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An overview of waste management in pharmaceutical industry

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Abstract
Pharmaceutical waste management is an important part in pharmaceutical industries. 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. Management of the hazardous wastes is an integral part of pharmaceutical industries. Pharmaceutical wastes are in different forms mainly as strips, expired products, manufacturing wastes etc. It comes from various sectors in the health care system including pharmaceutical developers and manufactures, hospitals, individual physicians and all those who are involved in the health care system. 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.

Keywords: Waste management, hazardous materials, non-hazardous materials, pharmaceutical wastes

1. Introduction
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. Wastes should else be recycled to another useful products. Wastes may be of different forms like household rubbish, sewage, sludge, wastes from manufacturing activities, packaging items, discarded cars, old televisions, garden waste, old paint containers etc. Thus, daily activities may give rise to a large variety of different wastes arising from different sources. This might be developed from households, commercial activities (e.g., shops, restaurants, hospitals etc.), industry (e.g., pharmaceutical companies, clothes manufacturers etc.), agriculture (e.g., slurry), construction and demolition projects, mining and quarrying activities and from the generation of energy.
With such vast quantities of waste production, it is of vital importance that these should be managed in such a way that they does not cause any harm to either human health or to the environment. There are a number of different options available for the treatment and management of wastes including prevention, minimization, re-use, recycling, energy recovery and disposal. Pharmaceutical wastes are of different types mainly hazardous wastes and non hazardous wastes.

1.1 Pharmaceutical Wastes
Pharmaceutical wastes are potentially generated through a wide variety of activities in the health care system, including syringes, and are not limited to intravenous (IV) preparation. Generally Pharmaceutical waste may include:
- Expired drugs
- Patients' discarded personal medications;
- Waste materials containing excess drugs (syringes, IV bags, tubing, vials, etc.);
- Waste materials containing chemotherapy drug residues;
- Open containers of drugs that cannot be used;
- Containers that held acute hazardous waste drugs;
- Drugs that are discarded; and
- Contaminated garments, absorbents and spill cleanup material.

Pharmaceutical waste is further classified in 3 categories:-
1. Hazardous waste,
2. Non-hazardous waste,
3. Chemo waste.

1.1.1 Hazardous Wastes
Wastes that are dangerous or potentially harmful to human health or the environment is called as hazardous waste. These can be liquids, solids, contained gases, or sludges.
Hazardous wastes are divided into two categories:
(1) Listed wastes, and
(2) Characteristic wastes.

Pharmaceutical wastes come under listed wastes since they 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 wastes
should be discarded according to state and/or local regulations, including regulated medical waste requirements.

Ignitability
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. 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
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
Reactive wastes are unstable under "normal" conditions. They can cause explosions, toxic fumes, gases, or vapors when heated, compressed, or mixed with water.

Toxicity
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. Wastes that exceed these concentrations must be managed as hazardous waste.

1.1.2 Non Hazardous Wastes
Materials in this category are considered to present no significant hazardous properties. It is worth nothing, 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 stuffs (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.

1.2 Biomedical Wastes
Biomedical wastes can be briefly defined as any solid or liquid waste that is generated in the diagnosis, treatment of immunization of human beings or animals in research pertaining thereto, or in the production or testing of biological material. According to World Health Organization (WHO) estimates 85% of hospital waste is actually non-hazardous and around 10% is infectious while the remaining 5% is non-infectious but consists of hazardous chemicals like methyl chloride and formaldehyde. Here, the main concern of infectious. Hospital waste is the transmission of HIV and Hepatitis B or C viruses. In this context, Syringes and needles have the highest disease transmission potential. Hospital waste, till recently was not being managed but it was simply 'disposed off'. The disposal of hospital waste can be very hazardous particularly when it gets mixed with municipal solid waste and is dumped in uncontrolled or illegal landfills such as vacant lots in neighboring residential areas and slums. This can lead to a higher degree of environmental pollution, apart from posing serious public health risks such as AIDS, Hepatitis, plague, cholera, etc. The waste produced in the course of health care activities carries a higher potential for infection and injury than any other type of waste.

2. Methodology
Pharmaceutical Waste Management and Disposal:
Pharmaceutical waste management is described in the India's pharmaceutical waste rules which describes various tools for effective management of wastes as follows:

2.1 Incineration
Incineration is an effective method used for disposal of wastes, 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 waste).
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.

2.2 Autoclaving

In autoclaving, saturated steam in direct contact with the BMW in a pressure vessel at time lengths and temperatures sufficient to kill the pathogens are used for sterilization. Minimum temperature, pressure, and residence time for autoclaves for safe disinfection are specified in the Biomedical Waste Rules. Before autoclaving, BMWs require shredding to an acceptable size which is 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. Regardless of all the benefits, autoclaving is not suitable for human anatomical, animal, chemical, or pharmaceutical wastes.

2.3 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. 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.

2.4 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. 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.

2.5 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 pre- pared 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.

2.6. Secure land filling

Secure 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 byproduct 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.

2.7. 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. They are filled to 75% capacity with solid and semi-solid pharmaceuticals, and the remaining space is filled by pouring in a medium such as cement or cement/lime mixture, plastic foam or bituminous sand. For ease and speed of filling, the drum lids should be cut open and bent back. Care should be taken to avoid cuts to hands when placing pharmaceuticals in the drums. Once the drums are filled to 75% capacity, the mixture of lime, cement and water in the proportions 15:15:5 (by weight) is added and the drum filled to capacity. A larger quantity of water may be required sometimes to attain a satisfactory liquid consistency. Steel drum lids should then be bent back and sealed, ideally by seam or spot welding. The sealed drums should be placed at the base of a landfill and covered with fresh municipal solid waste. For ease of movement, the drums may be placed on pallets which can then be put on a pallet transporter.

2.8. 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 pharmaceuticals are then ground and a mix of water, cement and lime added to form a homogenous paste. Worker protection in the form of protective clothing and masks is required as there may be a dust hazard. The paste is then transported in the liquid state by concrete mixer truck to a landfill and decanted into the normal urban waste. The paste then sets as a solid mass dispersed within the municipal solid waste. The process is relatively inexpensive and can be carried out with unsophisticated equipment. The main requirements are a grinder or road roller to crush the pharmaceuticals, a concrete mixer, and supplies of cement, lime and water.

2.9. Sewer
Some liquid pharmaceuticals, e.g. syrups and intravenous (IV) fluids, can be diluted with water and flushed into the sewers in small quantities over a period of time without serious public health or environmental affect. Fast flowing watercourses may likewise be used to flush small quantities of well-diluted liquid pharmaceuticals or antiseptics. The assistance of a hydro geologist or sanitary engineer may be required in situations where sewers are in disrepair or have been war damaged.

Hazardous Waste Management Statergy
2.10. 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).

2.11. Reuse
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.

2.12. 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.
Minimizing pharmaceutical waste:

3. Conclusion
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. 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. New classification for medical wastes for their easy removal and effective technique have to be developed in a continuous manner and it has to be ensured that these can decrease the cost of the waste management. For the reduction of waste materials the authorities must implement different techniques and strategies.

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