Pharmaceutical Waste Treatment and Disposal Practices

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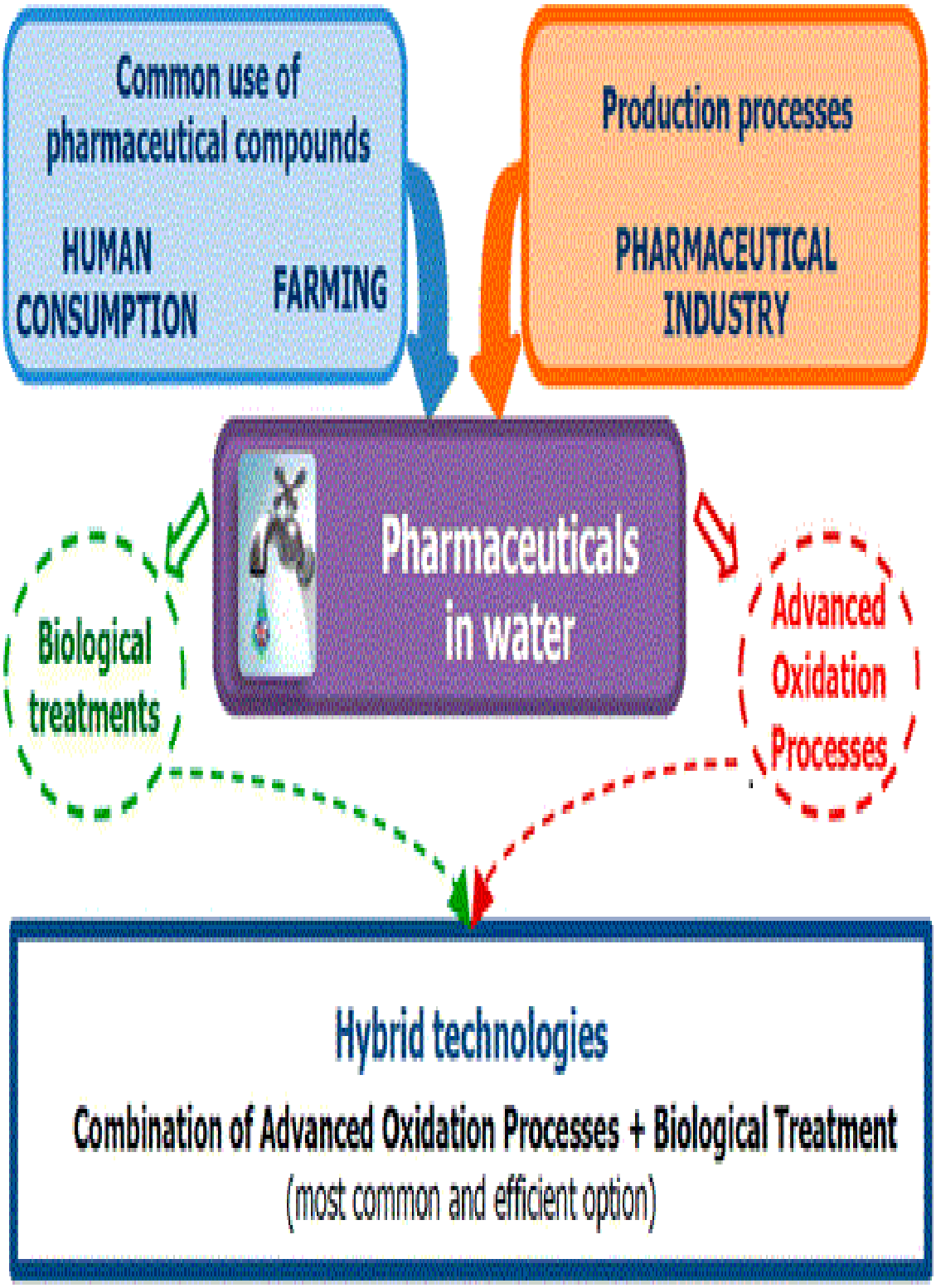
ABSTRACT
Now a days all over the world Pharmaceutical compounds are typically produced in batch processes leading to the presence of a wide variety of products in wastewaters which are generated in different operations, wherein copious quantities of water are used for washing of solid cake, or extraction, or washing of equipment. The presence of pharmaceutical compounds in drinking water comes from two different sources: production processes of the pharmaceutical industry and common use of pharmaceutical compounds resulting in their presence in urban and farm wastewaters. The wastewaters generated in different processes in the manufacture of pharmaceuticals and drugs contain a wide variety of compounds. Further, reuse of water after removal of contaminants, whether pharmaceuticals or otherwise, is required by industry. In view of the scarcity of water resources, it is necessary to understand and develop methodologies for treatment of pharmaceutical wastewater as part of water management. In this review, the various sources of wastewaters in the pharmaceutical industry are identified by Aurabindopharma and the best available technologies to remove them are critically evaluated. Effluent arising from different sectors of active pharmaceutical ingredients (API), bulk drugs, and related pharmaceutics, which use large quantities of water, is evaluated and strategies are proposed to recover to a large extent the valuable compounds, and finally the treatment of very dilute but detrimental wastewaters is discussed. No single technology can completely remove pharmaceuticals from wastewaters. The use of conventional treatment methods along with membrane reactors and advanced post treatment methods resulting in a hybrid wastewater treatment technology appear to be the best. The recommendations provided in this analysis will prove useful for treatment of wastewater from the pharmaceutical industry.
During conflicts and natural disasters large quantities of pharmaceuticals are often donated as part of humanitarian assistance. Undoubtedly many of the pharmaceuticals save lives and alleviate suffering, but some donations given by well-meaning but uninformed people may cause problems. Pharmaceuticals may arrive past or near their expiry date, may be inappropriate for the needs, be unrecognizable because they are labeled in a foreign language or may have been sent in unwanted quantities. Donated pharmaceuticals with a long shelf-life may be mismanaged, Quantifying pharmaceutical waste may be difficult. One Report states that 50-60% of medical supplies.



4.WASTEWATERMANAGEMENT

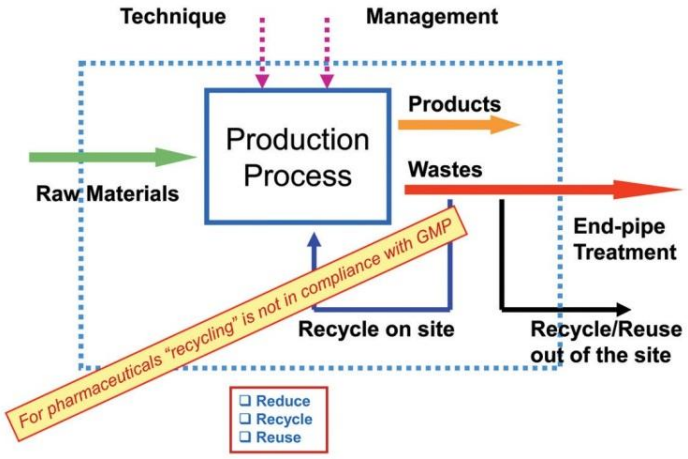


FIGURE 1 Wastewatermanagement

For waste management, the firstpriority is the prevention or reduction of pollutants into aquatic systems. The reuse of recycled compounds for pharmaceutical production is limited due to GMP compliance Figure. An exception is the API production where solvents, filtrates, etc., can be recovered andreused.

A good sample for recycle/reuse of residuals from the production of x-ray Contract Media (CM) is the incineration of bind iodine solutions and extraction as iodide solution by waste gas scrubbing, which can be sold on the worldmarked.

Iodine containing CM is used in computer tomography for diagnostic purposes. To be GMP compliant, recycled compounds cannot be reused for pharmaceutical production, but the iodine can be sold on the market. The iodine containing residuals comes, for example, from CIP processes during the Manufacturing process. Using a membrane filtration process (discussed in the case study below), the iodine load in wastewater can be reduced by > 99%; permeate can be discharged into an official sewage system Another example of wastewater reduction from pharmaceutical production facilities is the optimization of CIP processes. The wastewater from finished pharmaceutical facilities comes primarily from rinsing solutions from the manufacturing process. The wastewatercan be reduced by optimization of the water consumption for these cleaning processes by using PAT for detecting the maximum allowable level of residues present.Areal time, inline process monitoring tool, which can analyze water samples downto the defined maximum allowable level of residues presenton the vessels, can reduce the water consumption. A reduction of wastewater up to 50% ispossible.

Definition and interpretation of impurities for process equipment is product related. The concentration of micro- pollutants discharged into dedicated WWTP is needed to design the treatment process sufficiently that it is able to reduce aqua-toxic substances as much as possible belowNo Observed Effect Level(NOEL).

Due to this production integrated wastewater discharge and treatment process, sufficient production andoperation experience, as well as

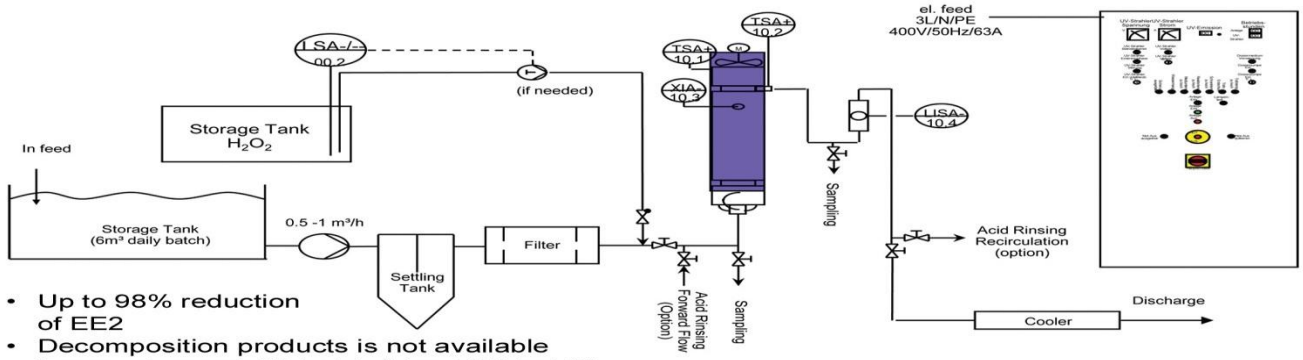
understanding regulatory requirements, are needed. Understanding the properties of the product is the pre-condition for a successful design and operation of production integrated dedicatedWWTPs.
CHAPTER 6

6. UV– H_2O_2 OxidationProcess

Today's biological wastewater treatment plants aredesigned so that they are able to eliminate carbon, nitrogen, and phosphorus from thewastewater.
The predicted environmental concentration (PEC) at effluent from municipal WWTP for EE2 is 0.1 Mg/l (0.1 ppb) due to domestic sewage only and by a factor of 10 below the (NOEC) received by chronic studies (1Mg/l).
Technical measurements are requested to reduce the in feed of rinsing water from the hormone production into the municipal sewagesystem.
SourcesofWastewaterfromtheProductionofOral ContraceptiveEE2 will be emitted into the wastewater by using waterfor rinsing for the production equipment cleaning process - *Figure*.

Thewastewaterfromthecontraceptiveproduction(ca.35 m^3/d at 50-60°C) with an average EE2 concentration of16µg/L will be collected in a separator for solidmatters.

In this separator, settleable particles will be discharged into two Polyethylene-containers below the separator and regularlydiscarded.
The wastewater will be cooled down to 30°C. Not settled particle > 2.5 mm will be filtered by a sieve before thewaste- water enters the UV reactor as the quality of the UV emitter will be reduced by particles and fouling at the UV emitter surfaces. Oxidizing agent H_2O_2 35%ig, 0.8 l/m (= 2 l H_2O_2/h) will be fed to the wastewater by a dosing pump. The capacity of the UV reactors is 2500l/h.
Wastewater from production is stored in two storage tanks, each 10 m^3, made of polypropylene. The wastewater willbefedtothecylindricalUVreactorwithtangentialwater injection.



- Up to 98% reduction of EE2
- Decomposition products is not available
- Energy demand: 21 kwh/m³ (ca. 735 kwh/d)
- Hydrogen peroxide ca. 2 l/h (0.8 ml H_2O_2/l ww)
- Limited lifecycle of UV-emitter 1000 to 2000 hrs (i.e., UV – emitter has to be changed two times per year)
- Creation of coated film burned-in on surface of the emitter (i.e., cleaning twice per week)

FIGURE 2 process flow of the uv-H_2O_2 Oxidation process

FIGURE3

FIGURE 4.Two UV oxidation reactors operating inparallel.

6.3 ResultoftheUV–H_2O_2OxidationProcess

UV resources have a relatively high energy density (50 to 200watt/cm).Withtheoxidationagenthydrogenperoxide, high activated hydroxyl radicals will be developed, which have the highest oxidationpotential. The oxidation agent H_2O_2 alone is not sufficient to destroy the Ethinylestradiol complex. The UV reactor ismade of stainless steel with a coolingjacket.

The outlet temperature after the second UV reactor increased to a maximum 41°C. The maximum wastewater temperature is limited to 30°C at the final effluent discharge point. An additional cooler had been installed to reach the maximum allowed discharge temperature into the municipal sewagesystem.

The UV emitter, type mercury (Hg) medium pressure 20 KW is installed in the cylindrical UV chamber. The radiation of the UV lamp is in the UV-C range (200 to 280 nm). With an energy in-feed of 21 KWh/m^3 wastewater, EE2 concentration is below detection limit. The energy demand is 735 KWh/d, i.e., 30.6 KW isneeded.

Due to the varying initial concentration of EE2 two 20 KW UV reactors were installed in series to ensure that the EE2 concentration is below the detectionlimit.

The depth of penetration of UV radiation into water is relatively low. The intensity will be reduced by

absorption of dissolved substances and turbid water as well as by reflection of watersubstances.Fouling problems have been encountered in the tubular reactors:

A milky film (covering) will be burned into the surface of the quartz tube (glass) and have to be cleaned with citric acid twice per week to avoid degrease of energy transferredintothewastewaterbytheUVlamp.Thecondition of the quartz tube is checked by a UV-sensor measuring system.

8.2 ResultoftheMembraneFiltrationProcess

- Iodine load in wastewater reducedby> 99% (AOI < 3.6 ppm, AOX < 1ppm)
- permeate can be discharged toa municipalWWTP Operation costs (without depreciation): 3.80 €/m^3 CIP rinsing water (6,000 m^3 CIP rinsingwater/a)
- Incineration is only needed for the concentrate (5-10% of the initial volume)

saving energy and treatmentcosts and OperationCosts The investment costs depend on the existinginfrastructure of the specific affiliate and cannot be compareddirectly.

Conclusion

The UV oxidation process can be used for small amounts ofdedicated pharmaceuticalwastewateronlywhenitisnot mixed with any other wastewater stream. The Ethinylestradiol complex can be reduced below limit of detection; unfortunately, it is unknown if this UV oxidation process creates any oxidation by-products (transformation by-products), which still have to bestudied.

Investment costs for the membrane process are in the range of the UV oxidation process; due to the high pressure demand for the membrane process, there is only a minor energysavingincomparisonwiththeUVoxidationprocess.To keep the operation cost low, this process is suitable for small amounts dedicated pharmaceutical wastewater streams only.

The RBC process has the lowest operation costs for treatmentofpharmaceuticalwastewaterasithasthelowest maintenance demand and lowest energy consumptionof all three processes. The wastewater compounds must be biodegradable; in this case, it would be appropriate tomix itwiththesanitarywastewaterorwastewaterfromother production facilities under the condition that it promotes the biodegradation of wastewater components. This is the most flexible process concerning wastewater compounds (as long they are biodegradable), shock load, and flow rate. The chosen biological oxidation process is able to build up a biological environment containing special organisms, whichhave a more selective effect on organic matters which are not easy forbiodegradation.

It is the company's responsibilityto ensure that their manufacturingoperation produces GMP compliantpharmaceuticals; it is also a company's responsibility to ensure environmental protection during the process. Municipal wastewater treatment facilities cannot reduce pharmaceutical micro pollutants sufficiently; only dedicated wastewater pre-treatment processes (at point of source) can support this target to reduce these micro pollutants below the levelof NOEC.

Despite advances in water treatment, a precautionary approach toward water and chemical management one that reduces introduction of problematic chemicals into the environment in the first place should be given a high priority for reducing risks to human health and ecosystemintegrity.

ABBREVIATIONS

1. AOX Adsorbableorganicallyboundhalogens,X=Cl,Br,I
2. API Active PharmaceuticalIngredient
3. BAT Best AvailableTechnology
4. CIP Cleaning InPlace
5. CM ContrastMedia
6. CT ComputerTomography
7. EDS EndocrineDisruptingSubstances
8. E2 17β-Estradiol
9. EE2 17α- Ethinyl estradiol
10. EEA European Environmental Agency EPA Environmental Protection Agency
11. ERA Environmental RiskAssessment
12. GEDRI Global Endocrine Disruptor ResearchInventory
13. GMP GoodManufacturingPractice
14. NOEC No ObservedEffectConcentration
15. NOEL No Observed EffectLevel
16. OC OralContraceptive
17. PEC PredictedEnvironmentalConcentration PLC Process LogicController
18. PP Poly propylene
19. RBC Rotating BiologicalContactor
20. RCMS Responsible Care ManagementSystem
21. WWTP Wastewater TreatmentPlant

Recommendations

1. Effective implementation of rules by surprise visits and inspection by appropriate authorities and fixing accountability of each and every person involved in management of Bio-Medical waste.
2. Transportation should be done in closed trolleys and by separate route.
3. Sensitization of waste generators ad health care providers should be done more frequently, and separate sensitization programs should be organized for sweepers and fourth class health workers, in local language emphasizing the importance of using personal protective measures and immunization for Hepatitis B
4. For the use of incinerator Training should be given to some number of persons from staff.
5. Private hospitals should also be allowed to use incinerator, which is installed, in govt. hospital. For this purpose a specific fee can be charged from private hospitals.
6. Bio-medical waste Management Board can be established in each District.
7. Either judicial powers should be given to the management board or special court should be established in the matters of environment pollution for imposing fines and awarding damages etc.
8. Housekeeping staff wear protective devices such as gloves, face masks, gowned, while handling the waste.
9. There is biomedical waste label on waste carry bags and waste carry trolley and also poster has put on the wall adjacent to the bins (waste) giving details about the type of waste that has to dispose in the baggage as per biomedical waste management rule.
10. Carry bags also have the biohazard symbol on them.
11. The entire waste management practices should be a part of total hygiene practice of the society rather than confining to hospital and health facility.
12. Intensive training programs at regular time interval for all the staff with special importance to the new comers.

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