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

Sterilization is an essential stage in the processing of any product destined for Parental 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, solid 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 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 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 ASSIGNMENT - Discuss the importance of sterilization in the production of pharmaceutical products.

It is <sup>an</sup> important process as it ensures the products remain sterile.

2

The purpose of sterilization procedures is to prevent transmission of microbes to hosts.

In addition to sterilization and disinfection, other important measures to prevent transmission are included in the protocol of standard precautions.

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 dental 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 sterilization process is started, the holding period must be established, which is the time of 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.

3 Explain Gaseous sterilization, its sterilizer design, and operation.

Sterilizing gases are typically used when exposure to other methods [heat or radiation] could damage the materials or equipment.

The most <sup>common</sup> ~~gases~~ <sup>used</sup> ~~materials~~ <sup>equipment</sup> for sterilization include ethylene oxide [EO], ozone, mixed oxides of nitrogen and chlorine dioxide.

Sterilizer design and operation. An ethylene oxide sterilizer consist of a leak proof

- This can be surrounded by 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 often employed to minimize variations in conditions through out the sterilizer chamber.

Absorption of ethylene oxide by the load is enhanced by the introduction

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- 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 long 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 sterilization relies on ionizing radiation, primarily gamma, X-ray or electron radiation, to deactivate microorganisms such as bacteria, fungi, viruses and spores.

Due to numerous advantages over heat or chemical based sterilization techniques, this method is particularly attractive in medicine and health care-related fields, for example, radiation sterilization is readily applied during tissue allograft preparation, pharmaceutical packaging and medical device manufacturing.

