PHA 206

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Pharmacology

1.) All sterilization processes (thermal, chemical, radiation, and filtration) are designed to destroy or eliminate microbiologic contaminants present in a product. The official test for sterility of the product is a destructive test on a selected sample; thus, the task of proving that all units of a product are sterile must involve the employment of probability statistics. The statistics of probability depend on such parameters as the length or degree of exposure to the steriliants, the type and number of microorganisms present, the desired level of microbial destruction or elimination, and the resistance of the microorganism(s) presented to the sterilization process.

2.) Sterilization can be defined as any process that effectively kills or eliminates transmissible agents (such as fungi, bacteria, viruses and prions) from a surface, equipment, foods, medications, or biological culture medium. In practice sterility is achieved by exposure of the object to be sterilized to chemical or physical agent for a specified time. Various agents used as steriliants are: elevated temperature, ionizing radiation, chemical liquids or gases etc. The success of the process depends upon the choice of the method adopted for sterilization.

pharmaceutical Importance of Sterilization

1.) Moist heat sterilization is the most efficient biocidal agent. In the pharmaceutical industry it is used for: Surgical dressings, Sheets, Surgical and diagnostic equipment, Containers, Closures, Aqueous injections, Ophthalmic preparations and Irrigation fluids etc.

2.) Dry heat sterilization can only be used for thermostable, moisture sensitive or moisture impermeable pharmaceutical and medicinal. These include products like; Dry powdered drugs, Suspensions of drug in nonaqueous solvents, Oils, fats, waxes, soft hard paraffin, silicone, Oily injections, implants, ophthalmic ointments and ointment bases etc.

3.) Gaseous sterilization is used for sterilizing thermolabile substances like; hormones, proteins, various heat sensitive drugs etc.

4.)U.V light is perhaps the most lethal component in ordinary sunlight used in sanitation of garments or utensils.

5.)Gamma-rays from Cobalt 60 are used to sterilize antibiotic, hormones, sutures, plastics and catheters etc.

6.) Filtration sterilizations are used in the treatment of heat sensitive injections and ophthalmic solutions, biological products, air and other gases for supply to aseptic areas. They are also used in industry as part of the venting systems on fermentors, centrifuges, autoclaves and freeze driers. Membrane filters are used for sterility testing.

3a.)

Gaseous Sterilization method

The chemically reactive gases such as formaldehyde, (methanol, H.CHO) and ethylene oxide (CH2)2O possess biocidal activity. Ethylene oxide is a colorless, odorless, and flammable gas.

The mechanism of antimicrobial action of the two gases is assumed to be through alkylations of sulphydryl, amino, hydroxyl and carboxyl groups on proteins and amino groups of nucleic acids. The concentration ranges (weight of gas per unit chamber volume) are usually in range of 800-1200 mg/L for ethylene oxide and 15-100 mg/L for formaldehyde with operating temperatures of 45-63°C and 70-75°C respectively.

A. Ethylene oxide sterilizer: An ethylene oxide sterilizer consists of a chamber of 100-300-Litre capacity and surrounded by a water jacket. Air is removed from sterilizer by evacuation, humidification and conditioning of the load is done by passing sub-atmospheric pressure steam, then evacuation is done again and preheated vaporized ethylene oxide is passed. After treatment, the gases are evacuated either directly to the outside atmosphere or through a special exhaust system. Ethylene oxide gas has been used widely to process heat-sensitive devices, but the aeration times needed at the end of the cycle to eliminate the gas made this method slow.

B. Low temperature steam formaldehyde (LTSF) sterilizer:

An LTSF sterilizer operates with sub atmospheric pressure steam. At first, air is removed by evacuation and steam is admitted to the chamber.

4.) Radiation sterilisation utilises ionising radiation to sterilise medical devices. Its usage has grown in recent decades as more facilities have been built, radiation resistant materials developed and dosage levels more tightly defined. The introduction of electron beam sterilisation has also expanded the use of radiation for sterilisation.