

# Pharmaceutical Waste Products and its Management

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**Abstract:** *Introduction: Medication disposal is an alarming issue today and gaining more and more awareness from the healthcare professionals as well as consumers.*

*Pharmacists have the potential to be on the forefront of this movement as a healthcare professionals and pharmacists are in an admirable position to educate patients about safe drug disposal.*

*Proper patient counselling on safe medication disposal can make a significant difference to public health and the environment. The knowledge on method of disposal of unused medicines is equally important as that of consumption of medicines.*

*Objective: This article aims to provide a background, the importance and significance of proper medication disposal, describe the correct methods to dispose of unwanted and expired medications.*

*Method: The information about methods of proper disposal as well as consequence of improper disposal was collected by extensive literature survey of all available resources..*

**Keywords:** Pharmaceutical Waste Management, Medication disposal, Patient education, Pollution.

## I. INTRODUCTION

Waste includes all items that people no longer have any use for, which they either intend to get rid of or have already discarded. Additionally, wastes are such items which people are require to discard, for example by lay because of their hazardous properties.

Many items can be considered as waste eg, household rubbish, sewage, sludge, wastes from manufacturing activities, packaging items, discarded cars, old televisions, garden waste, old paint containers etc. Thus all our daily activities can give rise to a large variety of different wastes arising from different sources. This is mainly made up of waste coming from households, commercial activities (e.g. shops, restaurants, hospitals etc.), industry (e.g., pharmaceutical companies, clothes slurry) construction manufacturers Mc.). agriculture.

The discovery of a variety of pharmaceuticals in surface, ground, and drinking waters around the country is raising concerns about the potentially adverse environmental consequences of these contaminants. Minute concentrations of chemicals known as endocrine disruptors, some of which are pharmaceuticals, are having detrimental effects on aquatic species and possibly on human health and development. The consistent increase in the use of potent pharmaceuticals driven by both drug development and our aging population, is creating a corresponding increase in the amount of pharmaceutical waste generated.<sup>3</sup>



Fig :- Pharmaceutical waste

Recent concerns regarding the documentation of drugs in drinking ground, and surface waters have led to a rapid rise in public awareness and calls for action at the federal, state, and local level. These developments are discussed in more detail in Step 3, Considering Best Management Practices.

Pharmaceutical waste is not one single waste stream, but many distinct waste streams that reflect the complexity and diversity of the chemicals that comprise pharmaceuticals. Pharmaceutical waste is potentially generated through a wide variety of activities in a healthcare facility, including but not limited to intravenous

(IV) preparation, general compounding spills breakage partially used vials, syringes, and IV, discontinued, unused preparations, unused unit doserepacks, patients personal medications and outdated pharmaceuticals.

In hospitals, pharmaceutical waste is generally discarded down the drain or land filled, excepts chemotherapy agents which are oftensent to a regulated medical waste incinerator. These practices were developed at a time when knowledge was not available about the potential adverse effects of introducing waste pharmaceuticals into environment.

Proper pharmaceutical waste management is a highly complex new frontier environmental management for healthcare facilities. A hospital pharmacy generally stocks between 2,000 and 4000 different items each of which must be evaluated against state and federal hazardous waste regulation Pharmacist and nurses generally not receive training on hazardous waste management during their academic studies and safety and environmental services managers may not be familiar with the active ingredients and formulations of pharmaceutical product.<sup>4</sup>

There are a number of different options available for the treatment and management of waste including prevention, minimization, re-use, recycling energy recovery and disposal.

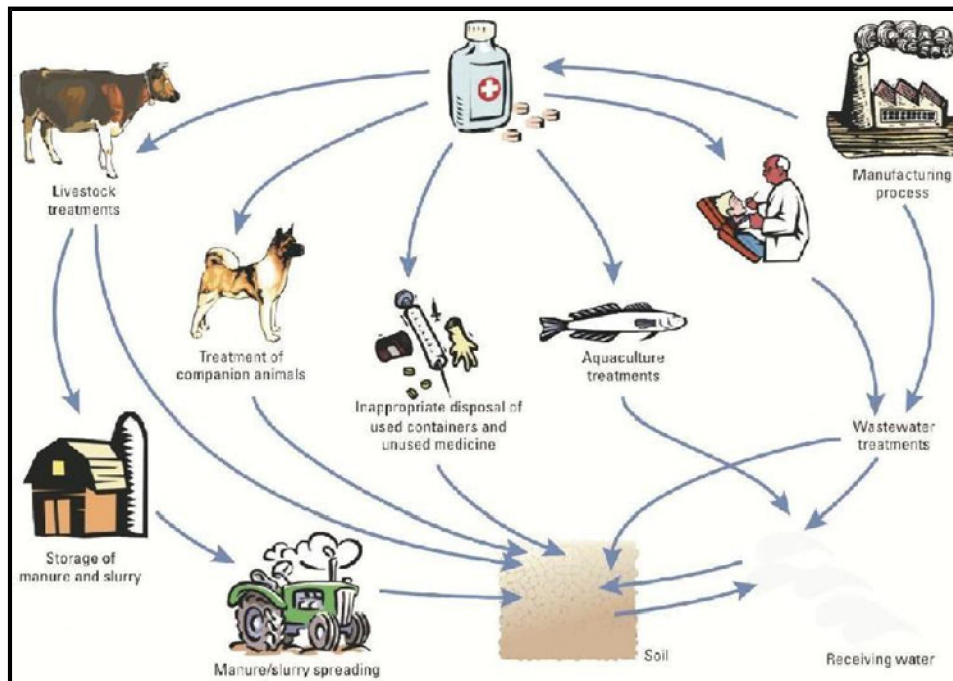


Figure 1: Routes of pharmaceuticals entering the environment ‘Reproduced with the permission of Alistair Boxall  
Pharmaceutical chemicals can enter into the environment by a number of passage such as From low cost pharmaceutical production industries in developing countries such as India and China.

Direct and improper disposal by patients/ humans by unused/expired medications in to the trash and through the excretion of urine or faeces.

Release from hospital waste/trash Disposal by pharmacies

Veterinary use as medicine as well as additives to animal food; which is excreted into soil or surface waters Dairy waste disposal

Household water/sewage, solid garbage mix with drug surplus Leaching from defective landfills

Release from aquaculture which has medicated feed, as well as excretion from the aquaculture Release from molecular farming/ pest control drugs

Disposal of euthanized/medicated animal carcasses

Even in many developing countries like India the physician samples which are given by companies to medical representatives for sales promotion purpose; Many times we read in local newspaper that such expired/unused drug products found across road side.<sup>16</sup>

Most common routes of pharmaceuticals entering the environment are shown in Figure 1.

### Impact of Improper Disposal

Improper disposal 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 into the market for resale and misuse.

Most of the expired pharmaceuticals are less efficacious and very few of them may develop a different adverse drug reaction profile.<sup>15</sup> Pharmaceuticals and Personal Care Products (PPCP) have been found as pollutant in water and the environment. This poses a serious issue of ecological imbalance due to indiscriminate disposal of expired pharmaceutical products.<sup>14</sup> Here are some of the examples of the impact of drugs through environment on human beings and animal. Evidence from rodent and fish study suggest that some endocrine-disrupting compounds, including those found in prescribed synthetic hormones, may contribute to tumour formation in humans.<sup>17</sup>

A large scale ecological disaster occurred in the Indian subcontinent was dramatic decrease in vulture population where vultures that fed on carcasses of cattle treated with diclofenac died from renal failure because they were unable to excrete the drug.<sup>18,19</sup> Antibiotics in the sewage could increase selection pressure and promote the transfer of resistance genes from harmless environmental microbes into deadly pathogens, leading to emergence of deadly drug resistant microorganisms.

Abnormal thyroid function, decreased fertility, decreased hatching success and alteration of immune function in birds and demasculinization and feminization of male fish has been linked to exposure to endocrine disrupting chemicals (EDCs) by-products of industrial waste.<sup>20,21</sup>

Some of the studies also tried to link the fall in sperm count in men that has decreased by 50% in 50 years.<sup>22</sup> Not only the drugs but also the excipients used in the formulations affect the environment.<sup>23</sup> In a study carried out by Cantrell et al. they measured the amounts of active ingredients in the medications which had expired 28-40 years ago, 12 of the 14 active ingredients persisted in concentrations that were 90% or greater of the amount indicated on the label and retained their full potency for 336 months or longer.<sup>24</sup>

A study carried out by Ramaswamy et al. showed that high levels of carbamazepine and triclosan were found in surface waters of Kaveri, Tamiraparani and Vellar rivers of Kerala.<sup>25</sup>

High levels (31,000 µg/L) of an antibiotic ciprofloxacin in a waste water treatment plant in Patancheru, India had been already reported.<sup>13</sup>

India is reportedly breeding ground for most of multi-drug resistant microbes due to extensive usage and improper disposal of pharmaceutical drugs into the environment.<sup>26</sup>

All the above studies suggest that pharmaceutical drugs in India were well spread in several environmental as well as biological media. In addition to this, anti-neoplastic or cytotoxic drugs must be handled carefully as they have the ability to kill or stop the growth of living cells and can have extremely serious effects, such as interfering with reproductive processes in various life forms.<sup>27</sup>

### Cost of disposal

The cost of drug disposal is higher than manufacturing and most of the people in Asian countries dump the waste materials in the earth, which is not good when considering the future.<sup>28</sup> The cost of pharmaceutical waste disposal by high temperature incineration; in US cost, between \$4.4 million and \$8.2 million.<sup>27</sup> In India, cost of such disposal is about 0.5 % to 2% of the total sales.

Environmental hazards are responsible for an estimated 25% of the total burden of disease worldwide, and nearly 35% in regions such as Sub-Saharan Africa.<sup>30,31</sup> An extensive research project investigated a total of 123,761 incidents of measured environmental concentrations of pharmaceuticals around the world.<sup>32</sup> It is evident that ever-increasing use of pharmaceuticals in clinical and veterinary practice can have adverse influence on the environment.

**Disposal Methods and Remedial Measures**

Habits of medicine disposal depend on socioeconomic culture as well as regulatory guidelines, norms that prevail in the country. Most commonly used methods are throwing medicines in sinking, toilet and dustbins, which are environmentally unfriendly. Despite various complex variables that combine to cause pollution the most effective best management practices (BMPs) would address source reduction, namely, reducing the amount of medicine that goes unused.

The Pharmaceutical Research and Manufacturers of America have evaluated unused medicine disposal options and have concluded that toilet flushing of unused medicine should be avoided whereas household trash disposal and take-back programs are effective to reduce their presence in the environment. An additional approach for a more environmentally sound handling of unused drugs is to use “social marketing”.<sup>17,33</sup>

Liquid medicines should be mixed with salt, flour, charcoal, or nontoxic powdered spice, such as turmeric or mustard, to give the mixture an unappealing smell and texture. Medicines in blister packs should be wrapped in multiple layers of opaque tape, and then placed inside

an opaque container for sealing. The lid of the medication bottle should be sealed with duct tape or packing tape, the medication bottle(s) should be placed inside a container that is not see-through and disposed off in the trash after sealing.

There are various disposal methods which are described here and summarized in Table 1.<sup>27,29,34</sup>

Take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash. Mix the prescription drugs with an undesirable substance, like used coffee grounds or kitty litter. Putting them in impermeable, non-descript containers, such as empty cans or sealable bags, will further ensure the drugs are not diverted.

Throw these containers in the trash.

Flush prescription drugs down the toilet only if the accompanying patient information specifically instructs doing so.

Community drug take-back programs that allow the public to bring unused drugs to a central Location for proper disposal. Several countries like United States, Australia, British Columbia, and Sweden, “drug take back programme” achieving the goals.<sup>35</sup> and need to implement these programs in developing countries like India and China which are the major centres for manufacture of pharmaceuticals

**Table 1: Summary of disposal methods in and after emergencies**<sup>27,29,34</sup>

Disposal methods	Types of pharmaceutical	Comments
Return to donor or manufacturer, trans-frontier transfer for disposal	All bulk waste pharmaceuticals, particularly antineoplastics.	Usually not practical-transfrontier procedures may be time consuming
High temperature incineration with temperatures greatly in excess of 1200°C	Solids, semisolids, powders, Antineoplastics, controlled substances.	Expensive.
Medium temperature Incineration with two-chamber incinerator with minimum temperature of 850°C. Cement kiln incineration	In the absence of high temperature Incinerators, solids, semi-solids, powders. Controlled substances.	Antineoplastics best incinerated at high temperature.
<b>Immobilization</b>		
Waste encapsulation	Solids, semi-solids, powders, liquids, antineoplastic, controlled substances.	

Inertization	Solids, semi-solids, powders, Antineoplastic, controlled substances.	
<b>Landfill</b>		
Highly engineered sanitary landfill	Limited quantities of untreated solids, semi-solids and powders. Disposal of waste pharmaceuticals after Immobilization preferable. PVC plastics.	
Engineered landfill plastics.	Waste solids, semi-solids and powders, preferably after immobilization. PVC	
Open uncontrolled non engineered dump	As last resort untreated solids, semisolids, powders-must be covered immediately with municipal waste. Immobilization of solids, semi- solids, powders is preferable.	Not for untreated Controlled substances.
Sewer	Diluted liquids, syrups, intravenous fluids, small quantities of diluted disinfectants (supervised).	Antineoplastics, and undiluted disinfectants and antiseptics not recommended
Fast-flowing watercourse	Diluted liquids, syrups, intravenous fluids; small quantities of diluted Disinfectants (supervised).	Antineoplastics, and undiluted disinfectants and antiseptics not

## II. LITERATURE SURVEY

- Government of India, Ministry of Environment and Forests Gazette notification No 460, New Delhi, 1998 :- Discovery of a verity of pharmaceuticals in surface, ground, and drinking waters around the country is raising concerns about the potentially adverse environmental consequences of these contaminants. Minute concentrations of chemicals known as endocrine disruptors, some of which are pharmaceuticals, are having detrimental effects on aquatic species and possibly on human health and development. The consistent increase in the use of potent pharmaceuticals driven by both drug development and our aging population, is creating a corresponding increase in the amount of pharmaceutical waste generated. Recent concerns regarding the documentation of drugs in drinking ground, and surface waters have led to a rapid rise in public awareness and calls for action at the federal, state, and local level. These developments are discussed in more detail in Step 3, Considering Best Management Practices.
- Pharmaceutical pollution does not appear to be harming humans at the moment, but alarming signals from aquatic life suggest that now is the time for precautionary measures. Water systems are generally checked for approximately 80 toxic compounds, the most dangerous of which include microbes, viruses, strong acids, chemical pesticides, and various metals. Pharmaceutical waste includes a wide range of goods, including OTC and prescription drugs. Drug residues infiltrate water systems mostly by people taking medications and then passively eliminating them through their entire bodies. These wastes are solid tablets and capsules, creams, liquids, and aerosols. Many pet medicines are similar or same as those provided for humans and must be treated with the same caution. Pharmaceutical waste came from a variety of sources, including healthcare institutions, agriculture, and flushing drugs down toilets. These entities are influenced by the environment and by humans. Human contact with drugs and other personal care items from the environment is a complex function of factors such as concentration, type, and pharmacokinetics of each drug, among others.
- The environment has a feminizing influence on male aquatic creatures and changes the female to male ratio. When healthcare and pharmaceutical goods are active at extremely low concentrations and continuously discharged in large or broad quantities, the disposal of leftover or unwelcome drugs becomes a developing and difficult environmental concern. The Illinois Environmental Protection Agency is collaborating with a variety of stakeholders to develop simple and environmentally appropriate methods for residents to

dispose of waste medicines. Medications and some possibly hazardous drugs should never be flushed down the toilet or down the drain to dispose of pharmaceutical waste.

Regulatory Bodies That Oversee Pharmaceutical Waste :-

- Environmental Protection Agency (EPA) Department of Transportation (DOT)
- Drug Enforcement Administration (DEA)
- Occupational Safety and Health Administration (OSHA) State Environmental Protection Agencies, State Pharmacy Boards, and
- Local Publicly Owned Treatment Works (POTW)

2) National Institute of Occupational Safety and Health Hazardous Drug Alert. Appendix A 5. Occupational Safety and Health Administration (OSHA). Technical Manual Section 6, Chapter 2. Appendix IV 2-1 OPNAVINST 5000 :-

Pharmaceutical waste is potentially generated through a wide variety of Activities in a health care facility, including syringes, and not limited to intravenous

(IV) preparation, general Pharmaceutical waste may include, but is not limited to:

- Expired drugs Patients' discarded personal medications,
- Waste materials containing excess drugs (syringes, IV bags, tubing,
- Waste materials containing chemotherapy drug residues Open containers of drugs that cannot be used Containers that held acute hazardous waste (p-listed) drugs.
- Drugs that are discarded; and
- Contaminated garments, absorbents and spill clean-ups material

3) Sharma N. Pharmaceutical Waste Management A Challenge to Make Environment Eco Friendly, 2010 :-

As design and implement your pharmaceutical waste management program, there are inherent limitations on the substitution of a less hazardous drug since the hazardous nature of the chemical often provides the therapeutic effect. However waste reduction can minimize compliance hassles, costs and risks. The following section provides a number of minimization opportunities to consider and explore.

1. Considering Lifecycle Impacts in the Purchasing Process
  2. Maximizing the Use of Opened Chemotherapy Vials
  3. Implementing a Samples Policy
  4. Labeling Drugs for Home Use
  5. Priming and Flushing IV Lines with Saline Solution
  6. Examining the Size of Containers Relative to Use
  7. Replacing Pre-packaged Unit Dose Liquids with Patient Specific Oral Syringes
  8. Controlled Substances
  9. Delivering Chemotherapy Drugs
  10. Monitoring Dating on Emergency Syringes
- Pharmaceutical waste is any leftover, unused, or expired medication that is being discarded.

### AIM AND OBJECTIVE

Aim :- Pharmaceutical Waste products and its Management

Objective :-

1. This article aims to provide a background, the importance and significance of proper medication disposal, describe the correct methods to dispose of unwanted and expired medications.
2. Waste management is intended to reduce the adverse effects of waste on human health, the environment, planetary resources, and aesthetics.
3. Recycle the waste after treating to the extent possible.

4. The destruction or recovery for reuse and/or the conversion of these substances to innocuous for that are acceptable for uncontrolled disposal.
5. To prevent misuse or abuse of waste
6. Here are the objectives of pharmaceutical waste management:
7. Environmental Protection: Prevent contamination of soil, water, and air.
8. Public Health Protection: Reduce the risk of exposure to hazardous substances.
9. Compliance with Regulations: Adhere to local, national, and international regulations.
10. Minimize Waste Generation: Implement strategies to reduce waste generation.
11. Proper Waste Disposal: Ensure safe and environmentally responsible disposal of pharmaceutical waste.
12. Employee Safety: Protect employees handling pharmaceutical waste from occupational hazards.
13. Community Awareness: Educate the public about the importance of proper pharmaceutical waste management.
14. Cost Reduction: Minimize waste disposal costs and reduce liability.
15. Reputation and Social Responsibility: Demonstrate commitment to environmental stewardship and public health.

#### **PLAN OF WORK**

Pharmaceutical Waste :- Pharmaceutical waste is potentially generated through a wide variety of activities in a health care facility, including syringes, and not limited to intravenous

(IV) preparation, general Pharmaceutical waste. Pharmaceutical waste is further classified in 3 categories:-

1. Non-hazardous wastes,
2. Chemo waste

#### **HAZARDOUS WASTE :-**

Waste that is dangerous or potentially harmful to human health or the environment is called as hazardous waste. It can be liquids, solids, contained gases, or sludges.

Characteristics of pharmaceutical waste :-

The LPA defines four characteristics of hazardous waste

- Ignitability (D001)
- Toxicity (D number specific to the chemical)
- Corrosivity (D002)
- Reactivity (D003)
- Ignitability D001[40 CFR 261.20]

#### **NON-HAZARDOUS WASTE :-**

Materials in this category are considered to present no significant hazardous properties. It is worth noting, however, that this is not an indication that there are no hazardous components present, only that any such components are below the threshold for causing harm to human health.

Chemo Waste :-

Chemo wastes are further classified as trace chemotherapy and bulk chemotherapy waste.

Trace Chemotherapy Waste :-

The federal RCRA regulations do not address trace chemotherapy waste. There is no recognized distinction between bulk and trace chemotherapy contamination for P- and U- listed hazardous wastes since there isn't a lower concentration limit under which these wastes can exit the regulatory system

Bulk Chemotherapy Waste:-

One chemotherapy agent is a P-listed constituent of concern and eight chemotherapy agents are U-listed. Trace chemotherapy containers have long been used to discard listed chemotherapy drug waste that should be managed as hazardous waste.

**Sources of Pharmaceutical Wastes:**

Pharmaceutical wastes have been present in the environment since decades but they have been quantified recently by the researchers.

1. Wastes from hospitals and dispensaries
2. Wastes disposal from pharmacies
3. Household wastes containing unused and expired drugs
4. Defective landfills causing leaching of drugs
5. Direct and improper disposal of unused/expired medications by patients in to the waste and also through excretion of urine or feces
6. Drugs released from sources like aqua culture medicated feed, molecular farming, pest control drugs, etc.

Methodology:-

**PHARMACEUTICAL WASTE TREATMENT AND DISPOSAL:-**

Pharmaceutical Waste Treatment and Disposal Technologies Specified in India's Pharmaceutical Waste Rules.

**1. Incineration**

Incineration is a disposal method in which solid organic wastes are subjected to combustion so as to convert them into residue and gaseous products. This method is useful for disposal of residue of both solid waste management and solid residue from waste water management. This process reduces the volumes of solid waste to 20 to 30 percent of the original volume. Incineration and other high temperature waste treatment systems are sometimes described as "thermal treatment". Incinerators convert waste materials into heat, gas, steam and ash.

**2. Autoclaving**

Autoclaving uses saturated steam in direct contact with the BMW in a pressure vessel at time lengths and temperatures sufficient to kill the pathogens. The Biomedical Waste Rules specify the minimum temperature pressure, and residence time for autoclaves for safe disinfection. Autoclaving is not suitable for human anatomical, animal, chemical, or pharmaceutical wastes before autoclaving, BMWs require shredding to an acceptable size, an operation that would involve frequent breakdown. Autoclaving produces a waste that can be land filled with municipal waste.

**3. Microwaving**

Application of an electromagnetic field over the BMW provokes the liquid in the waste to oscillate and heat up, destroying the infectious components by conduction. This technology is effective if the ultraviolet radiation reaches the waste material. Before microwaving, BMWs require shredding to an acceptable size and humidification. Microwaving is not suitable for human anatomical, animal, chemical, or pharmaceutical wastes, or for large metal parts. Microwaving produces a waste that can be land filled with municipal waste.

**4. Chemical disinfection**

Chemical disinfection is most suitable for treating liquid wastes such as blood, urine, stools, or health care facility sewage. Addition of strong oxidants-like chlorine compounds, ammonium salts, aldehydes, or phenol compounds-kills or inactivates pathogens in the BMW.

**5. Waste immobilization: encapsulation**

Encapsulation involves immobilizing the pharmaceuticals in a solid block within a plastic or steel drum. Drums should be cleaned prior to use and should not have contained explosive or hazardous materials previously.

**6. 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.

**HAZARDOUS WASTE MANAGEMENT:-**

**1. Waste minimization**

An important method of waste management is the prevention of waste material being created, also known as waste reduction. Methods of avoidance include reuse of second-hand products, Repairing broken items instead of buying new, designing products to be refillable or reusable (such as cotton instead of plastic shopping bags), encouraging consumers



to avoid using disposable products (such as disposable cutlery), removing any food liquid remains from cans, packaging, and designing products that use less material to achieve the same purpose (for example, light-weighting of beverage cans).

### 2. Re-use :-

It means the use of a product on more than one occasion, either for the same purpose or for a different purpose, without the need for reprocessing. Re-use avoids discarding a material to a waste stream when its initial use has concluded.

### 3. Recycling :-

It involves the treatment or reprocessing of a discarded waste material to make it suitable for subsequent re-use either for its original form or for other purposes. It includes recycling of organic wastes but excludes energy recovery. Recycling benefits the environment by reducing the use of virgin materials. Many different materials can be recycled.



Fig :- Recycling Waste Material

### Regulatory Bodies that Oversee Pharmaceutical Waste Management -

- Environmental Protection Agency (EPA) Department of Transportation (DOT)
- Drug Enforcement Administration (DEA)
- Occupational Safety and Health Administration (OSHA) Environmental Protection Agencies, State Pharmacy Boards, and
- Local Publicly Owned Treatment Works (POTW)

### Types of health care waste : <sup>5</sup>

**Communal waste:** Also known as "general health care wastes"

It is defined as solid wastes that are not infectious, chemical, or radioactive. Eg. Cardboard boxes, paper, food waste, plastic and glass bottles

**Biomedical wastes:** Also known as "hazardous health care wastes," or "health care riskwastes" or "special wastes" It is further classified as

**Infectious waste:** It is defined as wastes suspected of Cultures, tissues, dressings, swabs, and other bloods soaked items, waste containing pathogens from isolation wards.

**Anatomical waste:** It includes recognizable body parts, sharps, needles, scalpels, knives, blades, broken glass.

**Pharmaceutical waste:** It includes expired or no longer needed medicines or pharmaceuticals

**Genotoxic waste:** Wastes containing genotoxic drugs and chemicals (used in cancer therapy).

**Chemical waste:** It includes laboratory reagents, film developer, solvents, expired or no longer needed disinfectants and organic chemical wastes (for example, formaldehyde, phenol based cleaning solutions).

**Heavy metal waste:** Batteries, broken thermometers blood pressure gauges Pressurized containers Aerosol cans, gas cylinders (that is anaesthetic gases such as nitrous oxide halothaneEnflurane and ethylene oxide, oxygen, compressed air) comes under heavy metal waste.

**Radioactive waste;** It includes unused liquids from radiotherapy waste materials from patients treated or tested with unsealed radionuclides.

The Resource Conservation and Recovery Act (RCRA) were enacted in 1976 and govern the management of solid and hazardous waste generated within the United States. In the past several years, the Environmental Protection Agency (EPA) and state environmental protection inspectors have determined that healthcare facilities have not been managing hazardous waste in compliance with RCRA. A number of pharmaceuticals and formulations of pharmaceuticals meet the definition of hazardous waste under RCRA. EPA and some state environmental agencies are now requiring healthcare facilities to identify segregate, contain, and appropriately) label, store, transport, and dispose of these hazardous wastes in compliance with RCRA regulations. As a result of this focus on the part of regulators, surveyors for the Joint Commission (JC) are also including pharmaceutical waste management in their survey questions.

#### **PHARMACEUTICAL WASTE :<sup>6</sup>**

Pharmaceutical waste is potentially generated thorough a wide variety of activities is a health care facility, including syringes, and not limited to intravenous (IV) preparation, general Pharmaceutical waste may include, but is not limited to:

Expired drugs Patients' discarded personal medications,

- Waste materials containing excess drugs (syringes, IV bags, tubing,
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- Drugs that are discarded; and
- Contaminated garments, absorbents and spill clean-ups material Pharmaceutical waste is further classified in 3 categories

Hazardous waste,

Non-hazardous wastes,

Chemo waste

#### **HAZARDOUS WASTE**

Waste that is dangerous or potentially harmful to human health or the environment is called as hazardous waste. It can be liquids, solids, contained gases, or sludges. Hazardous wastes are divided in two categories.

- Listed wastes, and
- Characteristic wades

Listed wastes appear on one of four lists of hazardous waste [F,K,P and U]. Pharmaceuticals are found on two of these lists the P and U lists which both contain commercial chemical products. Characteristic wastes are regulated because they exhibit certain hazardous properties ignitability corrosivity reactivity and toxicity. Wastes that are not listed and do not exhibit a characteristic are considered solid waste. Solid waste should be discarded according to stank and or local regulations, including regulated medical waste requirements?

1. Listed hazardous waste

P-Listed Pharmaceutical waste

P-listed wastes are commercial chemical products that are categorized as acutely hazardous under RCRA as shown in table no. 1. One of the primary criteria for including a drug on the Mot as acutely hazardous is an oral lethal dose of 50 mg/kg (LD50) or less LD50 is the amount of a material, given all at once, which causes the death of 50% of a group of test animals. They are toxic and can cause death or irreversible illness at low dose.

When a drug waste containing a P-listed constituent of concern is discarded or intended to be discarded, it must be managed as hazardous waste if two conditions are satisfied;

The discarded drug waste contains a sole active ingredient (54 FR 31335) that appears on the P-list, and it has not been used for its intended purpose (54 FR 31336)

Empty Containers of P-Listed Wastes (40 CFR Part 261.7-A container that has held a P- listed waste is not considered "RCRA empty" unless it has been; Triple rinsed, and

The rinsed is managed as hazardous waste.

Since triple rinsing is not practical in healthcare settings, all vials, IVs, and other containers that have held a P-listed drug must be managed as hazardous waste, regardless of whether or not all of the contents have been removed. Some states have chosen to interpret needkeys stringently in the case of solid dosage forms (tablets, capsules) and are not regulating my warfarin stock bottles or snit-dose packaging.



**Characteristics of pharmaceutical waste :**

The LPA defines four characteristics of hazardous waste

- Ignitability (D001)
- Toxicity (D number specific to the chemical)
- Corrosivity (D002)
- Reactivity (D003)
- Ignitability D001[40 CTR 261.20]

The objective of the ignitability characteristic is to identify wastes that either present a fire hazard under routine storage disposal and transportation or are capable of exacerbating a fire once it has started. There are several ways that a drug formulation can exhibit the ignitability characteristic as mentioned in table 3. Many of the hazardous wastes that pharmacies handle are hazardous because they are ignitable. These wastes often pose the greatest management problems for pharmacies Ignitable wastes are easily combustible or flammable.

**Corrosivity D002 (40 CFR Part 261.22)**

Corrosive wastes corrode metals or other materials or burn the skin. These liquids have a pH of 2 or lower or 12.5 or higher Examples of acids that exhibit a pH of 2 or lower include glacial acetic acid Examples of bases that exhibit a pH of 12.5 or higher include Potassium Hydroxide and Sodium Hydroxide. Generation of corrosive pharmaceutical wastes is generally limited to compounding chemicals in the pharmacy

**Reactivity D003 (40 CFR Part 261.23)**

Reactive wastes are unstable under "normal" conditions. They can cause explosions, toxic fumes, gases, or vapours when heated, compressed, or mixed with water Examples include Clinatest (a test tablet to determine sugar in urine). While nitro-glycerine in its pure form is reactive, pharmaceuticals containing nitroglycerin are too weak to react and have been excluded from the reactive classification federally and in Florida.

**Toxicity; Multiple D Codes (40 CFR Part 261. 24)**

Wastes are toxic if they contain toxic organic chemicals or certain heavy metals, such as chromium, lead, mercury, or cadmium. Approximately 40 chemicals meet specific leaching 12 concentrations which classify them as toxic. Toxic D-listed chemicals used in drug formulation are shown in table 4. Forty chemicals have been included in RCRA as a concern in a solid waste landfill environment above certain concentrations. Wastes that exceed these concentrations must be managed as hazardous waste.

**1. NON-HAZARDOUS WASTE**

Materials in this category are considered to present no significant hazardous properties. It is worth noting, however, that this is not an indication that there are no hazardous components present, only that any such components are below the threshold for causing harm to human health. Importantly, this non-hazardous state is subject to change and the addition or removal of specific items from the waste stream may significantly alter the management options available.

Pharmaceutically inert: Certain medicinal products have no pharmaceutical properties but are still controlled and administered by medical staff (examples include sodium chloride or dextrose solutions). Through use, however, these products may become contaminated, or mixed with other compounds and therefore require assessment for hazardous properties prior to disposal.

**Difference between Hazardous Waste and Non Hazardous Waste:1**

Hazardous Waste	Non Hazardous Waste
Hazardous waste is waste that harmful to human health or the environment if improper disposed it. 9	Non Hazardous waste is waste which does not directly harm to human health or the environment, but it cannot dump in sewer line because of risk.9
Hazardous waste contains Explosive, Flammable Liquids/Solids, Poisonous, Toxic, Ecotoxic, Infectious Substances.10	Non Hazardous waste contains paper, plastic, metals, glass etc.9
The Hazardous waste regulated under the Resource Conservation and Recovery Act (RCRA).9	The non Hazardous waste regulated under state and local governments through the federal government.
It can be produced from companies and households as well as worksites.	This can be produced from general household waste like food or bathroom rubbish and recycling, and from industrial or agricultural sources.11
There are two types of Hazardous waste:- Listed and Characteristics waste.9	Disposal method of non Hazardous waste is vary because of different types of waste and various regulations governing them.9
Examples:- pesticides, herbicides, paints, industrial solvents, fluorescent light bulbs and mercury- containing batteries.9	Examples:- Agricultural waste, Batteries, Construction debris, Industrial waste, Medical waste, Municipal solid waste, Scrap tires, Special wastes.9

**2. CHEMO WASTE**

Chemo wastes are further classified as trace chemotherapy and bulk chemotherapy waste. Trace Chemotherapy Waste The federal RCRA regulations do not address trace chemotherapy waste. There is no recognized distinction between bulk and trace chemotherapy contamination for P- and U-listed hazardous wastes since there isn't a lower concentration limit under which these wastes can exit the regulatory system. Most state regulated medical waste regulations are either silent or not specific on the definition of trace chemotherapy waste. The original reference to segregating trace chemotherapy waste is found in an article written in 1984 by pharmacy personnel at the National Institutes of Health who pioneered applying the RCRA regulations to antineoplastic wastes.<sup>13</sup> California's Medical Waste Management Act and Wisconsin's Medical Waste Rules identify trace chemotherapy waste and require incineration at a regulated medical waste facility or other approved treatment method.

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Fig :-Trace Chemotherapy Waste

**Bulk Chemotherapy Waste**

One chemotherapy agent is a P-listed constituent of concern and eight chemotherapy agents are U- listed. Trace chemotherapy containers have long been used to discard listed chemotherapy drug waste that should be managed as hazardous waste. This is not only illegal but also inappropriate since trace chemotherapy waste is incinerated at an RMW incinerator, hazardous waste incinerator. RMW incinerators have less restrictive emissions limits and permit requirements. Discarding "bulk P- or U- listed chemotherapy agents as trace chemotherapy waste has been the cause of substantial enforcement actions and fines and should be one of the first changes you implement in your pharmaceutical waste management program.

**Importance of Pharmaceutical Waste Disposal:**

- Almost everyone has been goes to a hospital or a clinic at some point during their lives. These hospitals or clinics, even the smallest of them, use hundreds or sometimes even thousands of pharmaceuticals in a day. Have you ever wondered where much of this pharmaceutical waste goes
- Pharmaceutical waste is quite hazardous. It is totally different from regular waste and therefore special measures are required to dispose of it properly. It is a combination of different types of wastes that are generated in a medical facility. In most hospitals, this waste is usually drained with the exception of certain agents, which require being put into a waste incinerator. The proper disposal of pharmaceutical waste is of such great importance that there have been strict laws passed for it.
- Due to the harmful nature of the type of waste, there are specific methods used for their disposal. In addition to that, new methods always keep replacing the old ones to ensure safety and reduce the hazardous factor

involved in its disposal. Let us now go through some further reasons why it is extremely important to dispose of pharmaceutical waste properly.

- One of the basic reasons why this kind of waste must be disposed of properly is because it contains compounds that are considered a risk to a healthy environment. Furthermore, since most pharmaceutical chemicals do not get removed from the waste-water, they tend to enter aquatic environments via the sewage system. This sometimes goes on to affect the marine animals, potentially bringing harm to human beings via food chains.
- One of the most horrible aspects of not disposing off the pharmaceutical waste properly is that it can, and unfortunately has been, affecting several water sources. In fact, this has been the case for over four decades now. This can cause serious illnesses to people using those water sources.
- Among the greatest issues of not disposing of the waste-water from pharmaceutical waste properly is the affect it is having on wildlife. In fact, it is even being feared that the improper disposal of pharmaceutical waste may even lead to some fish going wiped out due to the difficulties they are facing in reproduction.
- The threat that improper pharmaceutical waste is posing is quite intense. These wastes are entering the environment through several different routes including landfill seepage, waste water and sewer lines. This is why it is completely important to make sure they are disposed of and in the safest way possible.

#### **Types of Healthcare Wastes or Pharmaceutical Wastes:<sup>1</sup>**

Communal wastes and biomedical wastes are known as “general health care wastes” and “hazardous health care wastes” or “health care risk wastes” or “special wastes” respectively.

Biomedical wastes are further classified as follows

- Infectious waste
- Pathological waste
- Genotoxic waste
- Chemical waste
- Wastes with high content of heavy metals
- Radioactive waste
- Pharmaceutical waste

#### **Infectious Waste:**

Pathogens such as bacteria, viruses, parasites or fungi are suspected to be present in infectious wastes that cause diseases in weak hosts when present in sample concentrations. They are further including:

Microbial cultures, stocks of infectious agents from pathological laboratories as well as wastes produced during the procedures carried on infected patients (disposable towels, gowns, aprons, gloves, etc.)

Tissues and materials or instruments that have been used during surgeries and autopsies on patients suffering from infectious diseases

#### **Pathological Waste:**

Tissues, human carcasses, blood and body fluids, body parts, human fetuses, etc. are all part of pathological wastes. They are also termed as anatomical wastes and usually considered as a subcategory of infectious wastes. Sharps include items like knives, broken glasses, hypodermic needles scalpel, etc. which could cause cuts or induce wounds. They are considered highly hazardous though infected or not.

#### **Genotoxic Waste:**

Genotoxic wastes generally include items that can induce carcinogenicity, teratogenicity or mutagenicity and usually create severe problems. Such wastes should be disposed of with decisive attention and caution. Cytotoxic drugs form a major part of this category. These drugs are utilized in the chemotherapy of cancer. Oncology and radiotherapy units are the departments where these drugs are used and their utilization has been increasing day by day. Some of the

drugs that are genotoxic are listed below. Drugs like Chlorambucil, Azathioprine, Cyclosporin, etc. are carcinogenic and drugs like Carmustine, Lomustine, Daunorubicin, Doxorubicin, Phenobarbital, Phenytoin, Chlornaphazine, Niridazole, Oxazepam, Phenacetin, etc. are probably carcinogenic.

**Chemical Waste:**

Wastes such as solid, liquid or gaseous chemicals that are discarded from the laboratories or other experimental units could be considered as chemical wastes. Chemical wastes are considered hazardous if they have at least one of the following properties:

- toxic
- corrosive
- flammable
- reactive genotoxic

Also, chemical wastes such as sugars, amino acids, and certain organic and inorganic salts are considered as non-hazardous since they do not possess any of the above mentioned properties. The examples of hazardous chemical wastes that are most commonly used in healthcare centers and hospitals are as follows:

- Solvents such as Chloroform, Methanol, Acetone, Acetonitrile, Formaldehyde, etc.
- Photographic chemicals such as 5-10% hydroquinone, 1-5% potassium hydroxide, 45% glutaraldehyde, acetic acid, etc.
- Organic chemicals such as disinfectants, oils, insecticides, rodenticides, etc. and inorganic chemicals such as acids and alkalis like sulfuric acid, hydrochloric acid, sodium hydroxide, ammonia solutions, oxidizing agents such as potassium permanganate and reducing agents like sodium sulfite, etc.

**Wastes with high content of heavy metals: <sup>5</sup>**

The main sources of heavy metals in the biomedical wastes are constituted of garden pesticides, pharmaceuticals, personal healthcare products, mercury wastes from broken clinical equipments etc. Wastes with heavy metal content are usually highly toxic and leach into soil which contaminates the soil with heavy metals like lead, copper, zinc, etc.

**Radioactive Waste:**

The biomedical wastes containing radioactive substances include unwanted solutions of radionuclide's intended for diagnostic or therapeutic use, waste from spills and decomposition of radioactive spills.

**Pharmaceutical Waste:**

Expired drugs as well as unused, spilt and contaminated pharmaceutical items including vaccines, sera that are no longer in use are supposed to be disposed of in an appropriate manner. Pharmaceutical wastes may also consist of packaging materials that are in contact with the drugs products such as glass bottles, aluminum packs, etc

**Sources of Pharmaceutical Wastes:**

Pharmaceutical wastes have been present in the environment since decades but they have been quantified recently by the researchers.

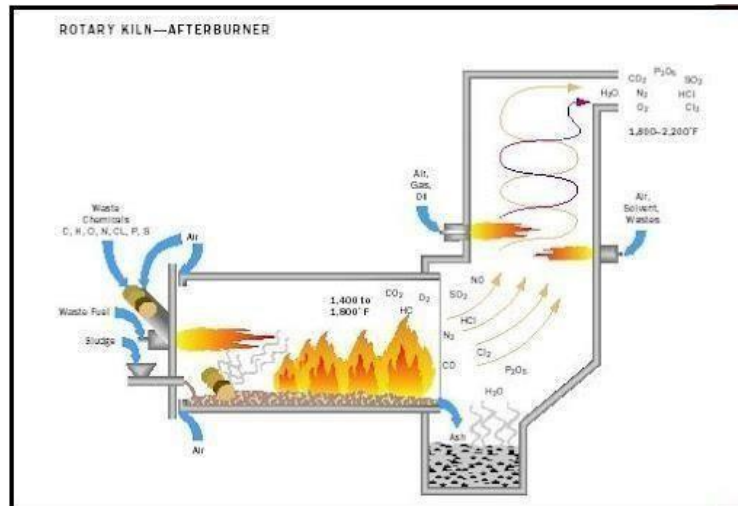
- Wastes from hospitals and dispensaries
- Wastes disposal from pharmacies
- Household wastes containing unused and expired drugs
- Defective landfills causing leaching of drugs
- Direct and improper disposal of unused/expired medications by patients in to the waste and also through excretion of urine or feces
- Drugs released from sources like aqua culture medicated feed, molecular farming, pest control drugs, etc.
- Even in many developing countries like India the physician samples which are given by companies to medical representatives for sales promotion purpose.

**III. METHODOLOGY :<sup>1</sup>**

**PHARMACEUTICAL WASTE TREATMENT AND DISPOSAL**

Pharmaceutical Waste Treatment and Disposal Technologies Specified in India's Pharmaceutical Waste Rules

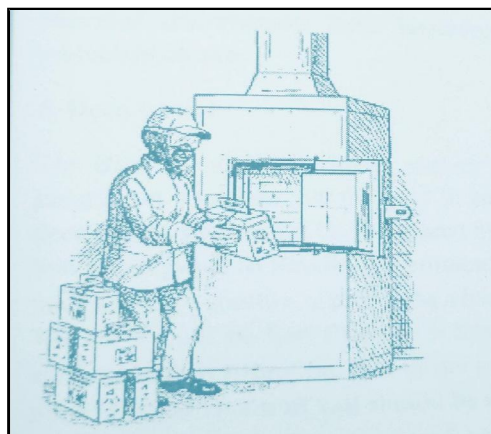
**Incineration**



Incineration is a disposal method in which solid organic wastes are subjected to combustion so as to convert them into residue and gaseous products. This method is useful for disposal of residue of both solid waste management and solid residue from waste water management. This process reduces the volumes of solid waste to 20 to 30 percent of the original volume. Incineration and other high temperature waste treatment systems are sometimes described as "thermal treatment".

Incinerators convert waste materials into heat, gas, steam and ash. Incineration is carried out both on a small scale by individuals and on a large scale by industry. It is used to dispose of solid liquid and gaseous waste. It is recognized as a practical method of disposing of certain hazardous waste materials [such as biological medical wastes]. Incineration is a controversial method of waste disposal, due to issues such as emission of gaseous pollutants. Incineration is not suitable for such health care wastes as pressurized gas containers, large amounts of reactive chemical wastes, wastes treated with halogenated chemicals, halogenated plastics such as polyvinyl chloride, wastes with mercury or cadmium (such as broken thermometers, used lead or mercury batteries, or radiographic wastes). Incinerators that meet the CPCB draft incineration regulations must have a sophisticated (for example, double-chamber) design and include a scrubber as the air pollution control equipment. Ash from these incinerators must be disposed of in a secure landfill such incinerators are associated with high investment and operating costs and require highly skilled operating personnel.

**Autoclaving**



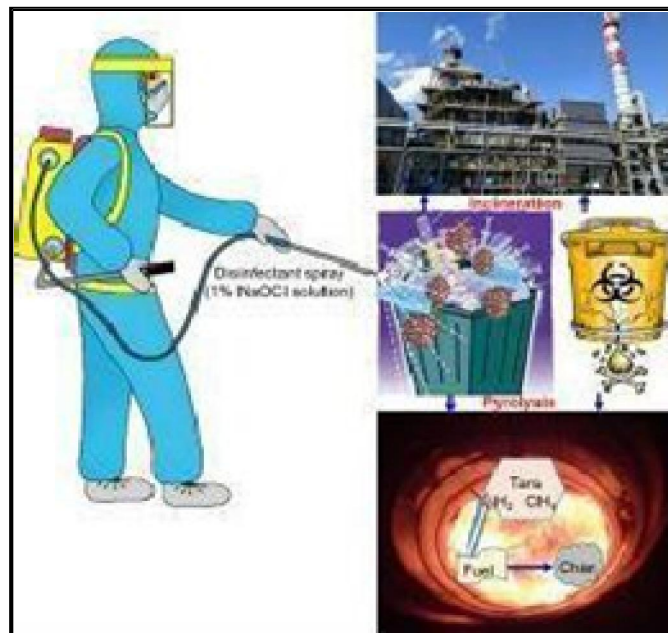


Autoclaving uses saturated steam in direct contact with the BMW in a pressure vessel at time lengths and temperatures sufficient to kill the pathogens. The Biomedical Waste Rules specify the minimum temperature, pressure, and residence time for autoclaves for safe disinfection. Autoclaving is not suitable for human anatomical, animal, chemical, or pharmaceutical wastes before autoclaving, BMWs require shredding to an acceptable size, an operation that would involve frequent breakdown. Autoclaving produces a waste that can be land filled with municipal waste. A wastewater stream is generated that needs to be disposed of with appropriate controls. Autoclave operation requires qualified technicians, and medium investment and operating cost.

**Microwaving**

Application of an electromagnetic field over the BMW provokes the liquid in the waste to oscillate and heat up, destroying the infectious components by conduction. This technology is effective if the ultraviolet radiation reaches the waste material. Before microwaving BMWs require shredding to an acceptable size and humidification. Microwaving is not suitable for human anatomical, animal, chemical, or pharmaceutical wastes, or for large metal parts. Microwaving produces a waste that can be land filled with municipal waste. The advantages of this treatment technology are its small electrical energy needs and no steam requirement. The disadvantages include the need for qualified technicians and frequent breakdown of shredders. This technology requires medium investment and operating costs.<sup>8</sup>

**Chemical disinfection**



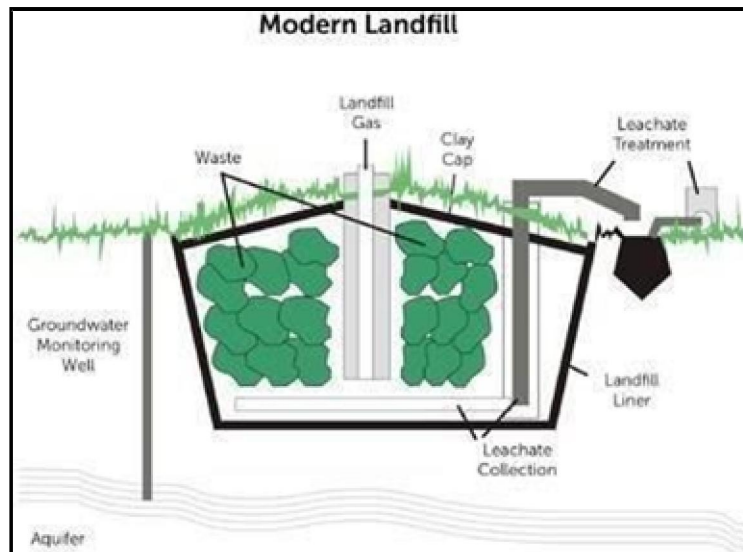
Chemical disinfection is most suitable for treating liquid wastes such as blood, urine, stools, or health care facility sewage. Addition of strong oxidants-like chlorine compounds, ammonium salts, aldehydes, or phenol compounds-kills or inactivates pathogens in the BMW. However, microbiological cultures, mutilated sharps, or shredded solids can also be treated by chemical disinfection. Disinfection efficiency depends on such factors as the type and amount of chemical used, and the extent and duration of contact between the disinfectant and the BMW. As chemical disinfectants have hazardous (in particular, toxic) properties, users should wear protective clothes.<sup>9</sup>

**Deep burial**



The Biomedical Waste Rules require that human anatomical and animal wastes in cities with population less than 500,000 and in rural areas be disposed of by deep burial. Accordingly, the deep burial site should be prepared by digging a pit or trench of about 2 meters deep in an area that is not prone to flooding or erosion, and where the soil is relatively impermeable, there are no inhabitants or shallow wells in the vicinity, and the risk to surface water contamination is remote. The pit should be half-filled with the BMW, and then covered with lime within 50 cm of the surface, before filling the rest of the pit with soil. On each occasion when BMW is added to the pit, a layer of 10 cm of soil should be added to cover the waste.

**Secure land filling**



land filling involves disposal of solid BMWs at a landfill designed and operated to receive hazardous wastes. The Biomedical Waste Rules require disposal of discarded medicines, cytotoxic drugs, solid chemical wastes, and incineration ash in secured landfills.

Disposing of waste in a landfill involves burying the waste, and this remains a common practice in most countries. Landfills were often established in abandoned or unused quarries, mining voids or borrow pits. A properly designed and well-managed landfill can be a hygienic and relatively inexpensive method of disposing of waste materials. Older,

poorly designed or poorly managed landfills can create a number of adverse environmental impacts such as wind-blown litter, attraction of vermin, and generation of liquid leachate. Another common by-product of landfills is gas (mostly composed of methane and carbon dioxide), which is produced as organic waste breaks down anaerobically. This gas can create odour problems, kill surface vegetation, and is a greenhouse gas. Design characteristics of a modern landfill include methods to contain leachate such as clay or plastic lining material. Deposited waste is normally compacted to increase its density and stability, and covered to prevent attracting vermin (such as mice or rats). Many landfills also have landfill gas extraction systems installed to extract the landfill gas. Gas is pumped out of the landfill using perforated pipes and flared off or burnt in a gas engine to generate electricity.

**HAZARDOUS WASTE MANAGEMENT**

**Waste minimization**

An important method of waste management is the prevention of waste material being created, also known as waste reduction. Methods of avoidance include reuse of second-hand products,

Repairing broken items instead of buying new. designing products to be refillable or reusable (such as cotton instead of plastic shopping bags), encouraging consumers to avoid using disposable products (such as disposable cutlery), removing any food liquid remains from cans, packaging, and designing products that use less material to achieve the same purpose (for example, light-weighting of beverage cans).

**Re-use**

Means the use of a product on more than one occasion, either for the same purpose or for a different purpose, without the need for reprocessing. Re-use avoids discarding a material to a waste stream when its initial use has concluded. It is preferable that a product be re-used in the same state e.g. returnable plastic pallets, using an empty glass jar for storing items and using second hand clothes. Reuse is normally preferable to recycling as there isn't the same requirement for the material to have gone through a detailed treatment process thus helping to save on energy and material usage.

**Recycling**



Recycling involves the treatment or reprocessing of a discarded waste material to make it suitable for subsequent re-use either for its original form or for other purposes. It includes recycling of organic wastes but excludes energy recovery. Recycling benefits the environment by reducing the use of virgin materials.

Many different materials can be recycled. Waste materials can either be recycled for use in products similar to their original use (e.g., paper recycling) or can be recycled into a product which is different than the original use (e.g.,

recycling plastic bottles into fleece jackets or using construction and demolition waste as road aggregate. In the EU up to 13% of municipal waste is recycled.



Fig: Recycling waste material2

### Energy recovery

The energy content of waste products can be harnessed directly by using them as a direct combustion fuel, or indirectly by processing them into another type of fuel. Thermal treatment ranges from using waste as a fuel source for cooking or heating and the use of the gas fuel (see above), to fuel for boilers to generate steam and electricity in a turbine. Pyrolysis and gasification are two related forms of thermal treatment where waste materials are heated to high temperatures with limited oxygen availability. The process usually occurs in a scaled vessel under high pressure. Pyrolysis of solid waste converts the material into solid, liquid and gas products. The liquid and gas can be burnt to produce energy or refined into other chemical products (chemical refinery). The solid residue (char) can be further refined into products such as activated carbon. Gasification and advanced Plasma gasification is used to convert organic materials directly into a synthetic gas (syngas) composed of carbon monoxide and hydrogen. The gas is then burnt to produce electricity and steam. An alternative to pyrolysis is high temperature and pressure supercritical water decomposition (hydrothermal monophasic oxidation).

Steps that should be followed to manage pharmaceutical wastes: Step 1:- Establish a pharmacy management plan

Step 2:- Identify your hazardous and non-hazardous wastes Step 3:- Implement best management practices

Step 4:-Determine your waste generator status

Step 5:-Comply with guidelines for transport and disposal

## IV. FUTURE SCOPE

Scope of Pharmaceutical Waste Management

1. Regulatory compliance: Adhering to local, national, and international regulations, such as the Resource Conservation and Recovery Act (RCRA) and the Hazardous Waste Management Rules.
2. Waste minimization and reduction: Implementing strategies to reduce waste generation, such as process optimization and recycling.
3. Proper waste disposal: Ensuring safe and environmentally responsible disposal of pharmaceutical waste, including incineration, landfilling, and recycling.
4. Employee training and awareness: Educating personnel on proper waste handling, storage, and disposal procedures.
5. Waste tracking and documentation: Maintaining accurate records of waste generation, storage, and disposal.
6. Environmental monitoring: Conducting regular environmental monitoring to detect potential contamination.
7. Community engagement and education: Raising awareness among the public about the importance of proper pharmaceutical waste management.

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