

Okunnu Ifedola Rachel

18/mhs07/039

Pharmacology

PHA206

1. Sterilization is an Essential stage in the processing of any product destined for parenteral administration, or for contact with broken skin, mucosal surfaces, or internal organs, where the threat of infection exists. 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 microorganisms. These processes may involve elevated temperature, reactive gas, irradiation or filtration through a microorganism-proof filter. The success of the process depends on a suitable choice of treatment conditions, e.g. temperature and duration of exposure. It must be remembered, however, that with all articles to be sterilized there is a

potential risk of product damage, which for a pharmaceutical preparation may result in reduced therapeutic efficacy, stability or patient acceptability. Thus, there is a need to achieve a balance between the maximum acceptable risk of failing to achieve sterility and the maximum level of product damage that is acceptable. This is best determined from a knowledge of the properties of the sterilizing agent, the properties of the product to be sterilized and the nature of the likely contaminants. A suitable sterilization process may then be selected to ensure maximum microbial kill/removal with minimum product deterioration.

2. **Sterilization** is a critical process in the pharmaceutical industry for the control of microbial populations. While most prevalent in the manufacture of sterile products it can be used in a variety of settings where microbes have potential impact on patients or products.

Importance:

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.

3. Gaseous Sterilization: Sterilizing gases are typically used when exposure to other methods (heat or radiation) could damage the materials or equipment. The most common gases used for sterilization include ethylene oxide (EO), ozone, mixed oxides of nitrogen, and chlorine dioxide. In any type of surgery, the ideal method of sterilization should be one that safely permits the sterilization of all instruments, sutures, and drapes as well as plastic and rubber materials together in the same sterilizer. Rusting, corrosion, charring, or deterioration in any form must not occur even after repeated sterilization. Gas sterilization with ethylene oxide gas is the only method available today that meets all of these requirements. A small portable sterilizer using ethylene oxide gas which is ideal for ophthalmic surgery has been used in these studies.*

4. There are 2 general types of radiation used for sterilization, **ionizing radiation** and **non-**

ionizing radiation. Ionizing radiation is the use of short wavelength, high-intensity radiation to destroy microorganisms. This radiation can come in the form of gamma or X-rays that react with DNA resulting in a damaged cell. Non-ionizing radiation uses longer wavelength and lower energy. As a result, non-ionizing radiation loses the ability to penetrate substances, and can only be used for sterilizing surfaces. The most common form of non-ionizing radiation is ultraviolet light, which is used in a variety of manners throughout industry.

One industrial application of non-ionizing radiation is the breakdown of ozone (O₃). By adding ozone to water, bacteria are unable to sustain life. Unfortunately, ozone also destroys process media. Therefore ozone must be broken down so water can be used for its designated purpose. Since ozone is very sensitive to ultraviolet light, pass the water stream under UV bulbs. This breaks the oxygen-oxygen bonds and results in safe process water.

Reference: jamannetwork.com

large.stanford.edu

qu.edu.iq

basicmedicalkey.com