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**ASSIGNMENT:** STERILIZATION IS AN ESSENTIAL STAGE IN THE PROCESSING OF ANY PRODUCT DESTINED FOR PARENTAL ADMINISTRATION OR FOR CONTACT WITH BROKEN SKIN. DISCUSS

DISCUSS THE IMPORTANCE OF STERILIZATION IN THE PRODUCTION OF PHARMACEUTICAL PRODUCTS.

EXPLAIN GASEOUS STERILIZATION, IT'S STERILIZER DESIGN AND OPERATION.

WHAT IS RADIATION STERILIZATION?

1. STERILIZATION IS AN ESSENTIAL STAGE IN THE PROCESSING OF ANY

## PRODUCT DESTINED FOR PARENTAL ADMINISTRATION OR FOR CONTACT WITH BROKEN SKIN. DISCUSS

Sterilization is the process of destroying or removing a micro-organism on an object. This processes may involve elevated temperature, reactive gas, irradiation or filtration through a micro-organism proof filter. The success of the process depends on a suitable choice of treatment condition e.g temperature and duration of exposure. Parental drug administration means a non-oral means of administration but it is generally interpreted as relating directly into the body, bypassing the skin and mucous membrane. Then, a broken skin or cracked skin is a symptom of dry skin but it can also occur in response to scratches or other trauma or infections. When the skin dries, it can become rough and flaky with small tears that can lead to deeper cracks called fissures which can extend into the deeper layers of the skin. Sterilization is essential in the processing of any product destined for parental administration or for contact with broken skin due to the threat of infection. Micro-organisms can cause infections and disease when introduced to the human body. Sterilization of products that come in contact with broken skin prevents skin infection or disease worse than the broken skin the patient posses already and they can enter the blood system, creating life threatening diseases especially in immune-suppressed people.

## 2. DISCUSS THE IMPORTANCE OF STERILIZATION IN THE PRODUCTION OF PHARMACEUTICAL PRODUCTS.

All medical and parental equipments are sterilized in batches and usually sterilized using heat. The products themselves however are not thermally sterilized as the heat may damage it, alternative methods such as filtration is used. Filtration reduces the risk of a product becoming contaminated.

- Sterilization procedures are employed to prevent transmission of microbes to patient through the pharmaceutical products they consume.
- Sterilization of pharmaceutical products prevents patients from having infections or disease due to the presence of micro-organisms.

- Not all micro-organisms have been discovered so sterilization prevents patients from coming in contact with a strange microbe.
- Sterilization stimulates the efficient function of any pharmaceutical product via the absence of microbes.

### 3. EXPLAIN GASEOUS STERILIZATION, ITS DESIGN AND OPERATION.

Gaseous sterilization is a chemical process resulting from reaction of chemical groups in the bacteria cell with the gas frequently used for items that are heat and moisture sensitive. Gaseous sterilization processes using ethylene oxide are far more commonly used on international bases than those employing formaldehyde. Gaseous sterilization is a technique of killing all micro-organisms using ethylene oxide gas under pressure used only for material and supplies that cannot withstand steam sterilizing. Ethylene oxide is highly explosive and flammable in the presence of air but these hazard are reduced by diluting it with carbon dioxide or fluorinated hydrocarbon. Automatically controlled ethylene oxide sterilizers are usually heated to a temperature of 54 C. A humidity level of 35 to 70 percent is recommended. The main disadvantages associated with ethylene oxide are the lengthy cycle time, the cost, its potential hazard to patients and staff. The main advantage is that it can sterilize heat or moisture sensitive medical equipment without deleterious effect on the material used in the medical devices. Acute exposure to ethylene oxide may result in irritation and central nervous system depression.

#### **Factors affecting the gaseous sterilization**

- Time of exposure
- Gas concentration
- Penetration of the gas
- Temperature

- Humidity in the sterilizing chamber

### **Gaseous sterilization design and operation using ethylene oxide ( ETO)**

- An ethylene oxide sterilizer consist of a leak proof and explosion proof steel chamber normally of 100-300 litre capacity.
  - This can be surrounded by a lot of water jacket to provide uniform chamber temperature.
  - Successful operation of the sterilizer requires removal of air from the chamber by evaporation, humidification and conditioning of the load by passage of sub atmospheric pressure steam.
  - Forced gas circulation is often employed to minimize variation in conditions through out the sterilizer chamber.
  - Absorption of ethylene oxide by the load is enhanced by the introduction of excess gas at the beginning or by the addition of more gas as the pressure drops during the sterilization process.
  - After treatment, the gases are evacuated either directly to the outside atmosphere or through the special exhaust system.
  - Filtered sterile air is then admitted either for a repeat of the vacuum or for air purging until the chamber is opened.
  - In this way safe removal of the ethylene oxide is achieved reducing the toxic hazards to the operator.

#### **4. WHAT IS RADIATION STERILIZATION.**

Radiation means to give off energy as waves or particles. Radiation is any form of radiant energy emission or divergence as of energy from all directions; from luminous bodies, particle accelerators, radio-graphical tubes, radio-active element and fluorescent substances. Radiation exerts its effect depending on its wavelength, intensity and

duration. Radiation sterilization is the use of radiation to control the growth of microorganisms. There are two types of radiation; ionizing and non-ionizing radiation. The ionizing radiation gives off electrons which causes the atoms to have a charge, the charges on the atomic particles make ionizing radiation unstable and reactive, the particles radiate because they are trying to stabilize themselves. The ionizing radiation is an high-energy end of the electromagnetic spectrum and it posses a higher frequency and shorter wavelength than the non- ionizing radiation, it is also more of a health hazard, exposure to it can cause burns, radiation sickness, cancer and genetic damage. It's wavelength size is 1nm. Examples of the ionizing radiation are X-ray, Y-ray, alpha particles, beta particles or high energy electron beam.

- Y-rays are emitted by radio-active cobalt.
- X-rays are produced by machines.
- Electron beam are generated by accelerating electrons to high energy in machines.
- Alpha particles do not penetrate the skin as X-rays and gamma ray.
- Beta particles are fast moving electron emitted by radioactive decay of substances.

Non-ionizing radiation: it refers to any type of electromagnetic radiation that does not carry enough energy per quantum to ionize atom or molecules that is, to completely remove an electron from an atom or molecules. The non-ionizing radiation only has sufficient energy for excitation, the movement of an electron to a higher energy state. It posses a lower frequency and wavelength longer than the ionizing radiation. The non-ionizing radiation losses its ability to penetrate substances and it can only be for sterilizing surfaces. It has a greater size than about 1nm. Examples of non-ionizing radiation are UV-light, near-ultraviolet, visible light, infrared, microwave, radio waves and long-wave.

- UV-light is a form of radiation that is visible to the human eyes. It is the most common form of non-ionizing radiation is the UV-light which is used in a variety of manner through the industry.