Research Article

A Mini Review on Minimization Options for Hazardous Compounds in Pharmaceutical Waste

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Abstract

Pharmaceutical compounds from different sources have been detected in sewage treatment plant (STP) effluents, surface waters and, less frequently, in groundwater and drinking water all over the world. Different sources are responsible for their appearance in the aquatic environment however, it is widely accepted that the main sources of this type of pollutants are STP effluents and pharma industry. The adverse effects of pharmaceuticals in the environment include aquatic toxicity, development of resistance in pathogenic bacteria, genotoxicity and endocrine disruption. Thus, the discharge of these compounds to the environment in STP effluents should be minimized. The pharma companies world wide should concentrate on reducing the generation of wastes at the source, or recycling these wastes. It will benefit pharmaceutical manufacturers by increasing product yields, reducing raw material needs, disposal costs, and the liabilities associated with hazardous waste management in the environment. The intention of current review is to stimulate the thinking of manufacturers about their own processes.

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1. Introduction

The magnitude of usage of the pharmaceuticals has increased globally and India is not an exception to this trend. This made to bring the awareness in the disposal of pharmaceutical compounds, either to landfills or as sewage where they can have potential adverse effects on the aquatic environment [1]. There are many studies which concerntrates on these effects for example, trace levels of the contraceptive ethynylestradiol found in water able to bring impairment in the sexual development and increase feminization of fish [2]. There is also a number of evidences on the presence of antibiotics in water streams which has impact on the bacteria present and may lead to antibiotic resistance [3]. Among these various pollutants, pharmaceuticals at mg/l levels are of particular concern due to their ubiquity in the aquatic environment and their health effects. These compounds on their hydrophicity are able to enter the aquatic environment or remain adsorbed on solid particles. The various sources of such compounds in the environment are households waste, water treatment plants, hospitals, industrial units and intensive animal breeding farms [4]. Many believe that as the detected levels are significantly below therapeutic levels there is no risk. However, this may not be true for all drugs and for all members of the public as the elderly, children or those who have renal or hepatic impairment will be at increased risk. As the production and use of pharmaceuticals continues to increase in this rate, measurable levels in water systems will be seen. The questions need to be asked to ourselves: Is it acceptable to have active pharmaceuticals in drinking water even at subtherapeutic levels regardless of the predicted risks?

It is not just the impact on human health that is relevant, but also on other animals, marine and aquatic life .These effects leads to ecosystem imbalance. For example, the environmental exposure of compounds like Diclofinac has been revealed as the cause of the declining vulture population in Pakistan [5]. Even our household pets may be at increased risk due to the difference in the metabolic pathways. For, Example cats are deficient in the glucuronidation pathway and can accumulate and actually increase the half-life and toxicity of paracetamol upon ingestion [6]. The main source of pharmaceutical contamination of the water system is manufacturing companies and to some extent human beings and animals.

Waste minimizing options from Pharmaceutical companies

The waste from the pharmaceutical industry is characterized by a low ratio of raw materials and finished products, during the drugs produced by natural product extraction and fermentation. Depending on the processes and materials involved, large amounts of extraction waste may be generated which may contain hazardous components. The fermentation media which is discharged may encourage the unwanted contaminating microorganisms in the soil and water. In the pharmaceutical waste source reduction is always the most desirable option with recycling, reuse or reclamination of part or the entire waste stream, being the next desired option. The source reduction and recycling options which may suit pharmaceutical manufacturing are discussed in the current review.

2. Source reduction

The first and fore most important control of pharmaceutical waste to reduce the hazardous wastes can be achieved in industry through changes in raw materials used, process technologies modifications, procedural and organizational practices and finally the type of product going to be produced. Pharmaceutical manufacture is a diverse and highly competitive industry. Because of the highend specific and often confidential nature of each company's specific operations, only optional raw materials may be discussed. The intention is to stimulate the thinking of manufacturers about their own processes.

2.1 Reformulation of the raw materials

The raw materials used can be substituted with less toxic and less waste generating materials to reduce the by products. For the pharmaceutical industry, however, product reformulation is likely to be very difficult due to the testing required to ensure that the reformulation has the same therapeutic effect, stability and purity profile as the original drug. Furthermore, a considerable amount of time is required for FDA approval of the reformulated drug. An additional concern is the effect of reformulation on the product's aesthetic qualities because changes in characteristics such as taste, color, or dosage form could result in customer rejection of the product.

Materials substitution has succeeded in the manufacturing of tablet coating operations to reduce hazardous waste generation. In one manufacturing plant, development of water-based solvent and new spray equipment for a tablet coating application eliminated the need for expensive ($180,000) air pollution control equipment. The resulting savings in solvent make-up cost was $15,000 per year (ILSR 1986) [7]. Another study revealed that the methylene chloride usage for tablet coating has reduced from 60 tons per year to 8 tons per year by changing conventional film coating to aqueous film coating (Wayman and Miller 1987) [8].

Another best way to reduce the hazardous materials in the waste like solvent-based solutions can be substituted with aqueous-based cleaning solutions. The chlorinated solvents can be replaced with non-chlorinated solvents. The waste minimization can be achieved by introducing the methodology at research and development (R&D) phase instead of production phase. The R&D phase can be carefully observed and materials can be used in manufacturing or formulating a pharmaceutical to reduce the toxicity of residuals and by products.

2.2 Modification of existing operation process

Besides going for investigation on substitution materials, pharma companies can concentrate on source reduction opportunities that can be obtained through updating and modernization of the existing method. In most cases the source/process yield determines the product/waste ratio. There are many reasons for high by product yield due to inadequate feed rate control, mixing or temperature control. By controlling the process parameters, reactor efficiency can be improved and byproduct formation reduced. Proper automation can also reduce the operational errors which can reduce the byproducts. For example, automated systems for material handling and transfer, such as conveyor belts for bagged materials, can help reduce spillage.

The deposits like crystallization, sedimentation, polymerization and corrosion on interior equipment surfaces reduce process operating efficiencies and increase waste generation. Proper agitator design and impeller are important in controlling temperature and efficiency of the process.

Besides, process modification option is to redesign chemical transfer systems to reduce physical material losses. For example, replacing gas pressurization with a pumped transfer eliminates the tank pressurizing step and its associated material losses (ICF 1987) [9]. We can also achieve the waste minimization by modifying tank and vessel dimensions to improve drainage, installing internal recycle systems for cooling waters and solvents, selecting new or improved catalysts, switching from batch to continuous processes for solvent recovery, and optimizing process parameters to increase operating efficiency.

The process modification can result in significant waste reduction; there may be different obstacles to this approach to waste minimization. Extensive process changes can be expensive; downtime will occur when production is stopped for new equipment installation; and new processes must be tested and validated to ensure that the resulting product is acceptable. In addition, to the extent that processes and process equipment is specified in an approved drug application, FDA approval is likely to be required prior to instituting any changes.

Along with the above discussed process modification methods there should be a good operating practices followed in the company can help to reduce hazardous and other waste generation and material losses.

3. Recovery and Recycle

Recovery and Recycling includes direct reuse of waste material, recovery of used materials for a separate use, and removing impurities from waste to obtain relatively pure substances. It is very difficult to recover the pure substances from the waste materials. The goal is to recover materials for reuse in the process or for reuse in a different application. The strict quality control requirements of the pharmaceutical industry often restrict reuse of substances, though some do exist. After a high degree of purification, materials recovered from manufacturing processes may be reused. Recycling can be performed either on-site or off-site. On-site recycling can be either integral to an operation or in a separate operating area.

Advantages include:

Reduced waste leaving the plant; management control of reclaimed material purity; reduced cost and liability of waste transported off-site; reduced reporting requirements; and lower unit costs for raw materials use.

Disadvantages include:

Capital expenditure for recycling equipment; additional operating and maintenance costs; potential additional permitting requirements; increased operator training; and increased risks to workers. The last three disadvantages do not apply when recycling is included in the initial design of a process. Off-site recycling, performed at commercial recycling facilities, is well suited for small quantity generators and firms who cannot accept the technical, economic, and managerial Requirements of on-site recycling. The recycler may charge the generator a straight fee or may base fees on waste volumes and in some instances, may credit the generator for the value of salable wastes. The value of a waste depends on the type, market, purity, quantity and frequency of generation, and distance between the generator and the recycling operation. Because generators can be held liable for future clean-up cost of wastes leaving their plants, it is important to select a recycler that is reliable.

4. Waste Exchanges

Waste exchange can be an alternative to recycling; this involves the transfer of a waste to another company for use as it is or for reuse after treatment. Waste exchanges are private or government-subsidized organizations that help to identify the supply and demand of various wastes. There are three types of waste exchanges that can be availed: information exchanges, material exchanges, and waste brokers. Information exchanges are clearing houses for information on supply and demand, and typically publish a newsletter or catalog. Material exchanges take temporary possession of a waste for transfer to a third party, in contrast to waste brokers, who do not take possession of the waste but charge a fee to locate buyers or sellers. Because of their high recovery value, metals and solvents are the most frequently recycled materials via waste exchange. Other wastes commonly recycled through waste exchanges include acids, alkalis, salts and other inorganic chemicals, organic chemicals, and sludges. Of the total materials listed with waste exchanges, approximately 20 to 30 percent are actually exchanged (Calif. DHS 1989) [10].

Conclusion

There are several advantages in the application of different methods which are mentioned above and the hazardous compounds can be minmized. At present nano particles are playing key role in all the emerging fields with their outstanding properties .The toxic compounds in the pharma effluents can be degraded by using zinc or silver nanoparticles.They can also be reduced by algal biodegradation to a greater extent than ordinary methods. A lot of potential is present in these methodologies by which treatment of effluent can be done in a better way. By implementing these methodologies water quality will be enhanced .The treated water can reused in the plant. The water free of harmful pharma effluents reduces the soil and water pollution.

References

[1] Halling-Sorensen, B.; Nors, N. S.; Lanzky, P. F.; Ingerslev, F.; Holten Lutzholft, H. C *Chemosphere* **1998**, *36*, 357-393.
[2] Kostich, M. S.; Lazorchak, J. M. *Sci. Total Environ.* **2008**, *389*, 329-339.
[3] Costanzo, S. D.; Murby, J.; Bates, J. *Mar. Pollut. Bull.* **2005**, *51*,218-223.
[4] A. Nikolaou, S. Meric, D. Fatta, Anal. Bioanal. Chem. (2007)
[5] Oaks, J. L.; Gilbert, M.; Virani, M. Z.; Watson, R. T.; *et al. Nature* **2004**, *427*, 630-633.
[6] Court, M. H.; Greenblatt D. *J. Biochem. Pharmacol.* **1997**, *53***,** 1041-1047
[7] ILSR. 1986. *Proven profits from pollution prevention: case studies in resource conservation and waste reduction,* Case Study 14. Institute for Local Self-Reliance.
[8] Wayman, C.H. and K.S. Miller. November 18, 1987. *Waste minimization through the adaption of coatings conversion and catalytic oxidation,* presented at the PMA workshop on waste minimization practices in the pharmaceutical industry.

[9] ICF Technology Inc. May 1987. *Waste Identification and Minimization: A Reference Guide*.
[10] Calif. DHS. 1986. *Guide to solvent waste reduction alternatives*. Prepared by ICF Consulting Associates, Inc. for California Department of Health Services, Alternative Technology Section, Toxic Substances Control Division.

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