

Category: Study procedures
Title: Separation, Storage and Shipment of Blood samples.
SOP No.: D 25/05
Date first effective: 01 Jan 2023 Review date: 31 Dec 2023

Department of Clinical Pharmacology, 1st 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.: 25 /05 Total pages: 07

Date first effective: 01 Jan 2023 Next Review date: 31 Dec 2023

Version: 05

Author: Dr. Dhruve Soni
DM Resident

Signature with date

Dr
31/Dec/2022

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

Bel
31/Dec/2022

Approved by: Dr. Nithya Gogtay
Professor and Head

Signature with date

W
31.12.22

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

Confidential

Category: Study procedures
Title: Separation, Storage and Shipment of Blood samples.
SOP No.: D 25/05
Date first effective: 01 Jan 2023
Review date: 31 Dec 2023

Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

Table of Contents

No.	Contents	Page No.
1	Purpose	3
2	Scope	3
3	Responsibility	3
4	Applicable rules, regulations and guidelines	3
5	Reference to other applicable SOPs	3
6	Detailed Instructions	4
7	Annexures	6

Category: Study procedures

Title: Separation, Storage and Shipment of Blood samples.

SOP No.: D 25/05

Date first effective: 01 Jan 2023

Review date: 31 Dec 2023

Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

1. Purpose

This 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 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 2021 (<http://icmr.nic.in/guidelines/GCLP.pdf>)
- Guidelines for the shipment and receipt of infectious specimens http://hiv.neuro.jhmi.edu/nead/resources/NEAD_protocol_5-10-06.doc
- New Drugs and Clinical Trials Rules, 2019

5. Reference to other applicable SOPs

- SOP No. D 03/05: Responsibilities of the study team
- SOP No. D 10/05: Procedure for collection of blood samples of trial subjects.
- SOP No. D 24/05: Waste Management.

Category: Study procedures

Title: Separation, Storage and Shipment of Blood samples.

SOP No.: D 25/05

Date first effective: 01 Jan 2023

Review date: 31 Dec 2023

Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

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. 10/01: 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 05 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 (8 times) or Shake the test tube to mix the sample well with anticoagulant.
 - Centrifuge the sample at 2500/3000 rpm for 10-15 mins at room temperature.
 - 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.

Category: Study procedures

Title: Separation, Storage and Shipment of Blood samples.

SOP No.: D 25/05

Date first effective: 01 Jan 2023

Review date: 31 Dec 2023

Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

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. 24/02 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.
- 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

Category: Study procedures

Title: Separation, Storage and Shipment of Blood samples.

SOP No.: D 25/05

Date first effective: 01 Jan 2023

Review date: 31 Dec 2023

Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

7. 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:

Category: Study procedures

Title: Separation, Storage and Shipment of Blood samples.

SOP No.: D 25/05

Date first effective: 01 Jan 2023

Review date: 31 Dec 2023

Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

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

MB
31/12/2023

Approved by:

Dr. Nithya Gogtay
Professor and Head

Signature with date

NG
31.12.22

Dr. Nithya Gogtay

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