

Category: Study procedures

Title: Waste Management

SOP No.: D 24 /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: Waste Management

SOP No: D 24 /05

Total pages: 06

Date first effective: 01 Jan 2023

Next Review date: 31 Dec 2023

Version: 05

Author: Dr. Sukant Pandit
DM Resident

Signature with date

Spandil
31/Dec/2022

Reviewer:

Dr. Bhaskar Krishnamurthy
Assistant Professor

Signature with date

B1-1c
31/12/22

Dr. Bhaskar Krishnamurthy
Assistant Professor,
Department of Clinical Pharmacology,
Seth GSMC and KEMH, Mumbai -400 012.

Approved by:

Dr. Nithya Gogtay
Professor and Head

Signature with date

N 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

Page 1 of 6

Category: Study procedures

Title: Waste Management

SOP No.: D 24 /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	Glossary	6

Category: Study procedures

Title: Waste Management

SOP No.: D 24 /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

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

2. Scope

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

3. Responsibility

Head of the Department, Principal Investigator, Study Coordinator or any other appropriately qualified staff in the team, will be responsible for waste management.

4. Applicable rules and regulation

- a. Bio-Medical Waste (Management & Handling) Rules, 1998.
http://mpcb.gov.in/biomedical/pdf/BMW_Rules_2016.pdf
[last accessed on 30th Apr 2022]
- b. Guidelines for Good Clinical laboratory Practice, ICMR, 2008
<http://icmr.nic.in/guidelines/GCLP.pdf>
- c. New Drugs and Clinical Trials Rules, 2019

5. Reference to other applicable SOPs

SOP No. D 10 /05: Procedure for collection of Blood sample

Category: Study procedures

Title: Waste Management

SOP No.: D 24 /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. Maintain a Biomedical waste record book with the Record Assistant (RA) in which the following details are recorded: Date & Time, no. of bags, name of Lab Attendant, Sign of Lab Attendant, sign of security guard and sign of RA.
2. Fill $\frac{1}{4}$ of the wide mouth sharps disposable cans with 1% of Sodium Hypochlorite **every morning at 10:00 am.**
3. All the sharps disposable cans must be labeled **“SHARPS, Department of Clinical Pharmacology, KEMH with date”**.
4. Dispose all “SHARPS” (e.g. needles, syringes, broken glass test tubes, scalpels, lancets, slides, glass vials, tips) in the ‘SHARPS’ can.
5. After collection of blood (SOP No 10/05: Procedure for collection of blood samples of trial participants), put the syringes with fixed needles or any other contaminated sharp object that may cause puncture and cuts, should be disposed in the SHARP can.
6. Drain all 1% Sodium Hypochlorite from the “SHARPS” can in wash basin by wrapping the mouth of the Can by gauze piece.
7. Cap all the “SHARPS” cans tightly before discarding.
8. Drain the bucket in the wash basin between 12.30 and 1.30 p.m. and discard the containers in wide mouth “SHARPS” can.
9. Dispose all the untreated infectious wastes in ‘RED BAGS’ (e.g. used cotton swabs, bandages, plastic/rubber gloves, gels, catheters, urine collection tubes/bags, bottles, intravenous tubes and sets).
10. Dispose all the untreated non-infectious wastes in ‘BLACK BAGS’ (e.g waste papers, food material etc).
11. 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’.

Category: Study procedures

Title: Waste Management

SOP No.: D 24 /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.

12. Dispose all the broken and contaminated glass including medicine vials and ampoules in 'BLUE BAGS'.
13. Dispose blood clot tubes/bulbs and urine sample containers in bucket containing 1% of Sodium Hypochlorite.
14. Fill the details in the waste record book
15. Tie untreated infectious wastes bags (RED BAGS) securely and label with Department name, time, date and signature of RA.
16. Cap the SHARPs can and label with Department name, time, date and signature of RA.
17. Discard all the waste i.e. red bags, yellow bags and sharps containers within 24 hrs near Gate no. 7 (Biomedical Waste Area of KEM Hospital) between 8.00 a.m. and 2 p.m. and black bag near Gate No. 8 between 8 a.m. and 6 p.m. after taking sign of the Security personnel of KEM Hospital on the Waste record book before discarding

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.: D 24 /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. Bhaskar Krishnamurthy
Assistant Professor

Signature with date

BK
31/12/22

Dr. Bhaskar Krishnamurthy
Assistant Professor,
Department of Clinical Pharmacology,
Seth GSMC and KEMH, Mumbai -400 012.

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.