

Category: Study procedures

Title: Waste Management

SOP No.: DCP/Ph1/002

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 procedures

Title: Waste Management

SOP No: DCP/Ph1/002

Total pages: 06

Date first effective: 01 Jan 2025

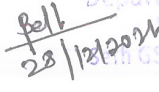
Next Review date: 31 Dec 2025

Version: 02

Author: Dr. Akanksha Tiwari
DM Resident

Signature with date: 
27/Dec/2024

Reviewer: Dr. Mahesh Belhekar
Associate Professor


28/12/2024

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

Signature with date:

Approved by: Dr. Nithya Gogtay
Professor and Head

Signature with date: 
28.12.24

Confidential

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

Page 1 of 6

Category: Study procedures

Title: Waste Management

SOP No.: DCP/Ph1/002

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.

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	Glossary	6

Category: Study procedures

Title: Waste Management

SOP No.: DCP/Ph1/002

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.

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to outline the procedure for Bio-Medical Waste management in the Phase 1 Unit of Department of Clinical Pharmacology.

2. Scope

This SOP is limited to the procedures for segregation and disposal of biomedical waste of Phase 1 Unit of Department of Clinical Pharmacology, KEMH.

3. Responsibility

Head of the Department, Biomedical Waste officer and Laboratory in charge as designated by the HOD, will be responsible for waste management.

4. Applicable rules and regulation

- a. Bio-Medical Waste Management (Amendment) Rules, 2018.
<http://www.moef.nic.in/content/gsr-234e16-03-2018-bio-medical-waste-managementamendment-rules-2018> [last accessed on 30th November 2022]
- b. Guidelines for Good Clinical laboratory Practice, ICMR, 2021
https://main.icmr.nic.in/sites/default/files/upload_documents/GCLP_Guidelines_2020_Final.pdf

5. Reference to other applicable SOPs

SOP No. P 01 /02: Procedure for collection of Blood sample

Category: Study procedures

Title: Waste Management

SOP No.: DCP/Ph1/002

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.

6. Detailed instructions

6.1.1. Sharps

- Dispose all “SHARPS” (e.g. needles, syringes, broken glass, test tubes, scalpels, lancets, slides, glass vials, tips etc.) in the ‘SHARPS’ container.
- The lab attendant should fill ¼ of the wide mouth sharps disposable containers with 1% of Sodium Hypochlorite **every morning at 10:00 am.**
- Following blood collection (SOP No P 01/02: Procedure for collection of blood samples of trial participants), the syringes with fixed needles or any other contaminated sharp objects which may cause puncture and cut wound must be disposed in the ‘SHARPS’ container
- When the SHARPS container is full, it should be drained of all 1% Sodium Hypochlorite in the wash basin by wrapping the mouth of the container with gauze piece.
- Cap all the “SHARPS” containers tightly before discarding
- Discard all the sharps containers within 24 hrs. Near Gate no. 7 (Biomedical Waste Area of KEM Hospital) between 8.00 a.m. and 2 p.m.

6.1.2. Untreated Infectious waste

- Dispose all the untreated infectious waste in ‘RED BAGS’ [e.g. including but not restricted to used cotton swabs, bandages, plastic/rubber gloves, gels, catheters, urine collection tubes/bags, bottles, intravenous tubes and sets. If any of these items have even a drop of blood or body fluid it is to be considered as soiled waste (See 6.4)].
- Discard all the untreated infectious waste with red bags near Gate no. 7 (Biomedical Waste Area of KEM Hospital) between 8.00 a.m. and 2 p.m.

6.1.3. Untreated non-Infectious waste

- Dispose all the untreated non-infectious wastes in ‘BLACK BAGS’ (e.g. waste papers, food material etc.).

Category: Study procedures

Title: Waste Management

SOP No.: DCP/Ph1/002

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.

- Discard the black bags near Gate No. 8 between 8 a.m. and 6 p.m.

6.1.4 Soiled waste

- Dispose all the soiled waste - Items contaminated with blood or body fluids like cotton swabs, expired or discarded medicines, chemical waste [discarded disinfectants] in 'YELLOW BAGS'.
- Discard all yellow bags near Gate No. 7 between 8 a.m. and 2 p.m.

6.1.5 Other waste

- Dispose blood clot tubes/bulbs and urine sample bottles in container with 1% Sodium Hypochlorite (SHARPS Container).
- 6.2 Fill the details in the waste record book with the signature of the designee, prior to disposal of the bags and SHARP containers
- 6.3 Tie untreated infectious wastes, non-infectious wastes, soiled wastes and contaminated or broken glass wastes in respective bags securely and label with Department name, time, date and signature of Biomedical Waste Officer.
- 6.4 All the sharps disposable containers must be labeled "SHARPS, Department of Clinical Pharmacology, KEM Hospital with date and signature of the Biomedical Waste Officer".

7. Glossary

Biomedical Waste:

Bio-Medical waste means any waste, which is generated during the diagnosis, treatment or immunization of human or animals or in research activities pertaining thereto or in the production or testing of biological, including categories mentioned in the Schedule I of the Bio-Medical Waste (Management & Handling) Rules, 1998.

Category: Study procedures

Title: Waste Management

SOP No.: DCP/Ph1/002

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.

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

MB
28/12/2024

Signature with date

Approved by:

Dr. Nithya Gogtay
Professor and Head

Signature with date

Dr. Nithya Gogtay

Professor & Head

Department of Clinical Pharmacology

1st Floor, MS Building,

Seth GS Medical College & KEM Hospital,

Parel, Mumbai - 400 012.

N
28/12/24