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PHARMACEUTICAL AND BIOMEDICAL WASTE MANAGEMENT: AN OVERVIEW ON PLANT LAYOUT AND LOCATION

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ABSTRACT: Biomedical and Pharmaceutical waste management is essential for safeguarding public health as well as environmental sustainability. Efficient waste management systems are crucial to minimize the adverse impact of biomedical waste. This article gives the key aspects of bio- medical and pharmaceutical waste management including plant location, land requirement, area, machines and equipment, infrastructure, collection and transportation. This article mainly focusses on the no-burn technologies used for treating most of the categories of pharmaceutical waste, highlighting the need for incineration for specific categories of waste and other equipment required for proper treatment of waste. This article also explains in detail the basic infrastructure setup of a common bio-medical waste treatment facility (CBWTF).

INTRODUCTION: Pharmaceutical waste results from various day-to-day activities occurring in the manufacturing facilities as well as healthcare systems. Pharmaceutical waste management is an integral part of pharmaceutical industries as well as healthcare systems. Effective management of pharmaceutical waste poses high significance in safeguarding and promoting public health and environmental sustainability. In order to minimize the environmental and health impact of pharmaceutical waste effective waste management systems have been established by various government regulatory bodies. Such a waste treatment facility should encompass different machines, equipment, appropriate location and layout facilities for the effective management of pharmaceutical waste.

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Plant Location: A Common Biomedical Waste Treatment Facility (CBWTF) should be located in an area which is considerably far away from residential areas in order to minimize the impact on the people residing there. Moreover, it should be located near to the area which generates waste by reducing the time required for transportation thereby enhancing operational flexibility. While starting a common biomedical waste treatment facility the location should be decided in consultation with the State Pollution Control Board (SPCB)/Pollution Control Committee (PCC) [1].

Land Requirement: Allocation of ample amount of land is essential for the effective working of a Common Biomedical Waste Treatment Facility. A minimum area of 1 acre is required, so preferably a CBMWTF should be set up on a plot size not less than that [1].

Coverage Area of CBWTF: In a particular area, only one CBWTF is allowed to serve up to 10,000 as prescribed by the respective Authority. A CBWTF's service is limited to a radius of 150km

and cannot cater to units beyond this distance. However, if 10,000 beds are not available within the area of 150 kms, an additional CBWTF may be allowed to service healthcare units outside the radius [2].

Equipment and Machines: As per Bio-medical Waste Rules, waste falling under most of the categories can be treated by non-burn technologies. Such waste holds 90% of total waste in a health care system. CBWTF should emphasize more on non-burn technologies for the treatment of waste. It has been made mandatory that a CBWTF should impart incineration for anatomical and other types of waste falling under catergoy 1 & 2 (Human anatomical waste & animal waste). For this purpose, an incinerator or adequate capacity shall be installed. Category 5 (discarded medicines, cytotoxic drugs) and category 10 (chemical waste) can be disposed of in landfills. A Common Bio-medical Waste Treatment Facility should have the following treatment facilities:

1. Incineration
2. Autoclaving
3. Microwaving
4. Hydroclaving
5. Shredder
6. Sharp pit
7. Vehicle/container washing facility
8. Effluent treatment facility

Incineration: Incineration is a controlled combustion process in which waste is completely oxidised in order to destroy/denature the microorganisms present in it under high temperature. The guidelines for "Design & Construction of Bio-medical Waste Incinerators" are prepared by CPCB and shall be followed while selecting/installing a better bio-medical waste. Incineration is usually carried out for the treatment of waste falling under yellow category (Human & Animal Anatomical Waste) [3].

FIG. 1: INCINERATOR [4]

Autoclaving: Autoclaving is a low heat-thermal process in which waste is brought in direct contact with steam in a controlled manner for sufficient time for disinfection of waste. For easy and safe operation, the system should be horizontally placed and exclusively designed for treating Biomedical Waste. Mainly two types of autoclaves are available they are gravity displacement autoclaves and vacuum autoclaves. For obtaining optimum results, a pre-vacuum, based system is preferred. It must have a tamper-proof control panel containing excellent display and recording devices for recording the critical parameters such as time, temperature, pressure, date, batch number *etc* [1].

Microwaving: Microwaving is a process carried out for inactivating microbes as a result of thermal effect of electromagnetic radiation having a spectrum ranging from 300 to 3000 MHz. Microwave heating is an intermolecular heating process which occurs in presence of steam [2].

FIG. 2: MICROWAVE [5]

Hydroclave:

FIG. 3: HYDROCLAVE [6]

Hydroclaving is similar to autoclaving except that in hydroclaving the waste is subjected to indirect heating by applying steam in the outer jacket. The waste is constantly tumbled in the chamber during hydroclaving.

Shredder:

FIG. 5: SHREDDER [7]

Shredding is a technique in which the waste is misshapen in order to make them unrecognizable as well as to prevent the reuse of such waste. A shredder used for shredding bio-medical waste must have the following requirements:

1. It must have a sturdy layout with minimal maintenance requirements.
2. Shredders should be nicely designed in a way that it reduces spillage and waste generation.
3. The hopper and slicing chamber of the shredder should be designed in such a way that it completely deals with the bag of bio-medical waste.
4. The shredder blade must be resistant and should be capable of shredding sharps such as syringes, vials, blades, plastics, catheters, damaged ampoules, IV sets/bottles, blood bags, gloves, bandages, etc.
5. Shredder blade must be non-corrosive and made up of hardened steel.
6. The shredder must ne installed in such a way that it does not generate excessive noise and vibration.
7. In case of shock-loading, there should be a mechanism to mechanically prevent the shredder from any emergency/accident.
8. The minimal ability of motor connected with the shredder will be 3KW for 50kg/hr, 5KW for a 100 kg/hr & 75KW for 200 kg/hr and there will be three segment induction motor [2].

Sharp PIT/Encapsulation: Sharp pit facility is provided for the disposal of treated waste falling under category 4 (waste sharps). An option may also be worked out for recovery of metals from sharps.

FIG. 6: SHARP PIT [8]

Vehicle/Container Washing Facility: Every time the vehicle carrying biomedical waste is unloaded, the vehicle as well as the empty containers should be washed thoroughly and disinfected, it could be performed in an open location however on an impermeable platform and liquid effluent so generated will be accumulated and dealt with in an effluent remedy plant. The impermeable location will be of suitable length, a good way to keep away from spillage of liquid all through washing [2].

Effluent Treatment Plant: An appropriate Effluent Treatment Plant must be made available to make certain that liquid effluent generated all through the technique of washing bins, vehicles, flooring etc. is disposed of after remedy. The treated effluent shall comply with the stipulated

standards for limits of various parameters according to regulatory requirements. Wards, laundry, laboratory, discharge of accidental spillage, firefighting, bathroom/toilet etc are the sources of waste waster in a healthcare unit. Liquid waste which is generated due to use of chemicals or discarded disinfectants, infected secretions etc must be collected separately and pre-treated before mixing with the rest of the liquid waste. The combined wastewater is treated in three levels; primary, secondary and tertiary.

FIG. 7: EFFLUENT TREATMENT PLANT [9]

Primary Treatment: Equalization, neutralization, precipitation and clarification.

Secondary Treatment: High-rate aerobic biological treatment, secondary settling tank.

Tertiary Treatment: Pressure Filtration, Disinfection and disposal to drain/sewer [1].

All the treatment equipment installed in a treatment facility shall comply with the standards of Bio-medical Waste Rules, 1998 [10].

Infrastructure:

Infrastructure set up: The CBWTF shall have sufficient area inside it to put in required treatment equipment, incoming and outgoing waste storage location, vehicle-parking and washing location, Effluent Treatment Plant (ETP), workers room etc. The required location for CBWTF could depend on the projected quantity of bio-medical waste to be treated via way of means of it. A CBWTF shall have the subsequent infrastructure:

1. Treatment equipment room
2. Main waste storage room
3. Treated waste storage room
4. Administrative room
5. Generator set
6. Site security
7. Parking
8. Sign board
9. Green belt
10. Washing room

Treatment Equipment Room: Separate housing can be allocated for every treatment equipment on the CBWTF including incinerator room, autoclave room, microwave room etc. as applicable. Each room shall have a well-designed roof and walls. Such a room should be properly ventilated and must be smooth to scrub. The ground and indoors completing of the room will be such that probabilities of sticking/ harbouring microorganisms are minimized. This may be attained with the aid of using presenting easy & nice ground and wall surfaces (to a top of two meter from ground) ideally of tiles. The range of joints in such surfaces will be minimal. The equipment room shall even have a separate cabin, to oversee the operation of the device and to document the waste dealing with equipment operational data. Attached to every equipment room, there should be waste storage rooms, one for storage of untreated waste and any other for treated waste. The waste storage room shall have provisions like that of an equipment room being adequately ventilated with smooth to scrub floors & walls, easy and fine surfaces etc. treatment equipment as well as storage rooms must contain ‘fly catcher/killing device’ and should be washed and cleaned with an appropriate disinfectant daily.

Main Waste Storage Room: The Main Waste Storage Room should be furnished close to the access point of the CBWTF to dump and save all bio-medical waste which have been transported to the treatment facility via way of means of

collection vehicles. The area of the room must be adequate for the storage of all waste transported to the CBWTF. The front part of the room will be applied for unloading the waste from the vehicle and the back portion will be applied for transferring the waste to the respective remedy system. In the front of the room wherein the vehicle is parked for unloading, the ground will be made impermeable in order that any liquid spilled throughout unloading does now no longer percolate into the ground. The liquid generated throughout dealing with waste and washing, will be diverted to the inlet of ETP. In the primary garage room, waste will be stacked with clean difference as in line with the colour coding of the boxes. From here, the coloured boxes can be despatched to the respective remedy system. The primary storage room too shall have provisions just like that of the system room together with roofing, properly ventilated, clean to scrub floors & walls, clean and great surfaces etc.

Treated Waste Storage Room: This is the room where the treated waste obtained from various treatment units is being stored. The waste will be stored in separate groups in line with the disposal options. Other provisions of the treated waste storage room are similar to that of the main storage room. Waste obtained from processes such as incineration (ash/vitrified ash) must be safely stored in separate areas, avoiding entry of rain water during rainy seasons. If the treated ash is hazardous in nature, it must be disposed of through any authorized vendor as per the regulations of Hazardous and other waste (management and Transboundary Movement) Rules, 2016.

Administrative Room: An administrative room is essential for managing operations, record-maintenance, and managing the overall facility. Administrative room must contain the basic infrastructural set up such as desks and cabins for staff, cabinets for storage of documents, table for conducting training as well as meetings, sufficient power outlets for computers, printers and other electrical gadgets. Adequate lighting should be provided in the room with uninterrupted electrical supply. A stable internet connection for data management and communication as well as a telephone for emergency communication must be equipped in the room. The room should contain surveillance cameras and access to the room should be limited to authorized individuals only. Fire alarm systems, fire extinguishers restroom facilities, waste bins, air conditioning and ventilation systems etc are some of the basic and most essential requirements which need to be maintained.

Generator Set: Every CBWTF shall have a generator set as standby association for electricity, with enough potential to run the treatment equipment throughout the failure of electricity supply. The generator set shall comply with the standards as that of the Environment (Protection) Rules, 1986. The generator room must have an ample amount of space for placement of generators, they should be placed in such a manner that there is availability of adequate space between them in order to facilitate maintenance works. Proper ventilation facilities must be provided in the generator room to fritter the heat and fumes from the generator. Fire alarms and fire extinguishers must be made available in case of any emergencies, the room should be made soundproof in order to minimise the noise produced from generators. The generator present should have sufficient capacity to serve various treatment equipment such as incinerators, autoclave, shredder etc without any interruption.

Site Security: High walls, fencing and protected gates shall be made available in the facility to prevent the entry of unauthorized personnel as well as livestock to the facility.

Parking: Provision for parking of vehicles carrying bio-medical waste shall be made for the efficient loading and unloading of waste.

Sign Board: An identity board of durable material and shall be displayed at the entrance of the facility. This should clearly display the name of the facility**,** name, address and telephone number of the operator and prescribed authority, hours of operation and emergency contact number should be made.

Green Belt: Green belt refers to land/open spaces which are protected from developmental activities such as construction of buildings factories etc [11]. The open area which is left in the CBWTF shall be used for the development of the green belt. The

green belt is considered as one of the major components of Environmental Management Plan [2].

Washing Room: A washing room should be furnished for eye washing/hand washing/bathing etc. Besides above, following crucial provisions have to be made in a CBWTF:

1. A telephone should be maintained
2. First Aid Box shall be furnished and maintained on the CBWTF.
3. Proper lighting fixtures will be furnished on the facility.
4. Facility should be kept free from surrounding odors.
5. Proper fore rescue facilities should be installed.
6. Measures to control pests should be installed.
7. Measures to control the escape of litter from the site must be installed.
8. Necessary provisions to control noise generation from treatment equipment must be installed.
9. Protective gear and clothing for workers must be provided.

Every CBWTF operator should submit a work-plan to the respective authority, which encompass the details of the facilities available there, their collection, transportation and storage of bio-medical wastes, operational details *etc* [2].

Collection and Transport: Collection and transportation are two important operations in which the chances of mix-up as well as contact with the public are high. In order to prevent this, appropriate care should be taken to ensure that the bio-medical waste handed over by healthcare units reach the facility without any damage, spillage or unauthorized access by public, animals etc.

Collection: Generator of the bio-medical waste is accountable for offering segregated waste to the CBWTF operator. The waste is segregated according to the guidelines prescribed by Bio-medical waste rules, 2016. The Common Bio-medical Waste Treatment Facility (CBWTF) provides a temporary storage room for segregated waste stored in coloured containers with proper cover. Each bag must be labelled according to schedule IV of Bio-medical Waste Management Rules therefore the healthcare units which do not segregate waste as per BMWR can be tracked. The coloured bags and containers have adequate strength in order to withstand damage which might occur during loading, transportation and unloading of waste from these containers. Collection of sharps such as needles, syringes etc should be in puncture resistant containers. The personnel authorized for the collection of BMWs must carry a register with him for maintenance of records such as name of the Health Care Facility (HCF), quantity of waste collected, time of collection, signature of authorized person from HCF etc.

Transportation: Transportation of collected biomedical waste must be carried out in vehicles owned by the CBWTF, registered under Motor Vehicle Act with the respective RTO/Transport department and the person involved in transportation must be registered with SPCB/PCC for collection of bio-medical waste from health care units. The segregated BMW collected in coloured containers must be transported to the treatment facility in a fully covered transportation vehicle which is solely used for the purpose of collection of bio-medical waste. Based on the amount of waste to be collected and transported the vehicle may be a three-wheeler, light or heavy motor vehicle. The transportation vehicle must have the following requirements:

1. Transportation vehicles must be equipped with GPS to track the location of the vehicle.
2. There must be separate cabins for drivers and for placing the collected waste.
3. Two wheelers are only used for the purpose of collection of waste from clinics or dispensaries located in places where accessibility of four-wheeler vehicle is difficult. Such two-wheeler and vehicle must be registered under Motor Vehicle Act should be equipped with a box for collection of waste which is marked with the bio-hazard symbol, contact details, proper closure, collection procedure for emergency spill, first aid box and other records in line with BMW Rules.
4. The waste cain must be leakproof in order to avoid the leakage of liquid during transportation.
5. The waste cabin must be designed in such a way that if facilitates the storage of waste in

tiers, easy for cleaning and disinfection, must have a smooth surface which minimises water retention.

6. Cabin must have sufficient provisions for the loading and unloading of waste from the vehicle.
7. The driver must always carry a copy of his license, registration of vehicle and also a, pollution under control, certificate issued authorized licensing authority [2].

Depending upon the area covered under the CBWTF, the path of transportation will be worked out. The transportation routes of the vehicle will be designed for maximum journey distance and to cover a range of healthcare units. As far as possible, transportation will be performed at times where the traffic is low. If the vicinity to be covered is very large, various sub stations are established in order to transport the waste with more ease. We must ensure that the time taken for collection, and transportation od bio-medical waste must not exceed 48 hours.

CONCLUSION: Biomedical and Pharmaceutical waste management is an integral part of pharmaceutical industry as well as healthcare system. Effective management of pharmaceutical waste is essential in safeguarding and promoting public health and safety, in order to ensure that, an appropriate waste treatment facility has been set up by following the guidelines of Bio-medical Waste Rules and that of SPCB. Such a treatment facility must encompass a minimum requirement of equipment, area and other infrastructure setup. The most common treatment equipment includes autoclave, incinerator, hydroclave, shredder *etc*. proper disposal of wastes after treatment should also be done according to the guidelines of Bio-medical waste rules 2016, which includes sharp pits, encapsulation etc. the facility must also provide provisions for the proper collection and transportation of segregated waste from the point of generation to the treatment facility.

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