
- If a sample is stable and is to be stored for a long duration the sample can be stored at in storage vials in the Deep freezer (-20°C).
- Samples should be labeled as per Annexure 1.
- If the samples are to be sent outside the department then the labeling will be laboratory specific.

6. Shipment of sample: -

- Blood specimens are often exposed to temperature fluctuations during transit. Appropriate temperature conditions are required for the transport of blood.
- Gel packs designed for shipment of sample are refrigerated at -20°C in the Genetics refrigerator
- The specimen vacutainer / storage vials is placed inside the plastic zip lock bag, along with the duly filled Test Requisition Form (TRF) and kept between two frozen gel packs in a Styrofoam container.
- The cold specimen pick-up will be done by the logistics personnel from the laboratory doing the actual processing.

**Category:** Study procedures

**Title:** Separation, Storage and Shipment of Blood samples.

**SOP No.:** D 25/06

**Date first effective:** 01 Jan 2024

**Review date:** 31 Dec 2024

Department of Clinical Pharmacology, First Floor, New MS Building,  
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

- The pick-up facility is available from 9.00 a.m. to 05.00 p.m. every day except on Saturday [9.00 am to 13:00 pm] generally. However, this may vary according to the trial and trial specific SOPs will have to be followed.

These are standard procedures. Clinical trial specific procedures should be followed as per the study protocol

#### 7. Annexures

##### Annexure 1:

#### Specimen Label Format of Department of Clinical Pharmacology

Department of Clinical Pharmacology	
Protocol Id:	
Subject Initials:	Screening Number:
Collection Date:	Visit:
Collection time:	Specimen type:

#### 8. Abbreviations:

- SOP:** Standard Operating Procedures
- PI:** Principal Investigator
- TRF:** Test Requisition Form
- ICMR:** Indian Council of Medical Research

**Category:** Study procedures

**Title:** Separation, Storage and Shipment of Blood samples.

**SOP No.:** D 25/06

**Date first effective:** 01 Jan 2024

**Review date:** 31 Dec 2024

Department of Clinical Pharmacology, First Floor, New MS Building,  
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

**Reviewer:**

Dr. Mahesh Belhekar  
Associate Professor

Signature with date

*M*  
~~31/12/23~~  
29/12/2023

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

**Approved by:**

Dr. Nithya Gogtay  
Professor and Head

Signature with date

*N*  
~~31/12/23~~  
**Dr. Nithya Gogtay**  
Professor & Head  
Department of Clinical Pharmacology  
1<sup>st</sup> Floor, MS Building,  
Seth GS Medical College & KEM Hospital,  
Parel, Mumbai - 400 012.