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 an essential stage in the processing of any product destined for parental administration or for the contact with broken skin , mucosal surfaces , or internal organs , where the threat of infection exist. In addition,the sterilization of microbiological materials, soiled dressings and other contaminated items is necessary to minimize the Health hazard associated with these articles. Sterilization processes involve the application of a biocidal agent or physical microbial removal process to a product or preparation with the object of killing or removing all micro organism 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.) Gaseous sterilization is used for sterilizing thermolabile substances like; hormones, proteins, various heat sensitive drugs etc.

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

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

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.