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**PHA 206 Assignment**

1. Question: Sterilization is an essential stage in the processing of any product destined for parental administration or for contact with broken skin. Discuss?

Answer:

The purpose of sterilization and disinfection procedures is to prevent transmission of microbes to patients. In addition to sterilization and disinfection, other important measures to prevent transmission are included in the protocol of “standard precautions” (previously known as Universal Precautions). These standard precautions should be used in interaction with all patients because it is unknown whether any particular patient may be the reservoir of transmissible bacteria, viruses, or other microbes.

Standard precautions include hand hygiene, respiratory hygiene and cough etiquette, safe injection practices, and proper disposal of needles and scalpels. Further, if exposure to body fluids or aerosols is likely, personal protective equipment (PPE) such as masks or face shields, gloves, gowns, and protective eyewear should be used. The precautions taken should be specific for the task rather than for the particular patient.

In addition, there are transmission-based precautions that supplement the standard precautions and should be employed when the patient is infected (or suspected to be infected) with a highly transmissible organism. The three categories of transmission-based precautions are contact, droplet, and airborne.

1. Question: Discuss the importance of sterilization in the production of pharmaceutical products

Answer:

**Pharmaceutical importance of sterilization**.

- 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.

- 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 no aqueous solvents, Oils, fats, waxes, soft hard paraffin, silicone, Oily injections, implants, ophthalmic ointments and ointment bases etc.

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

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

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

- 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 fermenters, centrifuges, autoclaves and freeze driers. Membrane filters are used for sterility testing.

- Pharmaceutical products are sterilized because the microorganisms that maybe present if not sterilized can reduce the effectiveness of the drugs.

1. Question: Explain gaseous sterilization, its sterilizer design, and operation.

Answer:

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. According to USP, “EO’s ability to penetrate through polymers, cellulosic, and other materials allows it to be used for the terminal sterilization of medical devices in their final packaging. This goes into detail about the following gas types:

Ethylene oxide: A powerful alkylating agent that destroys microorganisms by chemical reaction, primarily with cell DNA. The destructive mechanism largely follows first-order kinetics and depends on concentration, humidity, and temperature.

Ozone: A potent oxidizing agent produced by passing a stream of oxygen or air through a high-voltage electrical field. Ozone is an effective biocidal agent for treatment of water supplies and has demonstrated lethality at concentrations from 2%-10% in air.

Chlorine dioxide: An effective sterilizing gas. Pure chlorine dioxide is metastable and therefore is generated as needed. Chlorine dioxide in no carcinogenic, non-flammable, and effective at ambient temperatures.

Nitrogen dioxide: A sterilizing gas effective at ambient temperature. Liquid nitrogen dioxide is converted to a gas on introduction to the target chamber. Nitrogen dioxide is nonexplosive and its residues are no carcinogenic, no cytotoxic, and no teratogenic.

Also included in this chapter is information on the validation of gas sterilization, equipment qualification, empty chamber parameter distribution, component and load mapping, biological indicators, process confirmation and microbiological challenge, and routine process control

1. Question: What is radiation sterilization

Answer:

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. Here is a simple representation of the system.

Advantages:

* No degradation of media during sterilization, thus it can be used for thermally labile media
* Leaves no chemical residue
* Administration of precise dosage and uniform dosage distribution
* Immediate availability of the media after sterilization

Disadvantages:

* This method is a costlier alternative to heat sterilization
* Requires highly specialized equipment