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Green Chemistry to Design Eco Friendly Reaction Procedures and Synthesis and Reuse of API's from Expired Dosage Form







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ABSTRACT

Now that sustainability is on everybody's top-of-mind, Green Chemistry is more important than ever. Just think about the amount of industries that rely on chemistry and whose activity has a great impact on the environment: pharma, agriculture, colorants, materials, consumer products to name a few. This in part is due to the clear increase in awareness about environmental pollution. Especially since the last decades, people are becoming aware that we, as humans, are stressing the planet's finite resources, and acknowledging that our consumption and waste have to go somewhere. And the current COVID crisis has consolidated this feeling. Just to mention some facts, there is fair evidence about: Presence in the ocean of microplastics, that are entering the trophic chains, Chemical compounds manufactured by humans have been found in Antarctica ice and/or inside wild animals, Increase of average temperatures due to emission of gases such as CO₂. Drugs plays important role in our day today activities in order to prevent diseases and their treatment. A methodology is famous among people that drugs become toxic and dangerous after expire date but actually it's not like that, there is simple decrease in the therapeutic effectiveness of drug dosage forms. But after expire date we cannot use them and throw them without knowing that these drugs have lethal side effects on living organisms present around us. Sometime these effects are beneficial and sometime it may be lethal.

INTRODUCTION:

For the past few decades, the scientific community as well as society as a whole has raised its voice on the impact our actions have on the environment, pressing authorities and looking for solutions to address the problem. One of the main focuses has been set on Chemistry, as many "traditional" chemical processes are not sustainable in the long run, with devastating consequences for the environment and quality of life.

Green Chemistry¹

As the International Union of Pure and Applied Chemistry (IUPAC) puts it, Green Chemistry (also known as **Sustainable Chemistry**) encompasses the "invention, design, and application of chemical products and processes to reduce or to eliminate the use and generation of hazardous substances".

The Origins of Green Chemistry

According to the American Chemical Society (ACS) the term "Green Chemistry" was first coined by the US Environmental Protection Agency – Office of Pollution Prevention and Toxins around the 1990s. The idea of a greater consciousness regarding chemistry had been gaining power since the 60s and 70s, however, it was mostly focused on banning dangerous toxins like DDT and "cleaning up" the aftermath of certain chemical activities. It was not until the 80s and 90s that scientists started thinking differently about their way of doing chemistry, shifting the focus on how to prevent pollution before it even took place.

Then, in 1998, two scientists named Paul Anastas and John C. Warner published what today is popularly known as the «Twelve Principles of Green Chemistry».

The Twelve Principles of Green Chemistry²,

First published in the book "Green Chemistry: Theory and Practice", the Twelve Principles of Green Chemistry is a set of guidelines that other chemists can consult to work towards a more sustainable chemistry. The book marked a new era, by helping consolidate a movement that was destined to define how modern chemistry is made.

The principles highlighted in Anastas and Warner's book are:

- 1. Waste Prevention
- 2. Atom Economy
- 3. Less Hazardous Chemical Synthesis
- 4. Designing Safer Chemicals
- 5. Safer Solvents and Auxiliaries
- 6. Design for Energy Efficiency
- 7. Use of Renewable Feedstock's
- 8. Reduce Derivatives
- 9. Catalysis
- 10. Design for Degradation
- 11. Real-time analysis for Pollution Prevention
- 12. Safer Chemistry for Accident Prevention



Green Chemistry in Industry³

Now that sustainability is on everybody's top-of-mind, Green Chemistry is more important than ever. Just think about the number of industries that rely on chemistry and whose activity has a great impact on the environment: pharma, agriculture, colorants, materials, consumer products... to name a few.

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somewhere. And the current COVID crisis has consolidated this feeling. Just to mention some facts, there is fair evidence about:

• Presence in the ocean of microplastics, that are entering the trophic chains

• Chemical compounds manufactured by humans have been found in Antarctica ice and/or inside wild animals

• Increase of average temperatures due to emission of gases such as CO₂

If you watch the news, you might have noticed that some institutions are working non-stop to keep this issue present:

- World Economic Forum
- United Nations, with the Sustainable Goals and Paris Agreement

And special laws and regulations are being developed to promote more environmentally friendly, sustainable production processes and industries: REACH normative in European Union, ISO 14001, to name some of them.

In parallel, consumers are concerned about the impact the products they buy have in the environment and in their own bodies. Multiple initiatives inviting consumers to choose more "consciously" are nowadays on the front line, and they are demanding products that are respectful in the whole production chain: from manufacturing to recyclability.

The difference between green chemistry and general chemistry. The best way to describe it is that Green Chemistry's main goal is to achieve the same or equivalent chemical reactions with a decrease in environmental damage.

Some techniques that are used for this aim include:

• **Catalysis:** catalysis is the process of increasing a chemical reaction's rate by the addition of an element denominated catalyst (like enzymes!), that is not consumed during the reaction and therefore can act repeatedly.

• **Synthetic biology:** by applying engineering principles, the goal is to redesign and create new biological systems with the aim of providing novel solutions. Examples of this could be the creation of lab-grown meat, synthetic insulin or biofuels produced by algae.

• **Chemical synthesis:** as the Nature journal definition says, chemical synthesis is "the process by which one or more chemical reactions are performed with the aim of converting a reactant or starting material into a product or multiple products".

Green Chemistry focuses on sustainability⁴⁻⁶ by looking for ways of preventing pollution, hazardous activity and resource waste. That's why the use of industrial enzymes is such a sought-after solution for many companies who want to shift to greener production processes.

As biocatalysts, enzymes have a set of properties more beneficial than their non-enzymatic counterparts:

• They are **highly selective and specific**, which allows chemists to have more control over their desired results.

• They are effective under mild temperatures, which mean significant energy savings.

• They do not generate toxic waste.

Enzymes are pretty powerful, the main problem is adapting these enzymes to an industrial setting, which usually means tweaking the structure of an already existing enzyme to give it new features and make it work under certain conditions. With some time and effort, we can make the world become a little bit greener.

Drugs⁷⁻⁸ plays important role in our day today activities in order to prevent diseases and their treatment. A methodology is famous among people that drugs become toxic and dangerous after expire date but actually its not like that, there is simple decrease in the therapeutic effectiveness of drug dosage forms. But after expire date we cannot use them and throw them without knowing that these drugs have lethal side effects on living organisms present around us. Sometime these effects are beneficial and sometime it may be lethal.

ASPIRIN is well known ANALGESIC DRUG which can we use in plants in order to promotes the growth of roots of plant, and aspirin also help the flowers to survive for longer period of time even in harsh conditions after detached from the parent body of plants.

As per Literature it was found that higher dosage of ACETAMINOPHEN can cause death of cats and dogs. And in humans it causes gastric irritation and vomiting. Drugs effects also depends upon the BMI (Body Mass Index), hence action of drugs may sever in lower living organisms that might we responsible for extinction of living organisms. Nature works on simple law that what actions we do that always result in similar and opposite reaction. Some Active Pharmaceutical Ingredient (API) has potency to cause Genotoxicity which may further cause modification of genetic information in humans and living organisms. So, it is effective step to prevent non-beneficial and undesirable activities of expired drugs. In this case we simply try to extract API and use it in the synthesis of various drug derivatives for study purpose in laboratory which is found to be quite economical. We simply try to recycle that percentage of drug in educational purposes that we discard without knowing their effects on our surroundings. By designing economical extraction methods, we can extract wide range of drugs from their corresponding dosage forms. This reused quantity of drugs helps us to decrease the chemical pollution to fewer extents. This approach is effective against medical waste management. Extraction procedures can be modified according to the nature and type of dosage forms or the API present in dosage forms. Recently it was found that aspirin is used to revive tropical fishes from shock. But sometime these activity leads to worse when amount or concentration of API is increased in natural habitats.

Synthesis of dosage forms or new active pharmaceutical ingredients should be done by using principles of green chemistry, green chemistry approach is a way to reduce lethal effect on nature, because procedures we use during synthesis of drugs are long chemical processes and quantity of waste materials formed are very high and yield is very low.

Green chemistry opens the doors to design eco-friendly reaction procedures and synthesis in which we can reduce the formation of waste materials and increase the yield of reaction procedures. Microwave assisted reaction also helpful in order to decrease reaction time in which reaction completed. Here the list of medicines recommended by food and drug administration

U.S.⁷ that you should flush when they are no longer needed, In other words these drugs are recommended for disposal by flushing, as below.

Benzhydrocodone /Acetaminophen, Fentanyl, Diazepam, Hydrocodone, Hydromorphone Meperidine, Methadone, Methylphenidate, Morphine, Oxycodone, Oxymorphone, Tapentadol and Sodium Oxybate.

Safe disposal of drugs is important and we should aware regarding type of disposal methods we are using because exposure of some drugs to living organisms might be harmful. In developing countries medicines are expensive every pharmaceutical companies have different retail prices. Maximum drugs in developing countries are sold without a prescription, (SELF MEDICATION) and very little part on the basis of prescription. After a drug course when a drug user feel batter he stop using medicines, but the remaining quantity of drug no longer in use and undergo improper disposal¹. There a book which was reprinted 8 times by WHO, First published in 1992 is a way to investigate drug use in communities, a small but important book. Self-medication by individual is not safe because sometime these drugs show lethal side effects without adjusting or calculating their dose for whole day. Self-medication is more common in developing countries.

An eye sight should be kept by government health departments on use of medicines in community because abuse of these medicines is common now a days especially in PHARM PARTIES (when a group of teenagers get together to share drugs and have a good time).

Drugs are not simple things they might be lifesaving or sometimes life destroying one. Misuse of drugs especially antibiotics are more common, in which patient frequently shift their courses of medicines from one antibiotic to another which like a threat for their life, because self-medication immediately develop resistance in them. A new exposure to infection makes their treatment more complicated.

WHO⁹⁻¹¹ manual provides a practical guide to the methods that can be used to?

- Investigate the use of medicines by patient to highlight problems.
- Action taken to improve a medical disorder.
- Measure fluctuations.

Health workers undergo training for proper use and distribution of drugs in community, heath representatives, pharmacists and nurses should take care of these things which are related to the drug use in communities. A long-term exposure of drugs not good; mainly due to self-medications. Dependency on drugs have lethal damages on vital organs of human beings, excess production of these medicines have direct impact on our surroundings which due to excess abuse of medicines.

Waste drugs, from doctor's prescription, self-medication and over the-counter medicines for human and veterinary use, are now widely spread in surface water, groundwater and seawater worldwide. Traces of these drugs in water is major health and environmental concern that is very likely to worsen, expected increase in the use of pharmaceuticals due to higher standards of living worldwide, a growing and aging world population, and the correlated increase in animal farming. So far, more than 150 different pharmaceutical substances and metabolites have been found in various water bodies in Europe, including in drinking water supplies. Clofibric acid is an herbicide; it functions as a plant growth regulator against the plant hormone auxin. Clofibric acid is also a naturally occurring pharmaceutical compound, having been found in Swiss lakes and North Sea.

Other class of drugs used for the treatment of different conditions are metabolised by human beings and some of them are fully metabolised or transformed into different polar forms in order to enhances their excretion but some drugs are excreted as it is which shows some lethal side effects on living organisms. Rate of excretion of drugs in human beings directly depends on their age factors, with the increase in age ability to metabolise the drugs reduces. Heath systems in developing countries need some changes that especially clear the duties between a doctor and a pharmacist. In developed countries like USA a Doctor only diagnoses the patients and pharmacists prescribed the drugs.

In 2004 misuse of antibiotics are common in communities which leads to antibiotic resistance, but today to treat a new infection become a task to doctors due to malpractices of antibiotics during 2004 or before. Quick shuffling of antibiotics mainly leads to resistance in most case due to self-medications. AIDS and TB need long term treatment in order to ensure the health of patients; such chronic diseases are difficult to treat in such patients that show resistance to antibiotics. Differing environments, Treating AIDS is even more difficult, with lifelong therapy

to be taken at least twice a day. Understanding what can be done in the community to help patients take all of their medicines will be crucial for ensuring the success of treatment and preventing the emergence of resistance.

Another pathway is incorrect disposal of drugs usually flushing into sewers from the toilets or sinks or disposing drugs into waste bins. Household pharmaceutical wastes that disposed usually through toilets can reach waste water treatment plants, these plants have different grindings in different countries and they are not able to remove pharmaceutical waste in water and after this process water directly introduce into rivers and fresh water resources which cause contamination such pharmaceutical residues have lethal impact on that particular contaminated area. Therefore, we need to develop powerful waste water treatment plants that are able to remove any type of contamination in water and make it safe for use not only for human beings but also living organisms around us.

Detoxification of harmful molecules in our body is important in order to make our body fit and fine, but some time drug we administer remain as it is in our body and it excreted as it is without any change mean drug is in its active form and its side effects on living organisms is more as compared to other drugs that are converted into polar forms in order to facilitates excretion from body. Very low concentration of active drug is enough to cause lethal damage on living organisms. Human beings always took about development and golden era of health but he just trapping himself in web which is full of disappointments and diseases, it was found there is 20-30% increase in diseases due to contamination of natural resources. This number of diseases cases increases day by day, It is simple if nature healthy we are healthy nothing else, simple we have to respect our nature and living organisms around us, because each living one have important role to play in nature. We have to care not only our heath of other living organisms is also important for us. Contamination in nature is more in case of developing countries such as India, Pakistan, and Afghanistan because construction of residences is not according to rule and regulations; such residences also lack proper drainage systems, due to which this contaminated water is directly introduced into the main river streams which a unhealthy practice and need to be rectify as soon as possible to prevent irreversible damage to that particular biological zone. Some drugs in nature remain as it is which a matter of worry and these drugs have some lethal effects, concentration and amount of dug present in nature is unknown and this concentration decides the

type of impact that a drug can deliver on the nature. There may be additive and synergistic effects.

Aquatic organisms are the one who most affected by this pharmaceutical residues in water. The Feminization (shift in gender role and sex role in society) Demasculisation (remove testicles of a male animal) of male fish are attributed estrogens which are formed as by-product in industries. This Feminization and Demasculisation is due to Estrogen that flush out in sewerage and such effect on fish simply make them disable to reproduce and survive effectively. Human scarifies whole population of fishes for healthy of bunch of people. These effects of drugs can be stop by proper disposal techniques, simply convert aspirin into salicylic acid then into phenol (which act as bacteriostatic or bacteriocidal floor cleaning agent named EXPIRO PHENOL) and CRUDE OIL METHYL SALICYLATE which is a topical painkiller. In low concentration METHYL SALICYLATE is used as flavouring agents in chewing gum and mints. When mixed with sugar and dried it is a potentially entertaining source of TRIBOLUMINESCENCE, this effect can be observed by crushing wintergreen life savers in a dark room. Methyl salicylate obtained from expired aspirin tablets cannot use for living stock but can use on non-living stock e.g. methyl salicylate is used in restoring (temporarily) the elastomeric properties of old rubber rollers, especially in printers.

Discovery of new drugs and other health system is good approach but these developments have both advantages and disadvantages, especially the market of antibiotics are very huge and these antibiotics distributions and uses not in a proper way this simply due to malpractice in health systems. Frequent use of antibiotics in patients cause serious problems which is not reversed atoll. Antibiotics when come in contact with nature it causes genetic mutation especially in aquatic species, such mutations termed as geneotoxicity. Concentration of antibiotics in nature also has bad impact on that microorganism that plays a vital role in biological system. So, these microorganisms are completely destroyed due to unwanted concentration of antibiotic drugs in nature. With the increase in production and use of antibiotics, these residues of antibiotics in nature increases day by day, and the impact area also enhances. Environmental impact of medicines in European market reduced, pharmaceuticals have to undergo an authorisation process. This change in European constitution indicates a healthy practice, where an applicant should indicate the potential risk by medicinal product for the environment, this process of

authorization ensures the proper use and disposal of drugs and support conservation of nature. Such effective rule should be design for every country and nation. Collection of unused drugs from houses and other medical facilities is an effective step towards the proper management of these unused drugs.

Government should construct such rules according to which expired or unused drugs are collected by people and undergo proper processing; this collection of unused or expired drugs is an only hope to prevent the unwanted effects of expired drugs. Collection scheme should be strict and should regulate by government effectively. Today pharmaceutical waste reuse is a better option for us because it provides two things that is a new product to use on non-living stock and an effective recycling of pharmaceutical wastes. Formation of an effective frame work that deals with the pharmaceutical wastes in environment and reduces the risk or damages due to pharmaceutical wastes. Reuse pharmaceutical wastes look more effective as compare to disposal or dumping the pharmaceutical wastes because it increases the chances of contamination from soil to water during rain. Appropriate system is one which is strict and do not come under any influence that rule should be same for both V.I.P and a common man, if someone do not obey or disrespect the pharmaceutical waste collection authority, he or she deserve fine or punishment. Inappropriate collection or disposal of pharmaceutical waste is a crime against nature. Other living organisms have equal right to live in this world, and we have to respect this in any conditions and circumstances.

Although, several surveys have noted that the effectiveness of these collection systems and their results varies widely across Member States. For example, in the Netherlands, where collection schemes have been running for several years, a study from 2013 found that almost 68% of the respondents returned their unused medicines to the pharmacy or a hazardous waste collection point, 15% threw them in the bin and 7% flushed them down the toilet. A study in the UK found that, of those interviewed, 2/3rd discarded unused medicines in household waste, with the remainder either returning them to a pharmacist (21.8%) or flushing them into the sink or toilet (11.5%). As a last example, a survey in Latvia (fourth poorest European country) found that 41% of the respondents discarded without knowing their environmental risk. Ireland) unused medicines in the rubbish, while 15% flushed them down the toilet and only 7% returned them to pharmacies or hazardous waste collection sites.

In many Member States, people seem to be inactive about what they should do with expired or unused medicines and are not aware that they can take unused drugs to collection facilities. Awareness programs should be conducts in such states. The inactivity of citizens seems to influence the quantities of medicines put into collection schemes in Europe. But generally, the overall message for European citizens is patchy, unclear and lacking in many countries. Currently, it is not always clear for customers how they should and could dispose unused pharmaceuticals effectively and there is lack of knowledge on the environmental risk of incorrect disposal. Additional steps are needed to influence and change behaviour amongst the population. Consistent guidelines and advertisements in televisions, across Europe could contribute to a decrease in pharmaceutical residues in the environment. Different parameters have been used at national and international level to promote awareness of proper disposal schemes for unused pharmaceuticals and to raise the problems of pharmaceuticals in the environment Most of the parameters are based on communication activities towards the general public, such as ads or media inserts, websites, brochures and posters, but have also involved training camps for doctors and pharmacists who can then provide information to patients.

The Health Care without Harm (HCWH) helps the implementation of collection strategies for unused medicines is one of the measures, HCWH in Europe dramatically reduces the impact of pharmaceuticals in the environment, together with promoting green pharmacy, improving prescribing practices, and supporting the adaptation of effective wastewater treatment methods. For this report, HCWH Europe conduct a survey of the general public approach to disposal of unwanted medicines, in selected countries, to understand the current behaviour of citizens regarding collection schemes. This survey tries to understand consumer behaviour in handling household pharmaceutical waste (expired and unused medicines). One-to-one interviews were conducted in the city centres of the capital cities of six European countries: Belgium, Hungary, Italy, Lithuania, Portugal and the United Kingdom. The countries were selected taking into consideration about the types of collection systems for unused pharmaceuticals implemented at national, regional or local level. During interviews very few people participates and only problem highlighted in this is related to educational gaps that a educated person follows the instruction by pharmaceutical waste collection systems. Data present in this report do not represent the whole population.

For every country, at least one surveyor was selected to conduct the interviews. All interviewers participated in a training session that mainly focused on how to perform and document the interviews. The interviews took place during the first week of 08/ 2013; in each city approximately 100 people were interviewed. The target group of the survey was native speakers who were residents in the country where the interviews took place and aged 18 years or older. The interviewees were spread evenly across different ages. Surveyors approached people directly on the street in their native language. At the beginning of each interview, the surveyors explained the goal of the project. Each interviewee was given a study code and the surveyor completed the interview form. No any personal data were collected.

The respondents were asked several questions that covered demographic characteristics (age group and sex), behaviour and opinions in relation to the proper disposal of unused drugs, the collection system implemented in their country and the level of awareness of the problem of pharmaceuticals in the environment. Closed and open- ended questions (Question that simply reply by saying yes or no) were used. The open-ended questions were used to try to obtain truthful answers and avoid people feeling pressed to give answers that they thought the surveyor might want to hear.

Taking excess dose of drugs was more common in uneducated one; they mainly undergo selfmedication which increases the chances of overdosing and even lethal damage to vital organs of body. But graduated persons always follow the instruction regarding the use of drugs and do not undergo malpractices regarding use of drugs for treatment purposes. Interestingly, in this survey nearly all candidates checked the expiry date of medicine, before its purchase, while in another hand; in the Indian state of Gujarat many were not aware of the expiry date of medicines they simply use them without any worry. It is very important is to purchase or use of any medicine, the expiry date must be checked, and otherwise it may lead to serious harmful effects. The actual status of study shows that efforts towards disposal of unused and expired pharmaceutical were optimal but more than 95% of the candidates surveyed had left drugs at home and half of the interviewed candidates kept the unused medicines at home until they expired, which is a pool of potential health threat. Borrowing and sharing of drugs is known to be associated with several risk factors such as skittle parties or pharm parties in which teenagers collect drugs and enjoy hallucination due to these drugs which sometimes lead to death and multiple, chronic disease, but

such behaviour or attitude observed rarely among candidates which is good. In maximum of survey candidates accepted, that they throw away the expired medicines in the household garbage which highlights the malpractice. In Bussan city of Korea, wives disposed unused or expired medications using the standard garbage bag which again a malpractice.

It was believed that best way to discard unused or expired drugs is to flush though sinks or toilets WHO¹²⁻¹⁶ itself issued a list of drugs which is safe to discard though toilets or sinks its look odd and again a mal practice Previously it was believed that proper method of unused or expired medications disposal was to flush down the toilet / drain, as opposed to discarding them in the trash, where animals or humans have to face the consequences. About 10% of the candidates flushed the expired drugs down the toilet or sink, which are similar to the malpractices followed by the citizens in Kuwait, UK and USA, where it is the best practice for disposal of liquid medications. Very few candidates return the unused and expired drugs to medical stores, which is similar to people practice in the USA and Malaysia. In developing counties strict and strong measures leads to fruit full results such effective practices regarding disposal of unused or expired drugs plays a vital role in order to reduce the contamination rates of drugs in our environment. Pharmaceutical wastes should be transformed rather than dumping or disposing because such drugs need to detoxify properly before introducing in nature.

Effective guidelines for disposal of medical in different countries lacking due to flexibility of constitution specially in India; development of nation at different levels is important but this have a negative effect on our health and surroundings which should be considered and rectify as soon as possible; development of appropriate method for disposal of pharmaceutical wastes should needed for ensuring minimal impact on nature. In USA Nebraska medication society suggested some effective ways to deal with medical wastes; which includes tempered boxes use to collect unused or expired drugs from people and further return back to nearest pharmacy center for proper processing. But disposal of unused or expired drugs is not a possible solution because dumping increases the risk of soil contamination; which may or may not leads to water contamination. Best way to get rid of such risk is to reuse medicines by developing effective extraction techniques as I do in my work where I simply convert an expired aspirin tablets into phenol ad methyl salicylate which are only recommended to use on non living stocks. Some developed countries put a bench mark regarding returning medicines to health facilities such as

Sweden and Korea; this represents that the community aware regarding the potential risk of these unused or expired drugs on their surroundings and resources. Such malpractices regarding the use and disposal of drugs should be rectified in developing countries; this is possible when government take strict action and draw such policies which also include fine and punishments according to the type of drugs undergo malpractice. Unused or expired drugs Return Program or Take-back programs in Canada and Meds Disposal in Europe.

Government of some countries provide free medication to patients which leads to increase in medical wastes; government have to focus on this because excess drugs have lethal effects in nature e.g. extinction of species. Drugs should be dispensed according to conditions of diseases; but now a days dispensing of drugs in greater numbers by pharmacists become a integral part of pharma business which highlight a malpractice. The study results suggest that government, pharmacist, and pharmaceutical industry are responsible to create awareness, which is consistent with the suggestions made by others. Proper education regarding drug use and disposal is important in every part of world and it is only possible when educational departments of different countries introduce a particular subject of pharmacy which purely deal with use and disposal of unused or expired dugs in community.

CONCLUSION

Nature provides human beings everything but human always abuse it; in eyes of nature human is also a living organism; but human create artificial world which is full of diseases and infection which is mainly due to improper disposal of waste. Now its time to wake up and do some effective work regarding disposal of medical wastes. In my opinion disposal not a permanent solution for this we have create such methods or techniques through which we can convert expired or unused drugs into useful chemicals.

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