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ASSIGNMENT

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

Sterilization is important during the processing of products for parenteral administration in order to destroy any potential microbial contaminants (fungi, bacteria). It guarantees the consumers that the project is safe to use and also reliable. Sterility is one of the most Critical Quality Attribute (CQA) for all parenteral drug products as they are intended to circumvent body’s defense mechanisms and rapidly enter blood circulation. When the sterility of such product is compromised, it leads to microbial contamination of the drug products and presence of particles leading to serious adverse events including death. Correction of sterility related problems/deficiencies is usually time consuming as it requires a lot of scientists, manufacturing personnel and son to fix the root cause of the problem.

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

It prevents transmission of microbes to patients through the products. Sterilization ensures that all microorganisms in the products are killed before used in hospitals or any health clinic. The products should be properly sterilized to guarantee their quality and safety. The products should also be sterilized so that health professionals will rely on the products for the safety of their patients and also use it without a doubt or uncertainty.

When pharmaceutical products are being produced, it is very important to sterilize them because microorganisms from the factory where they are being produced can attach themselves to the products. If these products aren’t sterilized and taken to hospitals, pharmacies or any health clinic or place where they are being used, a patient can be infected through them.

1. Explain Gaseous Sterilization, its sterilizer design and operation.

Gaseous sterilization is the treatment of objects or materials with a chemical in the vapour or gaseous state to destroy all the microorganisms with which they have been contaminated. Ethylene oxide is a very good example of gas used in sterilization. It is highly explosive in a mixture of less than 3.6% v/v in air.

STERILIZER DESIGN AND OPERATION: An ethylene oxide consists of a leak proof steal chamber normally of 100-300liter capacity. This can be surrounded by a hot 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 employed to minimize variations in conditions throughout the sterilizer chamber. Absorption of this gas by the load is enhanced by the addition of more gas as the pressure drops during the sterilization process. The gases are evacuated directly to the outside atmosphere or through the special exhaust system after treatment. In this way safe removal of the ethylene oxide is achieved reducing the toxic hazards of the operator.

1. What is Radiation Sterilization?

Radiation sterilization is a form of sterilization that can be achieved using electromagnetic radiation such as electron beams, x-rays, gamma rays or irradiation by subatomic particles. Electromagnetic or particulate radiation can be energetic enough to ionize atoms or molecules (ionizing radiation) or less energetic (non-ionizing radiation). It is a useful method for industrial sterilization of heat sensitive products.