Review Article

Pharmaceutical Waste Management

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ABSTRACT

Since there has been a high demand for production of pharmaceuticals with the increase in the population, the utilization as well as the disposal of the pharmaceuticals has been linearly increasing. The pharmaceuticals and all the raw materials involved in their manufacturing form a huge part of biomedical wastes. Hence, studies were conducted on the sources, consequences and removal of pharmaceutical residues from the environment. The management of Biomedical Waste (BMW) continues to be a major challenge, particularly, in most healthcare facilities of the developing world. Poor conduct and inappropriate disposal methods exercised during handling and disposal of BMW is increasing significant health hazards and environmental pollution due to the infectious nature of the waste. This article summarizes a literature review into types of healthcare wastes produced and leach into the environment and existing BMW management practices in the healthcare centers. The information gathered in this paper has been derived from the desk study of open literature survey. Although, significant steps have been taken on matters related to safe handling and disposal of the biomedical wastes, but improper management practice is evident from the point of initial collection to the final disposal. In most cases, the main reasons of the mismanagement of BMW are the lack of appropriate legislation, lack of awareness and effective control. This review provides an overview on the fate and removal of pharmaceutical compounds by various solid waste treatment methods

Keywords: Wastes, Biomedical waste, Management, Pharmaceutical.

INTRODUCTION

Wastes usually include items that people do not intend to use any longer which they could get rid of or discard by several means. Wastes such as sewage sludge, household garbage, packaging items, electronic wastes, medical wastes from hospitals, slaughterhouse wastes, industrial chemicals, garden waste, etc. arise from a very huge variety of sources. Pharmaceutical waste do not comprise of a single waste stream. These include wastes from distinctive streams that affect the conformity and stability of chemicals mainly involving pharmaceuticals.[1,2]

It is an issue of high risk that involves Pharmaceutical Active compounds that are classified in diverse groups depending on their application and that constitute up to 70% of the chemical compounds in the world. [3]

During the last twenty years, the active pharmaceutical ingredients (API) and personal health care products has an increased detection in the aquatic environment. These compounds enter the environment through various routes. Many APIs being obstinate, these cannot be removed effectively with the help of a waste water treatment plant (WWTP). Drugs like Atenolol and Carbamazepine are not fully biodegraded during the treatment processes and thus have an elimination rates below 10%. [4]

Pharmaceutical contaminants consisting mainly of antibiotics and non-prescription drug were detected in large numbers and are known to produce many adverse consequences like degradation of quality of water, antibiotic resistance as well as endocrine disruption (problems in relation with physical, mental, and sexual development).

Improper management of pharmaceutical wastes ends up having many serious environmental, physical and economical consequences. There has been an increase in the cases of infertility, genital defects, and cancers due to irregulation of hormones Endocrine disrupters found in waterways could have effects that would interfere with normal functioning of the endocrine system (thyroid, adrenals, ovaries, and testicles), mimic hormones, and affect reproduction, development, and behavior and also affect the future generations. Since Antibiotics and Hormones are considered as emerging pollutants due to their presence in the ecosystem and lack of measures of their proper disposal. Many common antibiotics such as penicillin, macrolides, monobactams, tetracyclines, chloramphenicols, cephalosporins, glycopeptides, etc. and Hormones could be of natural origin or produced synthetically, such as estrone (E1), 17b-estradiol (E2), estriol (E3), 17a-ethinylestradiol (EE2), diethylstilbestrol (DES) and progesterone. [6]Table 1.shows examples of the most frequent Pharmaceutical compounds prescribed in human and veterinary medicine. [5]

Pharmaceutical waste from hospitals, clinics and healthcare systems is thrown into the trash or dumped into a sink or toilet which is led into the sewer waste stream. Most sewage and wastewater treatment facilities do not take pharmaceutical contaminants into

consideration and hence these wastes are not biodegraded and eliminated during the treatment.

Pharmaceutical packaging wastes are majorly composed of plastics and metals which are difficult to recycle. Pollution of the environment is also contributed by the presence of PVC wastes. These wastes threaten the life of the incinerators in which they are treated by generating hydrochloric acid gas, dioxins, etc. [6]

Table 1: Most frequently used Pharmaceuticals that are detected in wastewaters. [5]

Therapeutic Use of drugs	Name of drugs
Antibiotics	Sulfonamides: sulfamethoxazole, fluoroquinolones: ofloxacin , ciprofloxacin, bacteriostatic: trimethoprim, Penicillin group: penicillin G
Cardiovascular drugs	Propranolol , atenolol , metoprolol, clofibric acid, gemfibrozil, fezafibrate.
CNS (Central nervous system) drugs	Carbamazepine, cloanzepam, ethosuximide, gabapentine, Caffeine, Bromocriptine, selegiline,
Analgesic/Antipyretics	Acetaminophen , Diclofenac, naproxen, ibuprofen, ketoprofen,
Endocrinology treatments	17α-ethinylestradiol, estrone, 17β-estradiol, estriol

Overview of the Types of Healthcare 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 [1,7]

- Infectious waste
- Pathological waste
- Sharps
- 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 vulnerable hosts when present in ample concentrations. They are further include

- 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

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 carcinogenecity, teratogenicity or mutagenicity and usually create severe problems. Such wastes should be disposed off with ultimate 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.

Chemical wastes

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[8]

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 radionuclides 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 off 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 [9]

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 trash and also through excretion of urine or feces.
- Drugs released from sources like aquaculture 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; Many times we read in local news-paper that such expired/unused drug products found across road side.

Consequences of Improper Disposal of Wastes

Generally, Expired drugs do not pose a serious threat to the environment or other living beings but their improper disposal may lead to contamination of water supplies or other sources in contact with the wildlife. Most of the pharmaceutical drugs become less efficacious after their expiry date and few may even develop into compounds with adverse drug reaction profile.

- Certain antibiotics, antineoplastics as well as some disinfectants that are non-biodegradable may kill the bacteria necessary for the treatment of sewage thus they should not be disposed off into the sewage system or flushed in the watercourses.
- Usually wastes dumped in landfills leach out in aquifers, surface water or drinking water system which contaminates the aquatic systems.
- Toxic pollutants are released when pharmaceutical compounds or other healthcare wastes are burnt at low temperature.
- In some countries scavenging is hazardous in unprotected insecure landfills because expired drugs may come into the hands of scavengers and children.

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)
- State Environmental Protection Agencies,
- State Pharmacy Boards, and
- Local Publicly Owned Treatment Works (POTW)

Methods of Disposal of Pharmaceutical Solid Wastes [10,11]

Various methods for solid pharmaceutical waste disposal are enlisted below

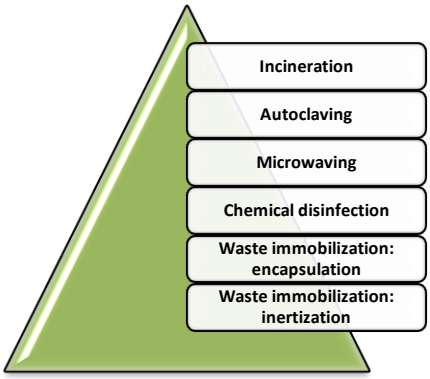

Figure 1: Various methods to treat solid pharmaceutical wastes.

Incineration

The advantages of incineration have led to its use as the preferred means of treating and disposing clinical solid wastes including certain types of pharmaceutical wastes. Incineration is a disposal method in which solid organic wastes are subjected to high temperature dry oxidation so as to convert them into residue and gaseous products. There are a few concerns regarding this method like the risk of infectious micro-organisms produced from the incineration of infectious clinical wastes.

Autoclaving

Saturated steam in direct contact with the Biomedical wastes (BMW) in a pressure vessel at time lengths and temperatures are sufficient to kill pathogens. This theory is used in autoclaving. The minimum temperature, pressure, and residence time for autoclaves are specified in the Biomedical Waste Rules to ensure safe disinfection. Autoclaving is unsuitable for human anatomical, animal, chemical, or pharmaceutical wastes. Before autoclaving, BMWs necessitate shredding to an acceptable size, an operation that would involve frequent breakdown. Autoclaving produces waste that can be land filled with municipal waste. The process generates a wastewater stream that needs to be disposed of with proper controls. Autoclave operation requires qualified technicians, and medium investment and operating cost.

Microwaving

Application of an electromagnetic field over the wastes provokes the liquid in the waste, either by the application of steam or naturally occurring moisture, to oscillate and heat up. This technology is effective only if the ultraviolet radiation reaches the waste material and the infectious components in the waste are destroyed by conduction.

Microwaving produces waste that may be land filled with municipal waste. The disadvantages include the need for qualified technicians and frequent breakdown of shredders and also non affordable to be utilized by the developing countries.

Chemical Disinfection

Chemical disinfection is the most suitable method to treat liquid wastes such as blood, urine, stools, or health care facility sewage. Strong oxidants like chlorine compounds, ammonium salts, aldehydes, or phenol compounds are used in this process which 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 a number of factors such 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 clothing. Care should be taken that these disinfectants do not discharge to surface waters and no large quantities are disposed into sewers.

Waste Immobilization: Encapsulation

The method of encapsulation involves immobilizing the pharmaceutical products in a solid block within a plastic or steel drum which should be cleaned prior to use and should not have contained explosive or hazardous materials previously. These drums are filled up to one-third of their capacity with the pharmaceutical products and the remaining space is filled up with cement or cement lime mixture or bituminous sand. This mixture requires a large quantity of water so that a paste of appropriate liquid consistency should be attained. The drums are then sealed and placed at the base of a landfill and covered with municipal wastes.

Waste Immobilization: Inertization

The method of inertization is a type of encapsulation. This method involves the separation of pharmaceutical products from their packaging materials and then the pharmaceutical products are ground and mixed with cement, lime and water to form a homogenous paste. The paste is then dispersed in an urban waste collection. The paste then solidifies within the municipal solid waste. The process is comparatively inexpensive and do not require any sophisticated instruments or equipments.

CONCLUSION

Pharmaceutical wastes accounts for a huge amount of wastes generated in the environment and the use and disposal of pharmaceuticals in the environment is unavoidable. The management of pharmaceutical wastes

deals with a great challenge since their adequate treatment is quite necessary. Pharmaceutical products that are released in the environment affect the flora and fauna as well as it possess a threat to the human life. The treatment of such wastes should be considered a priority and development of sophisticated techniques are required. There is a need for adopting cost-effective system for providing better pharmaceutical waste treatment and also require the implementation of new system to insure proper waste management and to reduce the amount of waste generation by awareness and education of all concerned.

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