Review Article **ISSN: 2349 – 7106**

Asian Journal of Research in Chemistry and Pharmaceutical Sciences

Journal home page: www.ajrcps.com

AN OVERVIEW ON PHARMACEUTICAL WASTE MANAGEMENT AND WASTE MANAGEMENT STRATEGIES

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ABSTRACT

In pharmaceutical industries the pharmaceutical waste management is an important part. Wastes are the unwanted materials which can no longer be used in the manufacturing processes that can eventually turn into hazardous or non-hazardous material, to humans/environment. Because of the dangers, pharmaceutical waste cannot be disposed of and requires special handling, whether it may come from a hospital, clinic, pharmacy, or private household. Pharmaceutical wastes may be in different forms mainly as strips, expired products, manufacturing wastes etc. 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 paper 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. It is necessary to understand the specific hazards of the waste product in order to safely handle and dispose of waste and the ability of a given disposal technique to manage them. Proper patient counselling on safe medication disposal can make a significant difference to public health and the environment.

KEYWORDS

Pharmaceutical Waste Management, Hazardous materials, Non-hazardous materials and Patient education.

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INTRODUCTON

Wastes are the unwanted or unusable materials that people will no longer use for, which are either intended to get rid of or have already been discarded. Moreover, wastes can be hazardous to human or the environment as such, which has to be discarded immediately, else may cause serious health related problems in human. Waste may includes all items such as people which have no

longer use of it, which they either intend to get rid of or have already discarded. Additionally, because of their hazardous properties waste should be discarded which can cause harm to the people. Many items which are concluded as the waste are household waste, sludge, wastes come from the manufacturing activities, hospital waste etc[1].

The production of waste in vast quantities, it is of vital importance it should be managed in such a way that they does not cause any harm to either human health or to the environment. The different options available for the treatment and management of wastes including prevention, minimization, re-use, recycling, energy recovery and disposal. Safe disposal of these unwanted or expired drugs often creates a major problem[2].

Sources of Entry of Pharmaceuticals into Environment

Pharmaceutical chemicals can enter into the environment such as

From pharmaceutical production industries in developing countries.

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

Dairy waste disposal

Contaminated garments, absorbents and spill cleanup material

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 news-paper that such expired/unused drug products found across road side[3-7].

Pharmaceutical waste is further classified in 3 categories

1. Hazardous waste,
2. Non-hazardous waste,
3. Chemo wast.

Hazardous Wastes

Wastes are called as hazardous waste which are dangerous or potentially harmful to human health or the environment. These can be liquids, solids, contained gases, or sludges.

Hazardous wastes are divided into two categories:

1. Listed wastes, and
2. Characteristic wastes.

Listed wastes should appear at least one of the 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 which exhibit certain hazardous properties - ignitability, corrosivity, reactivity and toxicity should be regulated. Wastes are called as solid waste that are not listed and do not exhibit a characteristic of it. Solid wastes should be discarded according to state and/or local regulations, including regulated medical waste requirements[8].

Listed hazardous waste

P-Listed Pharmaceutical waste

Under RCRA the categorized P-listed wastes are commercial chemical products that are acutely hazardous. One of the primary criteria for including a drug on the P-list as acutely hazardous is an oral lethal dose of 50mg/kg (LD50) or less. LD50 is the amount of a material, which is given at once, they are toxic can cause irreversible illness at low doses can also causes the death of 50% of a group of test animals. The waste should be discarded or intended to be discarded when a drug waste containing a P-listed constituent, it must be managed as hazardous waste if two conditions are satisfied:

1. 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).
2. Empty Containers which come under P-Listed Wastes (40 CFR Part 26):-A container that has held a P-listed waste is not considered “RCRA empty” unless it has been:

a) Triple rinsed, and
b) The rinsate is managed as hazardous waste.

U-Listed Pharmaceutical Wastes

U-listed chemicals comes to a broader range of pharmaceuticals and again it should be the sole active ingredient to come under regulation. There are 21 drugs on the U-list some of them are shown in Table No.2. These chemicals are listed primarily for their toxicity. Similar to a P-listed waste, when a drug waste containing one of these chemicals, it must be managed as hazardous waste if two conditions are satisfied otherwise it should be discarded.

1. The discarded drug waste contains a sole active ingredient that appears on the U list, and it has not been used for its intended purpose.
2. Empty Containers which come under U-Listed Wastes (40 CFR Part 261.7(b) (1)):- A container that has held a U-listed waste is considered "RCRA empty" if two conditions are met:

- All the contents have been removed that can be removed using normal means, such as drawing liquid out with a syringe
- No more than 3% by weight remains.

If the waste doesn't met the both of these criteria, the container must be managed as hazardous waste. Any residues removed from the empty container must be managed as hazardous waste[9].

Non-hazardous waste

Materials in this category doesn't have 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

Medical staff are still controlling and administering certain medicinal products which have no pharmaceutical properties (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[10].

Chemo waste

Chemo wastes are further classified into 2 types they are trace chemotherapy and bulk chemotherapy waste.

Trace Chemotherapy Waste

The federal RCRA regulations do not address trace chemotherapy waste. There is no recognized distinction contamination for P- and U- listed hazardous waste between bulk and trace chemotherapy 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 antineo plastic wastes. Items that are appropriate for management as trace chemotherapy waste include:

- "RCRA empty" vials, syringes, IV bags, and tubing;
- Gowns, gloves, wipes and other paraphernalia associated with routine handling, preparation, and administration of chemotherapy; and,
- Wipes and other materials used during routine cleaning and decontamination of a Biological
- Safety Cabinet or glove box (unless alcohols, phenols or other hazardous materials are used).

Bulk Chemotherapy Waste

In bulk chemotherapeutic waste consists of one chemotherapy agent is a P-listed constituent of concern and eight chemotherapy agents are U-listed. To discard listed chemotherapy drug waste which should be managed as hazardous waste the trace chemotherapy containers have long been used. RMW incinerators have less restrictive emissions limits and permit requirements. The cause of substantial enforcement actions and fines and

should be one of the first changes you implement in your pharmaceutical waste management program is to discard "bulk" P- or U- listed chemotherapy agents as trace chemotherapy waste[2].

Characteristic of waste

EPA established the hazardous waste into four characteristics they are ignitability, corrosivity, reactivity and toxicity.

Ignitability

Wastes that are hazardous due to the ignitability characteristic include liquids with flash points below 60°C, non-liquids that cause fire through specific conditions, ignitable compressed gases and oxidizers. Test methods for ignitability include the Pensky-Martens Closed-Cup Method for Determining Ignitability (SW-846 Test Method 1010A), the Setaflash Closed-Cup Method for Determining Ignitability (SW-846 Test Method 1020B) and the Ignitability of Solids (SW-846 Test Method 1030). To learn more about the ignitability characteristic see:

- 40 CFR section 261.21, and
- The Ignitability Characteristic Background Document.

Identifying wastes that either present a fire hazard under routine storage, disposal, and transportation or are capable of exacerbating a fire once it has started is the main objective of the ignitability characteristic. The waste handle by most of the pharmacies are hazardous because they are ignitable. For the pharmacies these hazardous wastes often pose the greatest management problems. Ignitable wastes are easily combustible or flammable.

Corrosivity

aqueous wastes with a pH of less than or equal to 2, a pH greater than or equal to 12.5 or based on the liquids ability to corrode steel are the waste due to corrosivity characteristic are the hazardous waste. The waste code for hazardous wastes are assigned by EPA is D002. To learn more about the corrosivity characteristic see:

- The regulations at 40 CFR section 261.22, and
- The Corrosivity Characteristic Background Document[9].

Reactivity

In normal conditions the Reactive wastes are in unstable. When they are mixed with water, heated or compressed they can cause explosions, toxic fumes, gases, or vapor. The waste code for reactive hazardous wastes was assigned by EPA D003. There are no test methods for reactivity. To learn more about this characteristic see:

- The regulations at 40 CFR section 261.23, and
- The Reactivity Characteristic Background Document.

Toxicity

Wastes that are hazardous are harmful when ingested or absorbed due to toxicity characteristic. Approximately 40 chemicals meet specific leaching 12 concentrations which classify them as toxic. Toxic D-listed chemicals are used in drug formulation forty chemicals having a concern in a solid waste landfill environment above certain concentrations are included in RCRA. Wastes that exceed these concentrations must be managed as hazardous waste[11].

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)[12].

PHARMACEUTICAL WASTE TREATMENT AND DISPOSAL

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

Incineration

For the disposal of wastes the incineration is the most effective method, so as to convert them into residue and gaseous products the solid organic

waste are subjected to combustion. For disposal of residue of both solid waste management and solid residue from waste water management this method is very useful. By using this process we can reduces the original volumes of solid waste upto 20 to 30 percent. Incineration and other high temperature waste treatment systems are sometimes described as "thermal treatment"[13]. This method is used to dispose of solid, liquid and gaseous waste, which is recognized as a practical method of disposing of certain hazardous waste materials. Incineration is also called as the controversial method of waste disposal, due to issues like emission of gaseous pollutants. Ash from these incinerators must be disposed of in a secure land fill. Such incinerators are associated with high investment and operating costs and require highly skilled operating personnel.

Autoclaving

In autoclaving, saturated steam is in direct contact with the BMW in a pressure vessel at time lengths and temperatures sufficient to kill the pathogens are used for sterilization. In biomedical waste rules Minimum temperature, pressure, and residence time are specified for autoclaves for safe disinfection. BMWs require shredding to an acceptable size before autoclaving which is an operation that would involve frequent breakdown. The waste produced by the Autoclaving 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. Regardless of all the benefits, for human anatomical, animal, chemical, or pharmaceutical wastes autoclaving is not suitable[14].

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. If the ultraviolet radiation reaches the waste material this technology must be more effective. BMWs require shredding to an acceptable size and humidification before microwaving. For human anatomical, animal, chemical, or pharmaceutical wastes, or for large metal parts microwaving is not suitable. Waste produced by microwaving can be land filled with municipal waste. This technology requires medium investment and operating cost[15].

Chemical disinfection

For treating liquid wastes such as blood, urine, stools, or health care facility sewage Chemical disinfection is usable. Addition of strong oxidants-like chlorine compounds, ammonium salts, aldehydes, or phenol compounds-kills orin activates pathogens in the BMW. However, microbiological cultures, mutilated sharps, or shredded solids can also be treated by chemical disinfection[10]. 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.

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 there are no inhabitants or shallow wells in the vicinity, and the risk to surface water contamination is remote the soil must be relatively impermeable[16].

Secure land filling

Secure land filling involves disposal of solid BMWs at a landfill designed and operated to receive hazardous wastes. In most countries disposing of waste in a landfill involves burying the waste, method of disposing of waste materials a properly designed and well managed landfill can be a hygienic and relatively inexpensive[17]. The greenhouse gas can create odour problems, and may kill surface vegetation. The landfill gas is extracted from many landfills throught and fill gas extraction systems. To generate the electricity, gas is pumped out of the landfill using perforated pipes and flared off or burnt in a gas engine.

Waste immobilization: encapsulation

The pharmaceuticals in a solid block within a plastic or steel drum involves immobilization of encapsulation. They should not have contained explosive or hazardous materials previously Drums

should be cleaned prior to use. They are filled with solid and semi-solid pharmaceuticals up to 75% capacity, and the remaining space is filled by pouring in a medium such as cement or cement/lime mixture, plastic foam or bituminous sand[18]. For ease and speed of filling, the drum lids should be cut open and bent back. When placing pharmaceuticals in the drums care should be taken to avoid cuts to the hands. A larger quantity of water may be required sometimes to attain a satisfactory liquid consistency, the drums may be placed on pallets for ease of movement which can then be put on a pallet transporter.

Waste immobilization: Inertization

Removing the packaging materials, paper, cardboard and plastic, from the pharmaceuticals involves the encapsulation of inertization. Pills need to be removed from their blister packs. To form a homogenous paste the pharmaceuticals are then ground and a mix of water, cement and lime are added. If there may be a dust hazard the worker should be protected in the form of protective clothing and masks the solid mass which is a paste is dispersed within the municipal solid waste. The process is relatively inexpensive and can be carried out with unsophisticated equipment[19]. Grinder or road roller to crush the pharmaceuticals, a concrete mixer, and supplies of cement, lime and water are the main requirements.

Sewer

Some liquid pharmaceuticals, e.g. syrups and intravenous (IV) fluids, over a period of time without serious public health or environmental affect they can be diluted with water and flushed into the sewers in small quantities. To flush small quantities of well-diluted liquid pharmaceuticals or antiseptics fast flowing watercourses may be used[14].

Hazardous Waste Management Statergy

Waste minimization

The prevention of waste material being created, also known as waste reduction is an important method of waste management. The amount of waste produced is intended reduced by the set of process called waste minimization[20]. Waste minimization involves redesining products and process and or chanching social pattrens of consumption and production. To promote the sustainable society waste minimization supports by reducing or eliminating the generation of harmful and persistent waste[21].

Reuse

Without the need for reprocessing the product is used more than one occasion, either for the same purpose or for a different purpose is called Reuse. When its initial use has concluded Re-use avoids discarding a material to a waste stream[17].

Recycling

Subsequent reuse of products either for its original form or for other purposes the treatment or reprocessing of a discarded waste material take place is called Recycling. Recycling not only includes the organic wastes but also excludes energy recovery. By reducing the use of virgin materials recycling benefits the environment.

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[22].

S.No	P-listed pharmaceutical waste	Code
1	Arsenic trioxide	P012
2	Epinephrine	P042
3	Nicotine	P075
4	Nitroglycerin	P081
5	Physostigmine	P204
6	Physostigmine salicylate	P188
7	Warfarin	>0.3% P001

S.No	U-listed pharmaceutical waste	Code
1	Chloral hydrate	U034
2	Paraldehyde	U182
3	Chlorambucil	U03
4	Phenol	U188
5	Cyclophosphamide	U058
6	Reserpine	U200
7	Resorcinol	U201
8	Daunomycin	U059
9	Dichlorodifluoromethane	U075

CONCLUSION

Pharmaceutical waste continues to be a new frontier in environmental management for health care facilities. In the recycling industry the management of pharmaceutical wastes poses a great challenge to the policy planners, city administers, medical personnel and workers. It is interdisciplinary in nature, involving pharmacy, nursing, environment services, infection control, quality assurance, risk management, etc. The management of waste is an increasingly complex task with new waste classifications and disposal techniques being developed and released on a continual basis.

ACKNOWLEDGEMENT

The authors are sincerely thanks to the Department of Pharmaceutics, Hindu College of Pharmacy, Amaravathi Road, Guntur-522002, Andhra Pradesh, India for providing the facilities to complete this review work.

CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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Please cite this article in press as: Sravya B *et al.* An overview on pharmaceutical waste management and waste management strategies, *Asian Journal of Research in Chemistry and Pharmaceutical Sciences,* 7(3), 2019, 790-797.