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DEPARTMENT: PHARMACOLOGY
COURSE: PHA 206
MATRIC NUMBER: 18/MHS07/013

1.Sterilization is anessential stage in the processing of any product destined forparenteral 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, soiled 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 acceptable risk of failing to achieve sterility and 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 to be 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.

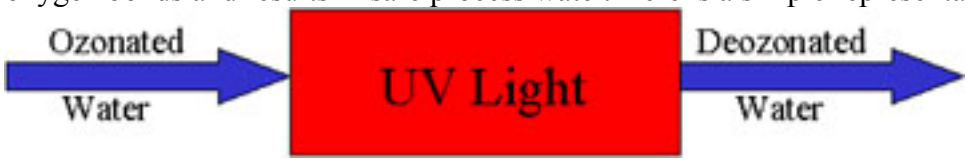
2. Importance Of Terminal sterilization In Pharmaceutical Industries. Terminal sterilization is the process of sterilizing a product in its final container. It is an important process as it ensures the product remains sterile.The products themselves however are not thermally sterilized as the heat may damage it.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.

3.Sterilizer design and operation • A LTSF sterilizer is designed to operate with sub atmospheric pressure steam. Air is removed by evacuation and steam is admitted to the chamber to allow heating of the load and to assist in air removal. 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.

Principle
• The sterilization action of EtO is based on alkylation reaction.
• Sterilizer design and operation: An ethylene oxide sterilizer consists of leak proof and explosion proof steel chamber normally of 100-300 liter capacity.

Sterilizer and operation (contd)
• This can be surrounded by a hot water jackets 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 you 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 the treatment, the gases are evacuated 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 purging until the chamber is opened.
• In this way, safe removal of the ethylene oxide is achieved reducing the hazards to the operator.

4. 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 more costly alternative to heat sterilization
Requires highly specialized equipment