F. No (E 22967)

# Government of India Directorate General of Health Services Central Drugs Standard Control Organisation (DTAB-DCC Division)

Dated:

To

2 6 MAY 2025

All State/ UT Drug Controllers

Subject: Guidelines on disposal of expired/unused drugs -regarding

Sir/ Madam,

The safe and proper disposal of expired/unused medicines/drugs is crucial for protecting the environment and public health. Ensuring the quality, safety and efficacy of drug products is a critical aspect which contributes significantly to strengthen the assurance in public health system including healthcare professional and other stakeholders. Improper disposal of expired/unused drugs may be hazardous to public health, animal health and environment. It is also been evolved as one of the important factors for growing Anti-Microbial Resistance (AMR).

Expired drug refers to drugs which had crossed the expiry date mentioned on the label. Further, unused drugs refer to the medications that have not been used by the individual for whom they were prescribed or purchased. The proposal for safe disposal of unused/expired medicine was placed in the 58<sup>th</sup> meeting of DCC which recommended for constituting a subcommittee to examine the issue and prepare the guidance document in this regard.

Subsequently, the said guidance document (WI/01/DCC-P-25) prepared by DCC sub-committee was also placed before the DTAB. The Board deliberated the matter and recommended that the CDSCO may circulate the same to all State/UT Drugs Controllers

In view of above, you are requested to encourage the concerned stakeholders in your State to adopt the guidelines for safe disposal of expired/unused drugs which will be an important step in combating AMR in the country.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi) Drugs Controller General (India)

#### Copy for necessary action to: -

- 1. All Zonal/ Sub-zonal offices of CDSCO
- 2. CDSCO website



# GUIDANCE DOCUMENT ON DISPOSAL OF EXPIRED/ UNUSED DRUGS

#### **Published By**

Central Drugs Standard Control Organisation

Directorate General of Health Services

Ministry of Health & Family Welfare

Government of India

Guidance document on disposal of expired/unused drugs (WI/01/DCC-P-25)

#### **Table of Contents:**

S. No.	Topics	Page No.
1.	Introduction	1
2.	Background	1
3.	Consequence of Improper Disposal or Non Disposal	2
4.	Objective	2
5.	Methods for Disposal of Expired/ Unused Medicines	2
6.	Existing Rule Position	4
7.	Procedure to be followed by Stakeholders for the Disposal of the Expired /Unused Drugs	5
8.	Collection, Storage and Transportation of the Expired /Unused Drugs	8
9.	Disposal of Expired Medicine/Unused Medicine by General Public	9
10.	References	9

#### INTRODUCTION

The safe and proper disposal of expired/unused medicines/drugs is crucial for protecting the environment and public health. Ensuring the quality, safety and efficacy of these products is a critical aspect which contributes significantly to strengthen the assurance in public health system including healthcare professional and other stakeholder. Improper disposal of expired/ unused drugs may be hazardous to public health, Animal health and environment.

Expired drug refers to drugs which has crossed the expiry date mentioned on the label. Further unused drugs refer to the medications that have not been used by the individual for whom they were prescribed or purchased. This can occur for various reasons, such as:

- 1. All recalled and sub-standard products
- 2. All unsealed products (expired or unexpired)
- 3. All cold chain damaged unexpired pharmaceuticals that should have been stored in a cold chain but were not (for example: insulin, polypeptide hormones, gamma globulins and vaccines).
- 4. All bulk or loose tablets and capsules. If unexpired these should only be used when the container is still sealed, properly labelled or still within the original unbroken blister packs;
- 5. An individual's condition improved and no longer requiring medication.
- 6. Change in treatment plan or medication regimen.
- 7. A person discontinuing medication due to side effects or lack of efficacy.

As per Drugs and Cosmetics Act and Rules thereunder, the requirements have been prescribed for manufacture for sale, sale and distribution of drugs. Further revised Schedule M under Drug Rules prescribed the requirements for manufacturers for proper and safe storage of waste material awaiting disposal.

This guidance document has been prepared to provide the best practices which may be followed for safe and proper disposal of expired/unused drugs. While preparing this guidance document, various international guidelines like WHO, USFDA etc. as well as Biomedical Waste (management and handling) Rules 2016 have been considered.

#### **BACKGROUND**

Earlier CDSCO received a letter from researchers referring an article regarding a study aimed to assess the extent of exposure of Active Pharmaceutical Compounds (APCs) in the hydrologic cycle in and around New Delhi. The study stated the role of ecological exposure due to the disposal of unused and expired pharmaceutical compounds into landfills and indicated that un-segregated drug disposal could be a reason for the emergence of drug resistance with special reference to antibiotics.

The issue was discussed in 58th Drugs Consultative Committee (DCC) held on

14.07.2020 and it was decided that there should be clear defined guidelines for disposal of expired/unused drugs, which can facilitate stakeholders in achieving the objective and recommended to examine the issue in details for preparation for guideline.

#### CONSEQUENCE OF IMPROPER DISPOSAL OR NON DISPOSAL

Improper disposal of expired/unused drugs is detrimental to human, animal and environment and may be hazardous if it leads to contamination of water supplies or local sources used by nearby communities or wildlife. Expired drugs may come into the hands of scavengers and children if a landfill is insecure. Pilfering from a stockpile of waste drugs or during sorting may result in expired drugs being diverted to the market for resale and misuse. Most pharmaceuticals past their expiry date become less efficacious and a few may develop a different adverse drug reaction profile. There are some categories of expired drugs or defective disposal practices that carry a public health risk.

#### **OBJECTIVE**

The objective of this guidance document is to provide clear and comprehensive instructions in accordance with the Drugs and Cosmetics Act and Rules and other laws as applicable for the safe disposal of expired and unused drugs. This document will also help to achieve the compliance with legal requirements. It will minimize the environmental impact and mitigate public health risk including the Antimicrobial Resistance. This guidance aims to establish procedures for disposal of the expired/unused drugs, ensuring compliance with law, protecting the environment and safeguarding the public health. This guidance document will help various stakeholders to dispose their expired/unused medicine in safer manner.

#### METHODS FOR DISPOSAL OF EXPIRED/ UNUSED MEDICINES

#### 1. Landfill:

Landfill means to place waste directly into a land disposal site without prior treatment or preparation. Landfill is the oldest and the most widely practiced method of disposing of solid waste. The following types are recognized:

#### (a) Open uncontrolled non-engineered dump

Untreated waste discharged into an uncontrolled, non-engineered open dump does not protect the local environment and should not be used. They should preferably be discharged after immobilization by encapsulation or inertization.

#### (b) Engineered landfill

An appropriate landfill consists of an evacuated pit isolated from watercourses and above the water table. Each day's solid waste is compacted and covered with soil to maintain sanitary conditions. The term 'safe sanitary landfill' refers to such a site that is adequately situated, constructed and managed.

#### 2. Waste immobilization: encapsulation

Encapsulation involves immobilizing the pharmaceuticals in a solid block within a plastic or steel drum. They are filled to 75% capacity with solid and semi-solid pharmaceuticals, and the remaining space is filled by pouring in a medium such as cement or cement/lime mixture, plastic foam or bituminous sand. For ease and speed of filling, the drum lids should be cut open and bent back. Once the drums are filled to 75% capacity, the mixture of lime, cement and water in the proportions 15:15:5 (by weight) is added and the drum filled to capacity. Steel drum lids should then be bent back and sealed, ideally by seam or spot welding. The sealed drums should be placed at the base of a landfill and covered with fresh municipal solid waste. For ease of movement, the drums may be placed on pallets which can then be put on a pallet transporter.

**Encapsulation of antineoplastic drugs** requires a slightly different technique. The drugs must be destroyed in a two-chamber incinerator, which operates at a high temperature of at least 1200°C in the secondary chamber, and is fitted with gas cleaning equipment. An after-burner (i.e. the secondary chamber) is important for the destruction of cytotoxic waste, as it is possible that antineoplastic solutions could become aerosolized following the initial combustion in the primary chamber. As a result, without a higher temperature secondary chamber, degraded antineoplastic material may be emitted from the chimney. The secondary combustion chamber consequently ensures that such antineoplastic substances are fully incinerated.

#### 3. Waste immobilization: inertization

Inertization is a variant of encapsulation and involves removing the packaging materials, paper, cardboard and plastic, from the pharmaceuticals. Pills need to be removed from their blister packs. The pharmaceuticals are then ground and a mix of water, cement and lime added to form a homogenous paste. Worker protection in the form of protective clothing and masks is required as there may be a dust hazard. The paste is then transported in the liquid state by concrete mixer truck to a landfill and decanted into the normal urban waste. The paste then sets as a solid mass dispersed within the municipal solid waste. The main requirements are a grinder or road roller to crush the pharmaceuticals, a concrete mixer, and supplies of cement, lime and water.

The approximate ratios by weight used are as follows:

Pharmaceutical waste: 65%

Lime: 15%Cement: 15%

Water: 5% or more to form a proper liquid consistency.

#### 4. Sewer

Some liquid pharmaceuticals, e.g. syrups and intravenous (IV) fluids, can be diluted with water and flushed into the sewers in small quantities over a period of time without serious public health or environmental affect. Fast flowing watercourses may

likewise be used to flush small quantities of well-diluted liquid pharmaceuticals or antiseptics. The assistance of a hydrogeologist or sanitary engineer may be required in situations where sewers are in disrepair or have been damaged.

#### 5. Burning in open containers

Pharmaceuticals should not be destroyed by burning at low temperature in open containers, as toxic pollutants may be released into the air. Paper and cardboard packaging, if they are not to be recycled, may be burnt. Polyvinyl chloride (PVC) plastic however must not be burnt.

#### 6. Medium temperature incineration

In emergency situations the responsible authorities may consider it acceptable to treat expired solid form pharmaceuticals using a two-chamber incinerator that operates at the minimum temperature of 850°C, with a combustion retention time of at least two seconds in the second chamber. It is recommended that the pharmaceutical waste be diluted with large quantities of municipal waste (approximately 1:1000).

#### 7. Novel high temperature incineration

Industries which use high temperature technology, such as cement kilns, coal fired thermal power stations or foundries, usually have furnaces that operate at temperatures well in excess of 850°C, have long combustion retention times, and disperse exhaust gases via tall chimneys, often to high altitudes. During burning the cement raw materials reach temperatures of 1450°C while the combustion gases reach temperatures up to 2000°C. The gas residence time at these high temperatures is several seconds. In these conditions all organic waste components are effectively disintegrated. Incinerators conforming to these regulations may be used for the disposal of halogenated compounds, X-ray contrast media and povidone iodine; lower temperature incinerators should not be used.

#### 8. Chemical decomposition

If an appropriate incinerator is not available, the option of chemical decomposition can be used in accordance with the manufacturer's recommendations, followed by landfill. This method is not recommended unless chemical expertise is readily available. Chemical inactivation is tedious and time consuming, and stocks of the chemicals used in treatment must be made available at all times. For disposal of a small quantity of antineoplastic drugs this method may be practical. However, for large quantities, for example, more than 50 kg of antineoplastics, chemical decomposition is not practical, as even small consignments need to be treated through repeated application of this method.

#### **EXISTING RULE POSITION**

#### (a) Disposal of imported drugs/APIs

The provisions of disposal of imported drugs declared Not of Standard Quality at the time of import have been prescribed under Rue 41 of Drugs Rule, 1945. However,

method of disposal may be followed as per the guidance provided in this document.

#### (b) Disposal of expired/unused medicine at Retail/Wholesale outlets

The requirements of separate storing of such drugs have been prescribed under Rule 65(17) of Drugs Rule, 1945. However, method of disposal may be followed as per the guidance provided in this document.

#### (c) Disposal of waste material at manufacture level

Revised Schedule 'M' under Drugs Rule, 1945 provides requirement for safe disposal of such drugs. As per the said Rules, provision shall be made by the manufacturers for proper and safe storage of waste materials waiting disposal. Toxic substances and flammable materials shall be stored in suitably designed, separate, enclosed cupboards.

As per requirement waste material shall not be allowed to accumulate. It shall be collected in suitable receptacles for removal to collection points outside the buildings and disposed of safely and in a sanitary manner at regular and frequent intervals.

The disposal of sewage and effluents (solid, liquid and gas) from the manufacturing area shall be in conformity with the requirements of the guidelines issued by the Environmental Pollution Control Board. All bio-medical waste shall be destroyed as per the provisions of the Bio-Medical Waste (Management and Handling) Rules, 2016.

The dispensing, packaging and transportation of radiopharmaceuticals shall comply with the relevant provisions of the Atomic Energy Act 1962 and the rules made thereunder.

## PROCEDURE TO BE FOLLOWED BY STAKEHOLDERS FOR THE DISPOSAL OF THE EXPIRED /UNUSED DRUGS

#### Collection and disposal of expired /unused drugs: -

Manufacturers are required to manufacture drug for sale in accordance with the conditions of manufacturing license. Manufacturers are required to release their products for sale and distribution through wholesaler which may include C&F agent/ Stockist/ Distributor. Manufacturer can also supply medicine to the procurement agencies/retailer directly. Wholesaler can be C&F agents/ stockist/ distributor and are required to supply medicine to other stakeholders i.e. Retailer or procurement/purchasing entity in accordance with the conditions of the wholesale license. Retailers are required to sell/dispense the medicine in accordance with the conditions of sale license issued for the purpose. The procedure for disposal at each such level is as under: -

#### Retailer:

The licensee is responsible for returning of the stock to the supplier or manufacturer within 30 days after its expiry from whom he has purchased and shall maintain a register or record of expired/ unused drugs as per **Annexure –A** with the details as

the case may be applicable.

Provided that if the supplier or manufacturer is not accessible due to certain administrative reasons the licensee can dispose of the expired/unused drugs in accordance with Biomedical Waste Management Rules 2016 and records in this regard shall be maintained. The records should be kept open for verification by Regulatory Authority whenever required.

#### Wholesaler/Distributor/Stockist:

Each licensee shall accept all the expired/unused drugs from the persons (retailers or wholesalers) to whom he has supplied the drugs. The licensee is responsible for receipt, handling, segregation and returning of the stock of expired /unused drugs. If multiple wholesalers/ stockists are involved in the supply chain, each level should ensure returning of such drugs to the next level within 30 days from level 1 to level 2, additional 30 days from level 2 to level 3, additional 30 days from level 3 to level 4 and so on. The licensee at each level shall maintain a register or record of expired/ unused drugs as per **Annexure –A** with the details as the case may be applicable.

In case if the wholesaler is directly an authorised agent of the manufacturer and if he is authorized to disposed of expired / unused drugs on behalf of manufacturer then he can dispose of the expired/unused drugs in accordance with Biomedical Waste Management Rules 2016 under intimation to the manufacturer and records in this regard shall be maintained.

Provided that if the supplier or manufacturer is not accessible due to certain administrative reasons the licensee can dispose of the expired/unused drugs in accordance with Biomedical Waste Management Rules 2016 and records in this regard shall be maintained. The records should be kept open for verification by Regulatory Authority whenever required.

#### **Manufacturer:**

The manufacturer shall accept all the expired/unused drugs from the persons (retailers or wholesalers) to whom he has supplied the drugs.

The manufacturer is responsible for handling and disposal of stock of expired/unused drugs including such returned drugs received from distributor/ stockist, wholesaler/ retailers or available at the site within 6 months of its expiry. No drugs should be available in supply chain after 6 months of expiry and records in this regard shall be maintained as per **Annexure-B**.

Disposal of the expired/unused drugs either at the site of manufacturer or by the vendor approved by Pollution Controlled Board (PCB) shall be as per Bio-Medical Waste (Management and Handling) Rules 2016 as amended from time to time. The records of such disposal should be kept open for verification by Regulatory Authority whenever required.

#### **Government / Private Hospitals / Government Agencies:**

The Government or Private Hospital/Government Agencies can directly dispose of the expired/unused drugs in accordance with Biomedical Waste Management Rules 2016 and records in this regard shall be maintained with disposal certificate. The records should be kept open for drugs inspector for verification whenever required.

In case these Hospitals/Government agencies want to return the unused/expired drugs to the supplier, the same shall be returned within 30 days after its expiry from whom he has purchased and shall maintain a register or record of expired/ unused drugs as per **Annexure –A** with the details as the case may be applicable. The records should be kept open for verification by Regulatory Authority whenever required.

#### Samples drawn by Drugs Inspector:

The samples are drawn by the Drugs Inspectors under the provisions of Drugs and Cosmetics Act 1940 and Rules 1945 for test and analysis either in three or four parts whichever applicable. At present there is no mechanism for disposal of expired sample parts which are of standard quality. Then the concerned Drugs Inspector can dispose of these samples in accordance with Biomedical Waste Management Rules 2016 and should maintain the records in this regard. Further it may be considered for supply of standard quality unexpired samples to Govt. institutions.

#### **ANNEXURE- A**

# Records to be maintained by retailer/ wholesaler/hospitals/Govt. Agencies

Sr. No.	Date	The name and address of the licensee /hospital /institution who returns the drug.	The name and address of the licensee to whom the drugs are return.	Product name	Batch/ Lot No	Exp Date	Qty For disposal	Date of transfer to next level, if any	Reason for disposal/ Remark	Signature

#### **ANNEXURE-B**

#### Recall & Disposal of Expired Drugs at the manufacturer level

S. No.	Date	Product name	Batch/ Lot No	Exp Date	Unsold or undistributed Qty in possession	Qty Distributed	Qty Returned	Total quantity disposed.	Reason for disposal/ Remark	Signature

### COLLECTION, STORAGE AND TRANSPORTATION OF THE EXPIRED /UNUSED DRUGS

The yellow coloured non-chlorinated plastic bags or containers are used for the collection of the expired/unused drugs. The bags or containers containing the expired /unused drugs are stored in a separate area or room which is appropriate to the quantities of expired /unused drugs and frequency of collection.

Cytotoxic drugs which are expired /unused are stored separately from other expired/unused drugs in a designated secure location.

Radioactive drugs which are expired/ unused are stored in containers that prevent dispersion, behind lead shielding and should be strictly in accordance with the AERB guidelines.

Controlled substances which are expired /unused are treated as normal solids and stored in yellow coloured non-chlorinated plastic bags or containers and stored separately in a designated secure location to prevent it from coming out into public domain as they may be abused.

The containers or bags containing the expired/unused drugs are transported from the premises of the manufacturer to any bio-medical waste treatment facility in the vehicles having label as provided in part 'A' of the Schedule IV along with necessary information as specified in part 'B' of the" Schedule IV of Bio-Medical Waste (Management and Handling) Rules, 2016.

The vehicles used for transportation of expired/unused drugs shall comply with the conditions if any stipulated by the State Pollution Control Board or Pollution Control Committee in addition to the requirement contained in the Motor Vehicles Act, 1988.

If the disposal is to be carried out at the manufacturer's site itself, then the bags or containers containing the expired /unused drugs are transported by means of wheeled trolleys, containers, or carts that are dedicated for such purpose or not used for any other purpose. Such equipments should be either be autoclaved before using it or disposed off as per the Bio-Medical Waste (Management and Handling) Rules, 2016 as amended from time to time. The procedures to be followed for different medicines are illustrated in **Annexure C.** 

It should be ensured that appropriate sorting is done to separate the pharmaceuticals into categories that require different disposal methods. Controlled substances (e.g. Narcotics), antineoplastics (cytotoxic) drugs, Anti-infective drugs and other hazardous drugs shall be separated and not to be mixed among the other pharmaceuticals.

#### DISPOSAL OF EXPIRED MEDICINE/UNUSED MEDICINE BY GENERAL PUBLIC

**Drug take back site:** Unscientific disposal of unused or expired drugs is considered as one of the primary reasons for environmental pollution. Used antibiotics which are often disposed of carelessly seeps into the soil and water bodies, eventually affecting human life. In an effort to tackle the unsafe disposal of unused drugs. The State Government in coordination of local bodies may establish the methodology and facility for the collection of and disposal of unused or expired drugs as per the provisions of Biomedical Waste Management Rules, 2016.

Initially State Drugs Control Departments and concerned Chemists and Druggists' Association may jointly launch 'Drug take back' site or program at designate locations, where people can drop expired or unused drugs from their homes and that can be disposed finally by such associations under intimation to concerned State Drug Licensing Authority with the help of registered/licensed external agencies as registered under Biomedical Waste Management Rules, 2016.

**Flush list:** There is a small number of medicines that may be especially harmful and in some cases, fatal with just one dose if they are used by someone other than the person for whom the medicine was prescribed. The list of expired, unwanted, or unused medicines that should flush down the sink or toilet to help prevent danger to people and pets in the home has been prepared, which is annexed as **annexure D** and is a dynamic list.

#### **REFERENCES**

- 1. Drugs and Cosmetics Rules, 1945
- 2. WHO Guidelines for the safe disposal of expired drugs
- 3. WHO Guidelines for safe disposal of unwanted pharmaceuticals in and after emergencies
- 4. US FDA guidelines Safe Disposal of Medicines
- 5. Biomedical Waste Management Rules, 2016
- 6. Narcotic Drugs and Psychotropic Substances Act, 1985

#### Annexure C

#### DISPOSAL METHOD FOR EXPIRED/ UNUSED DRUGS -

S. No.	Category of Drug/Dosage form/Packaging	Handling method	Method of Disposal	Remarks
1.	Solids Semisolids Powders (Except Biological waste)	<ul> <li>To be removed from their outer packaging but remain in their inner packaging and placed in clean plastic or steel drums, for treatment according to the method of encapsulation.</li> <li>The large quantity of loose tablets should be mixed with other medicines in different steel drums to avoid very high concentrations of a single drug in any one drum.</li> </ul>	<ul> <li>Landfill</li> <li>Waste encapsulation</li> <li>Waste inertization</li> <li>Medium and high temperature incineration (cement kiln incinerator)</li> </ul>	No more than 1% of the daily municipal waste should be disposed of daily in an untreated form (non-immobilized) to a landfill.
2.	Liquids (Except Biological waste)	The liquid vitamins which are readily biodegradable organic material may be diluted and flushed into sewer. Harmless solutions of different concentrations of certain salts, amino acids, lipids or glucose may also be disposed off in sewers.	Sewer     High-temperature incineration (cement kiln incinerator)	Anti- neoplastics not to be sent to sewer
		If there are no sewers or no sewage treatment plant which is functioning, the liquids should be diluted first with large volumes of water and poured into large watercourses, to be dispersed immediately and diluted by flowing river water.      The liquid pharmaceuticals		
		either diluted or not should not be discharged into slow moving or stagnant surface waters.		
3.	Ampoules	Ampoules should be crushed on hard	Crush ampoules and flush diluted	Anti- neoplastics

S. No.	Category of Drug/Dosage form/Packaging	Handling method	Method of Disposal	Remarks
		impermeable surface (e.g. concrete) or in a metal drum or bucket using wood or hammer. The workers who are involved in this work, should wear the protective equipments like eye protection, boots, clothing and gloves.  • The crushed glass should be swept up and placed in container suitable for sharp objects, sealed and disposed off in a landfill.	fluid to sewer	not to sewer.  Ampoules should not be burnt or incinerated as they will explode and cause injury to operators and damage to incinerator or furnace. When the temperature of incinerator is above the glass melting point then it will clog the grate of incinerator or furnace.
4.	Aerosol canisters		Landfill     Waste encapsulation	Not to be burnt: may explode
5.	PVC plastic, glass		Landfill	Not for burning in open containers
6.	Paper, cardboard		Recycle  burn  landfill	
7.	Anti infective drugs	<ul> <li>Anti-infective drugs should be treated before discarded.</li> <li>These should be diluted in water, left for two weeks and then disposed to the sewer.</li> </ul>	<ul> <li>Waste encapsulation</li> <li>Waste inertization</li> <li>Medium and high temperature incineration (cement kiln incinerator)</li> </ul>	Liquid antibiotics may be diluted with water, left to stand for several weeks and discharged to a sewer
ď.	Anti-neoplastics	• These drugs when	Return to donor or	• Not to

S. No.	Category of Drug/Dosage form/Packaging	Handling method	Method of Disposal	Remarks
		discharged into environment can have very serious effects like interfering with reproductive processes of various life forms.  • Hence, these should be segregated from other pharmaceuticals and kept separately in containers with rigid walls and marked clearly. Ideally these should be packed safely and returned to supplier for disposal.	manufacturer  • Waste encapsulation  • Waste inertization  • High-temperature incineration	Iandfill unless encapsulate d.  Not to sewer  No low or medium temperature incineration.
		disposed off in a landfill other than after encapsulation or inertization.  The workers who are handling these drugs should avoid the crushing of cartons or removing the product from its packages. They should be discharged into sewerage system after chemical decomposition and must not be discharged untreated into surface water drains or natural watercourses.  A special treatment is required for the antineoplastics. The drums should be filled with 50% capacity with drugs and		
		then a well-stirred mixture of lime, cement and water in 15:15:5 (by weight) proportions should be added and the drums filled to capacity. A large volume is required to attain satisfactory liquid consistency. The drums		

S. No.	Category of Drug/Dosage form/Packaging	Handling method	Method of Disposal	Remarks
		should then be sealed by seam or spot welding and left to set for 7 to 28 days and this will form a firm, immobile, solid block in which the wastes are relatively securely isolated. The drums are then placed at the working face of a landfill which has been lined with impermeable layer of clay or membrane.		
9.	Controlled drugs	<ul> <li>The controlled substances which are regulated under Drugs &amp; Cosmetics Act, 1940 and the rules made thereunder and Narcotic and Psychotropic Substances Act, 1985 shall be disposed off adhering to these Acts under intimation to the concerned authorities and shall be disposed off under the Bio-Medical Waste (Management and Handling) Rules, 2016.</li> <li>As per rule 52M of NDPS, Rules, 1985, Such stocks of essential narcotic drugs as may be in the possession of an</li> </ul>	<ul> <li>Waste encapsulation</li> <li>Waste inertization</li> <li>Medium and high-temperature incineration (cement kiln incinerator)</li> <li>Provisions of NDPS Rules, 1985 should be followed.</li> </ul>	Not to landfill unless encapsulate d
		authorised person, on the expiry or cancellation or surrender of his authorisation, shall be disposed of in such manner as may be specified by the Controller of Drugs in this behalf.  • The expired stock of essential narcotic drugs as may be in the possession of an authorised person or a		
		registered medical practitioner shall be destroyed in such manner as may be specified by the Controller of Drugs.		

S. No.	Category of Drug/Dosage form/Packaging	Handling method	Method of Disposal	Remarks
		<ul> <li>Further, as per, rule 52V of NDPS, Rules, 1985, the expired stock of essential narcotic drugs shall be destroyed by the recognised medical institution in the presence of an officer nominated by the Controller of Drugs.</li> <li>Also, the unused essential narcotic drugs returned by the patients shall be considered as receipts by the recognised medical institution.</li> </ul>		
10.	Disinfectants	<ul> <li>In general, there is no expiry dates for disinfectants. The large volumes of disinfectants should not be flushed into sewer, as they can kill the bacteria in a sewage work and can stop the biological treatment of sewage. In the same way, large quantities should not be put into watercourses as these can damage aquatic life.</li> <li>Small quantities of diluted disinfectants may be disposed off by discharge to a sewer of about 50 liters per day, with the disposal spread over the whole working day.</li> </ul>	To sewer or fast flowing water course: small quantities of diluted (maximum of 50 liters per day under supervision)	<ul> <li>No undiluted disinfectants to sewers or water courses.</li> <li>Maximum 50 liters per day diluted to sewer or fast-flowing watercourse</li> <li>No disinfectants at all to slow moving or stagnant watercourse s.</li> </ul>
11.	Radioactive drugs	<ul> <li>The radioactive waste is treated initially to change the characteristics of radioactive waste to improve safety or economy.</li> <li>Liquid LLW and ILW are typically solidified in cement, whilst HLW is calcined/dried then vitrified in a glass matrix.</li> </ul>	Deep geological disposal or as per AERB Guidelines	

S. No.	Category of Drug/Dosage form/Packaging	Handling method	Method of Disposal	Remarks
		Immobilised waste will be placed in a container suitable for its characteristics.		

#### **Annexure D-**

# MEDICINES RECOMMENDED FOR DISPOSAL BY FLUSHING BY GENERAL PUBLIC OTHER THAN RETAILER/WHOLESALER/MANUFACTURER -

There is a small number of medicines that may be especially harmful and, in some cases fatal with just one dose if they are used by someone other than the person for whom the medicine was prescribed. This list provides the details of expired unwanted or unused medicines containing the Active ingredients as mentioned in the following list, the general public should flush down the sink or toilet to help prevent danger to people and pets in the home.

S. No.	Name of the Drugs	
1	Fentanyl	
2	Fentanyl Citrate	
3	Morphine Sulfate	
4	Buprenorphine	
5	Buprenorphine Hydrochloride	
6	Methylphenidate	
7	Meperidine Hydrochloride	
8	Diazepam	
9	Hydromorphone Hydrochloride	
10	Methadone Hydrochloride	
11	Hydrocodone Bitartrate	
12	Tapentadol	
13	Oxymorphone Hydrochloride	
14	Oxycodone	
15	Oxycodone Hydrochloride	
16	Sodium Oxybate	
17	Tramadol	