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

All invasive procedures involve contact between a medical device or a surgical instrument and a patient’s sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of pathogenic microbes that could lead to infection. Failure to properly disinfect or sterilize reusable medical equipment carries a risk associated with breach of the host barriers. The level of disinfection or sterilization is dependent on the intended use of the object: critical items (such as surgical, which contact sterile tissue), semi critical items (such as endoscopes, which contact mucous membranes), and noncritical items (such as stethoscopes, which contact only intact skin) require sterilization, high- level disinfection and low-level disinfection, respectively. Cleaning must consider the advantages and disadvantages of specific methods when choosing a disinfection or sterilization process. Adherence to these recommendations should improve disinfection and sterilization practice in health care facilities, thereby reducing infections associated with contaminated patient –care items

2 EXPLAIN GASEOUS STERILIZATION ITS STERILIZER DESIGN, AND OPERATION.

Low temperature sterilization has been highlighted since the development of plastic made single use of medical devices and the appearance of more and more sophisticated endoscopic tools whose constitutive materials could not bear high temperature processing. After reviewing ideal criteria of gaseous proceeding the two families of sterilizing gaseous agents, the tow families of gas, alkylating agents and oxidizing ones are reviewed, as well as new technologies based on the use of cold plasmas. Their efficacy, management and drawbacks are considered. If alkylating agents such as ethylene oxide or formaldehyde have been used for many decades their drawback (toxicity for patients, staff and environment, mutagenicity or dangerous handling) banished them in many countries. Oxidizing agents are more promising despite their corrosion power on many materials. Among them, hydrogen peroxide and ozone seem to have good characteristics if properly used. In order to enhance their efficacy, several technologies have been developed in recent years using cold plasmas to increase production of free radicals. Some have been approved and are already in field use in certain countries. Combination of several adapted technologies could be a solution to a problem which is not totally solved to the present days.

3 DISSCUSS THE IMPORTANCE OF STERILIZATION IN THE PRODUCTION OF PHARMACEUTICAL PRODUCT.

Terminal sterilization is the process of sterilizing a product in its final container. It is an important process as it ensures the product remains sterile.

All medical, ophthalmic and parenteral equipment 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 are therefore used, such as filtration which also reduces the risk of a product becoming contaminated.

Before the sterilization process is started, the holding period must be established, which is the time the products must be held at the required temperature or exposed to other sterilization methods to ensure the microbial growth is killed effectively. Any microbial growth that occurs while the products are in storage can affect the quality of the product and must therefore be prevented.

**Methods of Terminal Sterilization:**

* Ethylene Oxide: for prefilled syringes and medical devices unable to tolerate high temperatures
* Irradiation: also for prefilled syringes and medical devices unable to tolerate high temperatures
* Moist Heat Sterilization: for large and small parenteral devices and ophthalmic products

During moist heat sterilization, hot water is sprayed inside the sterilizer, and the products to be sterilized are then placed inside. Steam is not used as the temperature is too high and may cause the drug to degrade. The temperature required varies depending on how sensitive the product is to heat, and no set combination of time and heat can be used for all products. It is important to reach the F0 value, which is a measure of the effectiveness of sterilization. This can be ensured by increasing the time while reducing the temperature, allowing effective sterilization at a lower temperature when a product is unable to tolerate a high temperature.

To allow effective and uniform sterilization, the products must be loaded into the sterilization chamber in a careful and ordered manner, allowing the heat to circulate around the chamber and access all areas of the products.

Before terminal sterilization, effects of terminal sterilization on the product’s integrity must be known, as the heat may degrade the product. The right combination of heat and time must therefore be selected for each product.

Any of the methods mentioned above, the ethylene oxide, irradiation or moist heat sterilization, can be used for terminal sterilization, however the right form is required depending on the product being used. Validation is also very important as part of the manufacturing process, as it ensures the product has been manufactured according to high standards.

4 RADIATION STERILIZATION

There are 2 general types of radiation used for sterilization namely

* Ionization radiation
* Non ionization radiation

**Ionization radiation:**

This is the use of short wave length, high intensity radiation to destroy microorganism. This radiation can come in the form of gamma or x-rays that react with DNA resulting in a damaged cell.

**Non ionization radiation:**

This radiation makes use of longer wave length and lower energy. As a result, non ionization radiation loses the ability to penetrate substances, and can only be used for surface sterilization. The most common form of non ionizing radiation is ultraviolent light, which is used in a variety of manners throughout industry.

**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 more costly alternative to heat sterilization
* Requires highly specialized equipment