



Pharmaceutical Waste Management: Significant for Health of Nature and Future

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ABSTRACT

Pharmaceutical waste management is an important part in pharmaceutical industries and health care system. Health care waste is currently major issue around the world. Waste generated from medical is hazardous, infectious. That's why proper management of waste is required to protect environment, general public and healthcare workers. Biomedical waste includes discarded blood, used bandages, unwanted microbial cultures, discarded gloves, animal or human tissue and body fluids. Because of the dangers, pharmaceutical waste cannot be disposed of like conventional waste and requires special handling, whether it comes from a hospital, clinic, pharmacy, or private household. Different regulatory bodies are participating to prevent pharmaceutical pollutions such as environmental protection organizations, law enforcement agencies, waste management agencies and governmental agencies. In this article we include types of pharmaceutical wastes, regulatory bodies which are primarily involved in waste management and waste management strategies and principally the effective methods for the management and disposal of pharmaceutical wastes.

Keywords: Pharmaceutical waste, biomedical waste, pollutions, regulatory bodies, management.

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INTRODUCTION

Pharmaceutical waste can result from many activities and locations in a healthcare facility. If you have a compounding pharmacy on site, it generates drug waste. Anywhere medicines are employed can be the site of spills, half-used bottles, IV equipment with residual medicine on it. Waste drugs or pharmaceuticals can pose a special treatment and management challenge. Small quantities at households can often be thrown away in the municipal waste stream (perhaps with some makeshift method of denaturing or making the drugs undesirable to interlopers). Large quantities kept at pharmacies, distribution centers, hospitals, etc. must be managed to minimize the risk of release or to exposure to workers and the public. This category of waste includes expired, unused and contaminated pharmaceutical products including vaccines and biological products used for therapy. Prescription and over-the-counter drugs end up as pharmaceutical waste as does belongings used in pharmacies: gloves, masks, bottles, etc.

In the past, health care facilities would routinely flush waste pharmaceuticals down the drain. As a society we did not know how harmful these drugs would be to the environment. Now biologists have found remaining pharmaceuticals in fish and the aquatic ecology and we

understand how bad the unprocessed disposals of drugs are. As responsible citizens and waste managers, we need to keep the preventive principle in mind. Pharmaceutical wastes can be hazardous under RCRA, but in many cases they are not. Solid pharmaceutical waste is generally easy to handle and package, but liquid waste poses more challenges in confining the waste and minimizing risk of release.

Unused medicines in their original packages can often be returned to the supplier you bought it from. This is win-win. You don't have to dispose of the drugs as waste and someone else who needs the medicine can use it.¹

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.²

Types of Healthcare Wastes or Pharmaceutical Wastes:

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:^{3, 4}

1. Infectious waste
2. Pathological waste
3. Genotoxic waste
4. Chemical waste
5. Wastes with high content of heavy metals
6. Radioactive waste
7. Pharmaceutical waste

1. 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.

2. 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.

3. 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, Ciclosporin, etc. are carcinogenic and drugs like Carmustine, Lomustine, Daunorubicin, Doxorubicin, Phenobarbital, Phenytoin, Chlornaphazine, Niridazole, Oxazepam, Phenacetin, etc. are probably carcinogenic.

4. 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.

5. Wastes with high content of heavy metals: ⁵

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.

6. 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.

7. 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: ⁶

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.
7. Even in many developing countries like India the physician samples which are given by companies to medical representatives for sales promotion purpose.

Pharmaceutical Waste Management and Disposal Methods: ⁷

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

1. Incineration:

Incineration is disposal method in which solid wastes undergoes combustion so it converts them into gaseous products and residue. This method is useful for disposal of solid waste management and waste water management contains solid waste. In this process around 20 to 30 percent of volume reduces from its original volume. It is also known as thermal treatment. Waste materials are converted into heat, gas, steam and ash by incinerators. Incineration is carried out on small scale and large scale by industry. It is used to dispose solid, liquid and gaseous waste. It is recognized as practical method of disposing of hazardous waste materials. It is dissent method of disposal of waste because it emits gaseous pollutants. Incineration is not suitable for pressurized gas containers, large amount of chemical wastes; waste treated with halogenated chemicals, plastic materials contains halogens such as polyvinyl chloride, wastes with mercury and cadmium or radiographic wastes. Ash from incinerators must be disposed in secure landfills. Highly skilled operator associated for this technique.

2. Autoclaving:

In this technique bio medical waste is directly contact with saturated steam in pressure vessel at specific time and temperature to kill pathogens. For safe disinfection BMW make some rules as minimum temperature, pressure, and residence time of autoclave. Autoclaving produces waste that can be land filled with municipal waste. A wastewater stream is generated that needs to be disposed of with appropriate controls. A qualified technician is required for operating autoclave with medium investment and operating cost.

3. Microwaving:

Electromagnetic field applied to destroy infectious component in BMW by conduction. This method is effective when UV radiation reaches BMW. This method is not suitable for human anatomical, animal, chemical, pharmaceutical waste and large metal parts. Microwaving method required small electrical energy and waste produced by this method can be land filled. Advantage of this technology is economic; require medium investment and low operating cost.

The disadvantage contains this method required qualified technicians and frequent breakdown of shredders.

4. Chemical disinfection:

This method is mostly used for treating liquid waste like blood, stools, urine, strong antioxidant, aldehyde and phenol compounds, it kills or inactivate microorganism. Microbiological culture, mutilated sharps, shredded solid



etc are also disinfected by chemical disinfection method. Efficacy of disinfectant depends on time of interaction with waste, concentration of chemical, type of chemical. Chemical disinfection is toxic hence it is not discharge in surface water and not large quantity allowed in sewers. Care should be taken by user during disinfection procedure as its lead to hazardous effects.⁸

5. Deep burial:

According to biomedical waste rule cities with population less than 5,00,000 and in rural areas waste should be disposed by deep burial. Site for deep burial should prepare by digging or trench of 2 m deep. The area should not susceptible to flooding or erosion. Biomedical waste should fill half of the height of pit, then it is covered by lime within 50 cm of surface, remaining pit is filled with soil. Every time when waste is added to the pit soil should added to cover pit.

6. Secure land filling:

Deposited waste is normally compacted to increase its density and stability, and covered to prevent attracting vermin (such as mice or rats). Biomedical waste rule states that disposal of discarded medicines, cytotoxic drugs; solid chemical waste and incineration ash is secured landfills. Secure land filling is disposal of solid waste and hazardous substance by land filling. Most of countries use secure land filling method for disposal of biomedical waste. Landfills done in unused land which is away from city. Properly designed and well managed land filling is effective, hygienic and economic method. Improper management can cause hazardous effects on environment. One of the disadvantages of this method is byproduct which is gas mostly methane or carbon dioxide. When organic waste breakdown an aerobically the gas is produced. Gas can create odour problem, it is greenhouse gas. Modern method of land filling includes leachate such as clay and plastic lining material. Some techniques include extraction of gas from landfill. Gas is pumped out of the land using perforated pipes which is used to generate electricity.

7. Waste immobilization: encapsulation:

Method involves plastic or steel drum in which pharmaceutical solid waste is immobilized. Drums should be cleaned thoroughly; they should not contain any hazardous or explosive material. Drums are filled with 75% capacity with solid or semi solid. Remaining 25% space filled with medium such as cement, plastic foam, cement /lime mixture or sand. When drums are filled to their capacity (75%), mixture of lime, cement and water add in proportion of 15:15:5 (by weight) then drum filled to its capacity. Sometimes more water is added to adjust the consistency of mixture. Steel drum is sealed by seam or spot welding. Sealed drums placed at the base of landfill and drums are covered with fresh Municipal solid waste.

8. 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 pharmaceutical materials are then ground and a mix with 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 process is relatively cheap and can be carried out with simple equipment. The main requirements are a grinder or road roller to crush the pharmaceuticals, a concrete mixer, and supplies of cement, lime and water.

9. Sewer:

Some pharmaceuticals like liquid for eg. Syrups and IV fluids which are diluted with water and flushed into sewers in small amount over period of time without serious public health or environment affect. Small quantities of diluted liquid pharmaceuticals or antiseptics flushed in fast flowing watercourses. The assistance of a hydro geologist or sanitary engineer may be required in situations where sewers are in disrepair or have been war damaged.

Biomedical Waste and Its Classification:

The solid or liquid waste that generated in the diagnosis, treatment of immunization of human beings or animals or in the production or testing of biological material is known as biomedical waste. As maintained by World Health Organization (WHO) estimates 85% of hospital waste which is non hazardous and around 10% is infectious while the remaining 5% is non infectious but it contains some amount of chemicals like methyl chloride and formaldehyde. Here the main trouble of infectious waste is the transmission of HIV and Hepatitis B or C viruses. Hence disease transmitted through needles and syringes.

The main sources of biomedical wastes in health care facilities include wards, delivery rooms, emergency and out-patient services, operation theaters, laboratories, and pharmaceutical and chemical stores. Due to BMWs some persons at risk of exposure include health care facility employees (doctors, nurses, health care assistants, maintenance personnel, and support personnel for waste handling, transportation, and laundry), patients and their visitors, and waste management facility employees and scavengers.

Difference between Hazardous Waste and Non Hazardous Waste:

Hazardous Waste	Non Hazardous Waste
1) Hazardous waste is waste that harmful to human health or the environment if improper disposed it. ⁹	1) 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
2) Hazardous waste contains Explosive, Flammable Liquids/Solids, Poisonous, Toxic, Ecotoxic, Infectious Substances. ¹⁰	2) Non Hazardous waste contains paper, plastic, metals, glass etc. ⁹
3) The Hazardous waste regulated under the Resource Conservation and Recovery Act (RCRA). ⁹	3) The non Hazardous waste regulated under state and local governments through the federal government.
4) It can be produced from companies and households as well as worksites.	4) This can be produced from general household waste like food or bathroom rubbish and recycling, and from industrial or agricultural sources. ¹¹
5) There are two types of Hazardous waste:- Listed and Characteristics waste. ⁹	5) Disposal method of non Hazardous waste is vary because of different types of waste and various regulations governing them. ⁹
6) Examples:- pesticides, herbicides, paints, industrial solvents, fluorescent light bulbs and mercury-containing batteries. ⁹	6) Examples:- Agricultural waste, Batteries, Construction debris, Industrial waste, Medical waste, Municipal solid waste, Scrap tires, Special wastes. ⁹

Effect of Pharmaceutical Waste on Environment and Humans:

Pharmaceutical compounds are used for various purposes in modern society but so many toxic contaminants released into environment directly or by chemical modifications by pharmaceutical industries.¹² Pharmaceutical compounds enter in environment by different ways like, discharge of waste water, seepage from landfills sites, sewer lines and animal wastes etc.^{13,14} Also due to various physical and biological process occur in aquatic ecosystem causes reduction of pharmaceutical compounds concentration of human and veterinary pharmaceutical compounds and their metabolites detected in different water sources.^{15, 16, 17} In world Indian pharmaceutical industries are third largest in terms of volume and 14th rank in terms of value. And it is growing at 8 to 9% annually and it worth 4.5 billion dollar. In India speedily growing different industries link pharmaceuticals, chemicals, paints etc. disposes their effluents in to stream directly or after partial treatment.¹⁸

Pharmaceutical compounds reached the environment and considered as pollutants. Many pharmaceutical production facilities were sources of much higher environmental concentration and it may be because of drugs.¹⁹ Huge quantity of wastes generate during pharmaceutical operation and it may be in waste water treatment plant effluents and drinking water sources and it will be harmful to human life and aquatic life.²⁰ There is currently no Bureau of Indian Standard (BIS) / regulations limiting levels of pharmaceuticals in waste water or drinking water. However, the United States Environmental Protection Agency²¹ has added for pharmaceutical compounds, which extensively used by human, to the most recent contaminant.

Pharmaceutical Waste Management in India and Other Countries:**➤ India:**

Economic development in India leads to huge amount of waste generation and its hazardous effect on environment.²² To control and manage the biomedical waste, the biomedical waste management and handling rule 1998 come into force in July 1998. Biomedical waste management rules 2016 were notified by central government. Each state pollution control board responsible to regulate new legislation.²³ This rule is apply to all persons who generate, collect, receive, store, transport, treat, dispose or handle biomedical waste from any form.²⁴ Different schedules and guidelines are mentioned in table 1.

Table 1: Schedule and guidelines

Schedule	Guidelines
Schedule 1	Treatment and disposal of biomedical waste.
Schedule 2	Generated waste is segregated into different containers or bags.
Schedule 3	Containers are labelled.

Regulatory Bodies that Oversee Pharmaceutical Waste Management:²⁵

1. Environmental Protection Agency (EPA)
2. Department of Transportation (DOT)
3. Drug Enforcement Administration (DEA)
4. Occupational Safety and Health Administration (OSHA)
5. State Environmental Agencies,
6. State Pharmacy Boards, and
7. Local Publicly Owned Treatment Works (POTW)



In other countries:**➤ UK:**

In UK biomedical waste is closely regulated by legislation includes Environmental Protection Act 1990, Waste Management Licensing Regulation 1994 and the Hazardous Waste Regulations 2005.²³

➤ United States of America:

US federal government passed the Medical Waste Tracking Act in 1988 which allowed the EPA to establish rules for management of medical waste in some part of country. After 1991 the laws of disposal of medical waste is regulated by individual states. The states vary in regulations.²³ Medical waste management market is highest for US which is then followed by Europe.²⁶ Medical Waste Production in different countries mentioned in table 2.

Table 2: Medical Waste Production in different countries

Country	Quantity (Kg/bed/day)
UK	2.5
US	4.5
France	2.5
Spain	3.0
India	1.5

Examples of Companies of Waste Management:**1. NSWAI:**

National solid waste association of India (NSWAI) is the organization which does solid waste management including biomedical waste, toxic waste and hazardous waste. This organization was formed in 25 January 1996 at New Delhi. This organization helps Ministry of environment and forest in the field of solid waste management.²⁷

- Greenzen Bio Private Limited
- Indian Society of Hospital Waste Management
- Need Innovation
- Top Tech Biomedical
- Ramky Group
- Biotic Waste Solution Pvt.Ltd.²⁸

CONCLUSION

Pharmaceutical waste and biomedical waste are hazardous to health of human and animal also causes serious effects on environment. Pharmaceutical waste management is a challenge to the medical personnel who works in the recycling industries, government administrations, policy planning's, quality assurance, etc., for the effective waste management. The government and non-government organization are concerned towards this issue, and make provisions for disposal of this waste. New classification for medical wastes for their easy removal and effective technique has to be developed in a continuous manner and

it has to be assured that these can reduce the cost of the waste management. All persons involved in health care system like physician, pharmacist and nurses take care of waste disposal. Along with them government, NGOs and public should work together to reduce burden of unused and expired drug in environment. Proper waste management is required to ensure the safety of health and environment.

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