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A Review on Solid Waste Management in Pharmaceutical Industry

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ABSTRACT

This paper reviews the complexities of pharmaceutical solid waste management, highlighting the importance of adhering to local regulations and adopting effective disposal methods such as incineration, microwaving, deep burial, secure landfilling, encapsulation, and inertization. Each method presents specific advantages and limitations, from the efficient volume reduction of incineration to the environmental risks of landfilling. It emphasizes the critical role of pharmacists in preventing improper disposal and ensuring safe handling of expired medications. The paper also addresses significant challenges, including inadequate regulatory training, insufficient infrastructure, and environmental contamination issues. Recommendations include enhancing regulatory oversight, improving healthcare professional training, and optimizing packaging to minimize waste, aiming to reduce the environmental and health impacts of pharmaceutical waste.

KEYWORDS: - Pharmaceutical Waste Management, Solid Waste Management, Disposal Methods, Regulatory bodies, Precaution.

INTRODUCTION

Pharmaceuticals wastes are drugs or any other substance that can no longer be used because of being expired, unused, withdrawn, recalled, damaged, contaminated, or for any other reason.⁽¹⁾ Pharmaceutical waste management is an important part in pharmaceutical industries. Wastes are the unwanted materials, which can eventually turn into harmful material, to humans and environment. There are various 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. Management of the hazardous wastes is an integral part of pharmaceutical industries.⁽²⁾ Today the management of solid waste and wastewater is a major concern for humanity.⁽³⁾

Types of waste in pharmaceutical industry Major classification

- Hazardous waste
- Non-hazardous waste
- Chemo waste



Hazardous waste

- The hazardous wastes are waste, which can be dangerous, or potential harmful to human being and environment. This can be solid, liquid or gas. Its subdivided into;
- Listed waste,
- Characteristic waste.⁽⁴⁾

Non-hazardous waste

The non-hazardous wastes are believed that once the producers wrapping is opened, any unutilized or partly used product. Examples include unexploited or relatively used vials, syringes, ampoules, inhalers or bottles; unused or partially used intravenous bags and tubing containing drugs; discontinued medications that cannot be reused; and tablets and capsules that have been unhand or expectorate out by patient.

NOTE: Non-hazardous pharmaceuticals should never be autoclaved.

Chemo waste

The chemo wastes are the waste which can cause cancer to cells. Regulated Medical Waste Incinerators (RMWI) is used for the incineration of pharmaceutical chemo wastes.

These are of 2 types:

- 1. Trace Chemotherapy waste
- 2. Bulk Chemotherapy waste.⁽⁵⁾

Other pharmaceutical wastes

- Expired drugs;
- Waste materials containing excess drugs ;
- Waste materials containing chemotherapy drug residues;
- Open containers of drugs which cannot be used;
- Drugs that are discarded; and

Contaminated garments, absorbents and spill cleanup material.⁽²⁾

Steps of disposing of pharmaceutical waste recommended by the WHO

Here main steps;

Decision: The pharmaceutical industries should determine to dispose of pharmaceutical waste.

Approval: The authorities concerned the authorization to disposal of the pharmaceutical waste. In Kenya, disposal is carried out under the National Environment Management Authority (NEMA) oversight and the PPB. The waste generator should fill out the disposal form appropriately and pay the PPB a fee of 2,500Ksh.In Hong Kong, one has to apply as a chemical waste generator to the Environmental Protection Department (EPD), after which a waste generator number is given to the applicant.

Planning: This is crucial if money, human capital, skills, time, equipment, and methods of disposal are to be made available. The volume of pharmaceutical waste should be estimated at this stage and is determined in weights per quantity using 0.2 metric tons per m³.

Developing working teams: The disposal teams are composed of pharmacists, pharmacist technicians, and pharmaceutical warehouse staff. Conditions of the worksite, composition, and volume of pharmaceutical waste determine personnel size and ratio.

Safety and health work teams: The groups handling disposal should be provided with protective equipment such as masks, gloves, helmets, boots, etc...



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Sorting: Pharmaceutical wastes are available in different pharmacological and dosage forms. Different disposal methods are needed for each of the categories, and some can be safely returned to the supply chain, so it is essential to sort. Pharmaceutical waste should be separated, stored securely, and labelled before disposal.

Disposal: There are several options for waste disposal that should be determined in terms of cost, safety, simplicity, and practicability of the methods.

Record: The record should contain the date and location of destruction, disposal method, pharmaceutical name, dosage form and amount, the value of items, reasons for disposal and name and signature of pharmacist disposing of and a witness before destruction

Security: In dealing with narcotics, psychotropic, and antineoplastic, strict protection and regulation must be maintained to avoid diversion during sorting, scavenging, and pilfering.⁽⁶⁾

Pharmaceutical Waste Management and Disposal:

Incineration

The residue of solid waste management and solid residue from wastewater managements disposed of by this method efficiently. Especially, this process the large volume of solid converted into ashes, which can reduce 20-30% of the original volume. This method is not only for industries but also for small scale by individuals. This method is not suitable for inorganic and metal compound waste like health care wastes as pressurized gas containers, large amounts of reactive chemical wastes, halogenated plastics such as polyvinyl chloride, wastes with mercury or cadmium or radiographic wastes. Incinerators must be designed in manner to control air pollution. Ash from these incinerators must be disposed of in secure landfill.

Autoclaving

Autoclaving used for sterilization. In this method the saturated steam in direct contact with the BMW in a pressure vessel at time lengths and temperatures sufficient to kill the pathogens. The minimum temperature, pressure, and residence time for autoclaves for safe disinfection are listed in the Biomedical Waste Rules. Before autoclaving, BMWs are converted into an acceptable size by an operation that involve frequent breakdown. After autoclaving, the produced waste can be land filled with municipal waste. The autoclaving is not suitable for human anatomical, animal, chemical, or pharmaceutical wastes.

Microwaving

In microwaving, the electromagnetic field is generated over the waste that excites the liquid in the waste to heat up and destroy the infectious substance by conduction. The waste require humidification and tearing into an appropriable size before microwaving. This method is not suitable for large metal parts, chemical, animals and human anatomical waste. The waste generated by the microwaving can be land filled with municipal waste. In this technology, the small electrical energy and no stream is required. Medium operating costs is required for this method.

Chemical disinfection

Chemical disinfection is most suitable method for treating liquid wastes such as blood, urine, stools, or health care facility sewage. Addition of strong oxidants is kills or inactivates pathogens in the BMW. The microbiological cultures, mutilated sharps, or shredded solids can also be treated by this method. Disinfection efficiency depends upon the 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 most of pharmaceutical waste require the method deep burial. The site should be prepared by digging a pit which should be approximately 2.5 meters deep. The area should be remote for surface water contamination. The pit should be half-filled with the waste, and then covered with lime within 50 cm of the surface, before filling the rest of the pit with soil. Between each occasion 10cm of soil should be added to cover the waste, when waste is added to the trench.

Secure land filling

The discarded medicine, cytotoxic drug, solid chemical waste and incineration ash are most conveniently disposed by this method. The land selected for this method should be highly secured. For disposing of waste material, this method should be hygienic, well managed, properly designed. Deposited waste in the land increases vermin such as mice or rats. The gas extraction system also present in many modern landfills for preventing gas formation which creates problems like foul smell, surface vegetation is destroyed and causes evolution of greenhouse gas.

Waste immobilization: encapsulation

The Pharmaceutical solid wastes are inactivating by Encapsulation in a solid block within steel drum or a plastic. The drum should be cleaned and check that it does not contain any hazardous materials or explosive materials previously. 75% of drums are filled with pharmaceutical such as solid or semi-solid and the remaining 25% of drums are filled by pouring in a medium such as cement, plastic foam or bituminous sand. The drum lids should be sealed by welding or seam. The sealed drums should be placed beneath the landfill.

Waste immobilization: Inertization

The inertization is the process of mobilization of packaging materials, cardboard, plastic and paper from the pharmaceuticals. It is an alternative method of encapsulation. A homogenous paste is formed with cement, lime, water and pharmaceuticals. Concrete mixer trucks are used for transport of paste in liquid form. Then the truck is taken to landfill and pour out into the normal urban waste. The liquid form paste then converts into dispersed solid mass within the municipal solid waste. This method is comparatively inexpensive and carried out with unsophisticated equipment.

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.⁽⁷⁾

SOLID WASTE MANAGEMENT

Solid wastes should be discarded according to state and/or local regulations, including Pharmaceutical regulated medical waste requirements.⁽²⁾ Solid waste management has become the center of attention within research and academic circles in recent years due to its paramount importance from environmental, social and economic points of view. Its covers the concept of waste reduction and reuse as well as the processes and technologies of recycling, valorization/recovery, aerobic or anaerobic treatment, thermal treatment with or without energy recovery, fuel production and land filling.⁽⁸⁾ Overproduction is the unfocused experimentation and too many projects. Within a project this refers to experimentation that does not aim to solve project issues. This can be because of lack of diversity and



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flexibility within the company, as well as poor project focus by, for example, technology oriented units. Prioritization can reduce the amount of projects, although it leads to inventory waste. A better approach is to remain committed to a limited amount of projects.⁽⁹⁾ Increasing amounts of organic solid waste production have become a global problem. World production of OSW was 48 million tons in 2009. This amount is estimated to increase by 1.6 fold over the next sixteen years.⁽¹⁰⁾ Industrial solid waste refers to waste generated by the industrial, and on a lesser extent, the institutional sector.⁽⁸⁾ The disposal of untreated pharmaceutical wastes from industries into soil and water bodies produces pollution problems. Enzymes are the main mediators of different degradative processes. Two important hydrolytic enzymes in particular, protease and cellulose, are responsible for the hydrolysis of proteins and cellulose, respectively.⁽¹¹⁾ Pharmaceutical compounds are remaining biologically active for long periods of time, and majority of their metabolites and respective Eco toxicity are either unknown or poorly understood. The pharmaceuticals most often detected in aquatic systems comprise acetaminophen, caffeine, carbamazepine, ibuprofen, and sulfamethoxazole.⁽¹²⁾ A very large quantity of solid waste is generated from extraction processes used in the herbal industry, and is often disposed illegally to the environment.⁽¹³⁾ Recent studies have shown pharmaceutical compounds entering sewage treatment systems are not fully and are discharged to the aquatic environment.⁽¹⁴⁾

Method used for treatment of pharmaceutical solid wastes Management of organic pharmaceutical solid waste: Incineration

The residue of solid waste management and solid residue from waste water management is disposed of by this method efficiently. Especially, this process the large volume of solid converted into ashes which can reduce 20-30% of the original volume. This method is not only for industries but also for small scale by individuals. This method is not suitable for inorganic and metal compound waste like health care wastes as pressurized gas containers, large amounts of reactive chemical wastes, halogenated plastics such as polyvinyl chloride, wastes with mercury or cadmium or radiographic wastes. Incinerators must be designed in manner to control air pollution. Ash from these incinerators must be disposed of in secure landfill.

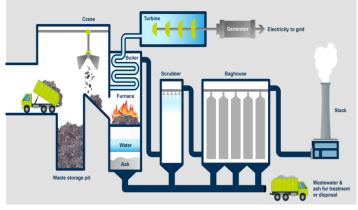


Fig 1:- Incineration

Management of other pharmaceutical solid waste:

Microwaving

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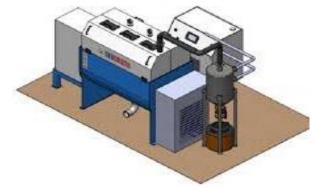


Fig 2:- Microwaving

Deep burial

The most of pharmaceutical waste require the method deep burial. The site should be prepared by digging a pit which should be approximately 2.5 meters deep. No settlers should be there and the area should be remote for surface water contamination. The pit should be half-filled with the waste, and then covered with lime within 50 cm of the surface, before filling the rest of the pit with soil. Between each occasion 10cm of soil should be added to cover the waste, when waste is added to the trench.

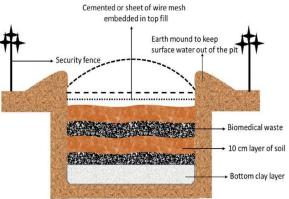


Fig 3:- Deep burial

Secure land filling

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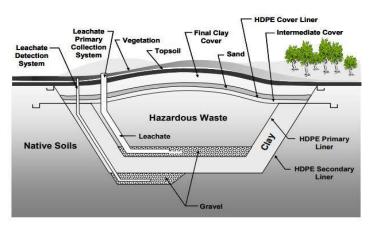


Fig 4:- Secure land filling

Scope of landfilling

This study evaluated the potential release of active pharmaceutical ingredients (APIs) into surface water from landfill leachate, focusing on unused pharmaceuticals discarded by consumers. Data on annual API sales were sourced from IMS Health. The study estimated API concentrations in landfill leachate by using a partitioning coefficient and accounting for biodegradation processes occurring within landfills. The analysis also considered the effluent limitations set by the US Environmental Protection Agency (USEPA) for Subtitle D landfills, including both publicly owned treatment works (POTWs) and privately owned treatment facilities. For comparative purposes, the study also included estimated API releases from POTWs due to patient use and excretion.⁽¹⁵⁾

Waste immobilization: encapsulation

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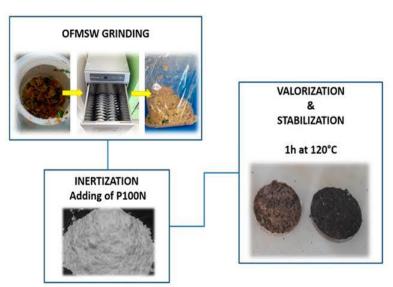
Fig 5:- encapsulation



Waste immobilization: Inertization

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paste is formed with cement, lime, water and pharmaceuticals. Concrete mixer trucks are used for transport of paste in liquid form. Then the truck is taken to landfill and pour out into the normal urban waste. The liquid form paste then converts into dispersed solid mass within the municipal solid waste. This method is comparatively inexpensive and carried out with unsophisticated equipment.⁽⁷⁾



ONE STEP PROCESS

Fig 6:- Inertization

Sources of Entry of Pharmaceuticals into Environment

For human pharmaceuticals, the main entry pathway into surface waters is commonly recognized to follow the sequence of patient use, excretion into sewage, wastewater treatment, and effluent into receiving waters.⁽¹⁶⁾

- Wastes from pharmaceutical production industries in developing countries like India and China.
- Wastes from hospital trash
- Improper disposal by patients
- Pharmacies disposal
- Leaching from the defective landfills
- Veterinary medicine waste by animals
- Release from pest control drugs.⁽¹⁷⁾



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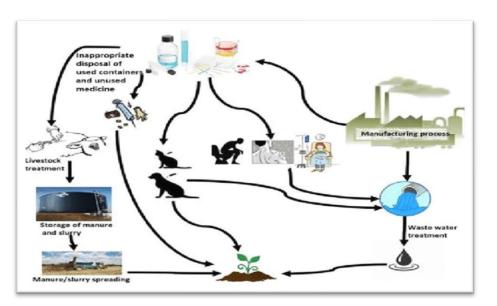


Fig 7:- Sources of Entry of Pharmaceuticals into Environment

Regulatory bodies that involved in pharmaceutical waste management

- Environmental Protection Agency (EPA)
- Department of Transportation (DOT)
- Drug Enforcement Administration (DEA)
- Occupational Safety and Health Administration (OSHA)
- State Environmental Agencies
- State Pharmacy Boards
- Local Publicly Owned Treatment Works (POTW).⁽¹⁸⁾

Role of a pharmacist in managing solid pharmaceutical waste

Pharmacists play a crucial role in managing the disposal of unused pharmaceuticals. They must prevent disposal through open dumpsites, incineration, or insecure landfills due to the associated public health risks. Pharmacists are responsible for advising on the costs and options for proper disposal and for identifying suitable disposal services. They are key in the pharmaceutical management cycle, helping to ensure rational drug use and minimizing environmental harm. Studies show that pharmacists generally have superior knowledge of waste disposal compared to other healthcare professionals. For instance, in Ethiopia, pharmacists identified issues such as improper storage and handling of near-expiry drugs that lead to waste. They should address overprescribing and ensure drugs are used efficiently, managing inventory to prevent excess and spoilage. Establishing standard operating procedures for disposing of expired or damaged pharmaceutical waste management is critical, as highlighted by studies in Serbia, Palestine, and Nepal, which found that trained staff handles waste more safely. Regular training and education are necessary for healthcare workers to improve disposal practices and ensure compliance with safety standards.⁽⁶⁾

Challenges to managing pharmaceutical waste

Interactions with respondents reveal that regulatory bodies often lack adequate training and awareness



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regarding the management of hazardous pharmaceutical waste. This gap in knowledge suggests that pharmaceutical waste, an emerging contaminant, is not yet a significant priority for federal and state governments. The health impacts of pharmaceutical waste are considerable, as it poses risks to public health and economic stability. While developed countries are advancing research on managing such contaminants, developing nations like Nigeria face challenges in addressing solid waste management, including pharmaceutical waste, due to inadequate government focus and poor management practices. Despite the establishment of regulatory bodies and environmental ministries, these entities often lack the resources and effectiveness needed for proper waste management. Awareness remains insufficient, and even in states like Lagos, which hosts annual waste management summits, challenges persist due to deficiencies in training, monitoring, evaluation, and infrastructure.⁽¹⁹⁾ Every year, thousands of tons of crops wastes are generated in Europe.⁽²⁰⁾

Precaution to be taken at the time of disposal

- Contamination of drinking water must be avoided. Landfills must be sited and constructed in a way that minimizes the possibility of leaching entering a ground water, surface water or drinking water system.
- Non-biodegradable antibiotics, antineoplastic and disinfectants should not be disposed into the sewage system as they may kill bacteria necessary for the treatment of sewage. Antineoplastic should not be flushed into watercourses as they may damage aquatic life or contaminate drinking water. Similarly, large quantities of disinfectants should not be discharged into a sewage system or watercourse. They can be introduced if well diluted.
- Burning pharmaceuticals at low temperatures or in open containers results in release of toxic pollutants into the air. Ideally this should be avoided.
- Inefficient and insecure sorting and disposal may allow drugs beyond their expiry date to be diverted for resale to the general public. In some countries scavenging in unprotected insecure landfills is a hazard.
- In the absence of suitable disposal sites and qualified personnel to supervise disposal, unwanted pharmaceuticals present no risk, provided they are securely stored in dry conditions. If stored in their original packing there is a risk of diversion and to avoid this they are best stored in drums with the pharmaceuticals immobilized.⁽¹⁷⁾

Conclusion

Effective management of pharmaceutical solid waste is crucial for protecting environmental and public health. With rising pharmaceutical production and consumption, it is vital to utilize various treatment methods—such as incineration, microwaving, deep burial, secure landfilling, encapsulation, and inertization—tailored to the waste type and local conditions. Pharmacists play a key role by promoting proper disposal practices, preventing over prescription, and educating both patients and healthcare workers. Regulatory bodies must enhance oversight, improve infrastructure, and enforce regulations to mitigate contamination risks. Additionally, optimizing packaging and ensuring precautions against water contamination and toxic emissions are essential. A collaborative effort involving pharmacists, regulatory agencies, and the public, supported by effective policies and practices, is necessary for sustainable pharmaceutical waste management.



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