ORIGINAL RESEARCH PAPER
Volume - 11 | Issue - 07 | July - 2022 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

A STUDY ON PHARMACEUTICAL WASTE MANAGEMENT IN SELECTED PHARMACEUTICAL INDUSTRIES

Environmental Science

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ABSTRACT

Pharmaceutical waste is not one single waste stream, but many distinctive waste streams that can affect the integrity and uniformity of the chemicals that involve pharmaceuticals. Pharmaceutical waste includes expired and unused drugs, spilt, vaccines and sera that are no longer required and need to be disposed of appropriately. These pharmaceutical compounds may pose the risk of ecotoxicology in many organisms including fish in the aquatic ecosystem and may also interfere with hormone synthesis and reproduction. During the present research work, a survey has been conducted in selected pharmaceutical industries to know the type of drugs manufactured and its management. In order to know the waste management, with the help of questionnaires, a survey has been conducted and the information's were collected from the respective management persons in selected pharmaceutical industries. The survey was conducted in the following pharmaceutical industries like Cipla, Supreem, Biocon, Microlabs, Millennium, Reckitt and Benckiser and Jubilant and Strides Pharma. From the study, it was found that, in most of the industries, the types of the pharmaceuticals manufactured are active pharmaceutical ingredients. Based on the survey, it was found that, most of the industries have got their own set of standard operating procedures for the wastes that are released. It was found that, in most of the industries, the frequency of expired drugs dispose into the collection point in a year 3-5 times. The frequency of expired drugs cleaning up is for 7-12 months. The type of the drugs reserved is of common diseases or chronic diseases. It was also found that almost all industries follow the guidelines under KSPCB norms. The disposal methods followed in most of the industries are burning, incineration, land filling, plasma pyrolysis, and adsorption and encapsulation treatment methods.

KEYWORDS

Pharmaceutical wastes, Treatments, Expired Drugs, Encapsulation, Incineration

INTRODUCTION:

Worldwide, the use of pharmaceutical has been increasing for the past century and will continue to increase future with the development of new medicines to cure recently discovered diseases as well as previously untreatable conditions [1]. Pharmaceuticals are a class of biologically active compounds used in human and veterinary medicine, while some of them may be applied for feed production and plant growth stimulation. Primarily, they are applied for therapeutic and preventive purposes, but not solely, since they are widely used in animal husbandry and food production, they are called as growth stimulants. The advanced developments in pharmaceutical industry, has achieved many benefits in the field of pharmaceutical protection of health and life of people and animals [2]. Moreover, pharmaceutical compounds may enter the environment by different routes such as discharge of treated wastewater, seepage from landfills sites, sewer lines, runoff from animal wastes etc. Pharmaceuticals are any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care treatment, or prevention of disease or injury of a human or other animal. When drugs are prescribed prophylactically or in response to an acute or chronic illness, only a portion of the active ingredient of the drug is metabolized. The non-metabolized parent compound, as well as the metabolites, enters the natural aquatic environment through waste discharges into receiving streams, which may pollute recreational lakes or even the intakes of drinking water treatment plants [3]. These pharmaceutical compounds may pose the risk of ecotoxicology in many organisms including fish in the aquatic ecosystem and may also interfere with hormone synthesis or reproduction. Soil sorption properties are of major significance for determining the fate and behavior of pharmaceuticals in environment due to the mechanisms of its degradation processes. As a result of inappropriate management of drug-containing waste from industries, hospitals or households, these substances are discharged into the environment without any treatment. Widespread application of effluents and biosolids for fertilizing purposes contributes to the release of significant amounts of pharmaceuticals into the environment. For example, such substances as, among others, fluoroquinolones, ciprofloxacin and norfloxacin, which are not degraded in the wastewater treatment process, accumulate in significant quantities in sewage sludge. According to estimates, the release of pharmaceutical active substances into the environment due to the use of veterinary medicines is many times higher than that resulting from the human drug application[2].

A number of studies have demonstrated the translocation and uptake of personal care products and pharmaceuticals used in human and veterinary medicines into plant tissue and soil environment. From the study, it was found that, the uptake of pharmaceuticals depends on the crop type and physiochemical properties of the chemical compound that are exposed [4], [5]. Studies have explored the fate and uptake of a variety of active pharmaceutical ingredients (API) with a particular focus on antibacterial chemicals including carbamazepine, sulfadiazine, sulfamethoxazole, sulfamethoxypyridazine, ciprofloxacin, norfloxacin, tylosin, trimethoprim into numerous plant species including root and shoot crops such as soybean, lettuce, raddish, ryegrass and carrot [1], [6]. Some of the research has done on adsorption of antibiotics on an agricultural land and the effects of earthworm's species on the performance of tetracycline antibiotic degradation pathways and bacterial communities' structure in laterite soil [7][11]. The adsorption of the drugs into the soil depends on its physiochemical characteristics, texture, organic matter and climatic conditions.

The main objective of the present research work is to study on pharmaceutical wastes management in selected pharmaceutical industries.

MATERIALS AND METHODS:

In the present research work, a survey has been conducted in selected pharmaceutical industries to know the condition of pharmaceutical waste management options. At present, the following industries have been included for the survey, a concise questionnaire has been supplied to the respective in-charge persons in the respective industries and information's were collected. The industries included for the survey are as follows:

a. Reckitt and Benckiser India Pvt. Ltd, Mysore.
b. Supreem Pharmaceuticals Pvt. Ltd, Nanjangud, Mysore.
c. Micro Labs Limited, Bangalore.
d. Biocon Pharmaceutical Industry, Bangalore.
e. CIPLA Ltd, Bangalore.
f. Jubilant Generics Ltd, Nanjangud, Mysore.
g. Millennium Chemi Pharma (Mysore) Pvt. Ltd.
h. Strides Pharma Science Limited, Bangalore.

Based on the survey, the Reckitt and Benckiser industry in Mysore is of a pharmaceutical formulation type of industry having the capacity of 800 members. The products which are manufactured in this industry includes: Dettol Antiseptic Liquid (4000 KLT/M), Disperin (135 KLT/M), Colspirin Pharmaceutical Tablets and Geolora Antiseptic Pain Reliver (1403 KLT/M). In the industry, the frequency of expired drugs into the collection point in a year is 1-2times. The frequency of

expired drugs cleanup is 3-6 months. From the industry, the waste generated includes solid and hazardous wastes such as broken glass, metal and paper scrap, oil soakeds cotton waste, empty barrels/ liners contaminated with hazardous chemical wastes, used spent oil and used filters, chemical sludge from wastewater treatment, waste plastic bags and unbleached papers. The amounts of solid and hazardous wastes generated in the industry are around 2477 megatons/annum. The wastes are collected, separated and stored in a secure manner and disposed to Karnataka State Pollution Control Board (KSPCB) authorized recycler and handed over to KSPCB incinerator / co-processing in cement klin. The waste such as date and expired products like drugs or medicines are collected in polythene bags and handed over to KSPCB authorizers. The approximate range of effluents released in effluent treatment plant (ETP) is 35 KLD and sewage treatment plant (STP) is 40 KLD. The treatments methods followed for the effluents released in the industry are screening, equalization, membrane bio-reactor (MBR) and membrane filtration.

Supreme pharmaceutical industry in Mysore is of a pharmaceutical type of industry having a capacity of 140 members. The product which is manufactured in the industry is Nutraceuticals such as Vitamin B_{12}, Vitamin C, Vitamin D_3, free flowing folic acid, Vitamin E, calcium, Alpha-Lipoic acid, Methylcobalamin, Biotin and so on. The frequency of expired drugs clean up in the industry is 7-12 months. More than 10 types of drugs have been stored in the industry. The frequency of reserving drugs is occasionally small amount of drugs. The wastes generated in the industry are of non-hazardous drug waste, hazardous drug waste and wastewater treatment plants wastes. The quantity of solid waste generated is less than 50kg. The current practice and disposal methods of solid wastes, unused and expired drugs are dumping, burning, incineration, landfilling and encapsulation. The treatment methods adopted for the effluents released in the industry are distillation, adsorption and verification.

Micro labs Ltd, Bangalore industry is of a pharmaceutical industry having 22 divisions in it. The types of pharmaceuticals manufactured in the industry are Amlong, Dolo-650, Lubrex, Diapride, Avas, Tripride, Arbitel and so on. The frequency of expired drugs dispose into collection point in a year is often 1-2 times. The type of drugs reserved in the industry is for chronic diseases and other common diseases. The wastes generated in the industry are both solid and hazardous waste. These wastes are segregated and handover to other landfill site under KSPCB norms. The two types of effluents released in the industry are high and low total dissolved solids. The treatment methods adopted for the effluents released are incineration, process reactors, landfilling. Hazardous wastes are carried for disposal by certain vendors.

Biocon industry, Bangalore, is a pharmaceutical industry having a capacity of 9000+members. The products manufactured in this industry includes: Insugen, Basalog, Biomab Egfr, Blisto, Canmab, Evertor, Tacrograf, Alzumab and Krabeva. The types of drugs stored are of common diseases like diabeties and chronic disease like cancer. More than 10 types of drugs are stored in the industry. Occasionally small amount of drugs have been reserved in the industry. The types of wastes generated are hazardous, bio wastes and general wastes. Hazarrdous wastes are neutralized with neutralizing solutions. Solid bio-wastes are decontaminated by performing decontamination autoclave as mentioned in standard operating procedures. Liquid bio wastes are decontaminated by chemical decontamination procedure. Solid general waste and non-bio wastes are collected, stored and transferred to decon unloading area and disposed as mentioned in standard operating procedure.

According to survey carried, CIPLA is a pharmaceutical industry having a capacity of 16000 employees. The products manufactured in the industry are Acivir cream, eye ointment, tablets, I.V injections, Actorise gel and injections, Adgain capsules, Advent I.V injections, Aerocort inhaler, Aerocort rotocaps and Actipeel gel. The wastes generated in the industry are solid and hazardous wastes. The current methods followed for managing the pharmaceutical solid wastes are incineration, plasma pyrolysis or deep burial, autoclaving, mutilation, or combination of sterilization and sent to energy recovery and encapsulation. Expired cytotoxic drugs and items contaminated with cytotoxic drugs are returned back to manufactures or suppliers for incineration at temp >1200^{0}C to common biomedical waste treatment facility.

Jubilant Generics Ltd, Nanjangud, Mysore is of Active Pharmaceutical Ingredient type of industry having a capacity of 2500-3000 members. The products which are manufactured in the industry are antibiotic tablets, cardiovascular tablets, genitor urinary tablets, antihistamines tablets. More than 10 types of drugs have been stored. The types of wastes generated in the industry are municipal solid waste and solid hazardous waste. A separate storage facility is provided for storage of solvents and raw materials. Chemicals are handled as per material safety data sheet and dully approved by public employment services office. The wastes are disposed through municipal composting facility as per Central Public Health and Environmental Engineering Organization (CPHEEO). Approximate range of the effluents released is 120-150 KLD. Zero discharge process is carried out. ETP's sludge is being stored and handed over to cement klin for processing based on calorific value.

Based on the survey carried, Millennium Chemi Pharma Pvt Ltd, Mysore is a type of industry which manufactures only intermediates used in pharmaceuticals and specialty chemical manufacturing plant. The industry does not manufacture any drugs. The approximate range of industrial effluent released is 7 KLD and the treatment of industrial effluent given type is multiple effect evaporation method.

Strides Pharma Science Limited is a type of bio- pharmaceutical industry having a capacity of 5000+ members. The products manufactured in the industry are General Tablets, Hard Gelatin Capsules, Soft Gelatin Capsules, Sachets, Semi Solids, Ointments and Creams. The quantity of manufacturing the pharmaceuticals is 2 billion. The wastes generated in the industry are hazardous and non-hazardous waste. Hazardous wastes include process waste like rejected powders, tablets, capsules, process spillage, expired control samples, periodic inspection samples, dust extractor rejection, gelatin waste, used filter cloth, used filter paper, rejected liquids. Empty chemical glass wares, reagent bottles, used HPLC (High Performance Liquid Chromatography.) columns, GC (Gas Chromatography) vials, Reject chromatographic columns broken mirrors. Bio-medical wastes, bio-medical waste from microbiology.

QC expired chemicals / reagents, organic waste – mobile phase / HPLC waste / washing and rinsing solvents / spent analytical solutions and E-waste. Non-hazardous waste includes wooden pallets, wooden packing materials, used shipper carton, cut drums, other plastic scraps and other solid waste, nylon sacks, jute bags, cotton waste, bubble wrap, shrink wrap, pieces of carton box, packing foam, rejected leaflet. Metal and non- metal waste includes heavy metals, pipes, channels, metal cases and metal such as bolts, screws, belts, gasket and flanges, rejected punches and dies. Waste are segregated and to segregate the scrap and assist effective checks at various stage of scrap management, a colour coding of scrap colleting bags are maintained. Non-hazardous wastes are regularly arranged in segregation point and transfer the waste to scrap storage area and dispose to approved scarp vendor. Few wastes are ensured that the waste segregation is confirmed for compliance and must be verified by used department as mention in the label format of ' Waste for Disposal' and transfer the waste to scrap storage area and disposed through approved scrap vendor. Paper waste activities are followed as per SOP titled “Document Management”. Handling of hazardous waste, expired chemicals, E-wastes ensures that there is no damage in the packing and the packed waste shall be transferred to scrap storage area. If the waste is bulk or liquid form same shall be packed double red color polybags and kept inside the HDPE (High-Density Polyethylene) drums and follow the SOP procedure for final disposal. All the hazardous, biomedical wastes generated at OHC and microbiology is disposed to authorized vendors by PCB/ CPCB.

DISCUSSION:

Based on the survey, it was concluded as follows:

- The type of industry and the class of drugs manufactured were found.
- The information on the types of waste generated and its management and disposal of the wastes are obtained. Almost all the industries are disposed in a secure manner under as per KSPCB norms, except few industries unused medicines and expired drugs left over are disposed through other private agencies or disposed in the domestic solid waste management locations.
- The current practice and disposal methods of solid wastes, unused and expired drugs are dumping, burning; incineration, landfilling and encapsulation.
- The treatment methods adopted for the effluents released in the industries are done through distillation and adsorption process.

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