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1. Sterilization is an essential stage in the process of any product for parenteral administration because it must undergo any form of sterilization is generally a preferable method . Sterile product manufacturing requires specialized expertise many pharmaceutical companies rely on contract service providers . Choosing a CDMO with demonstrated commercializing terminal sterilization process is essential to ensure patient safety . Demand for sterile injectable drugs has been increase steadily in recent years , this is to ensure patient safety parenteral drugs products must be sterilized to destroy any potential microbial contaminants . The most

common sterilization method involves heating under pressure in the presence of water to generate steam . Generally steam sterilization is performed in an autoclave and can be used for drug products , medical devices , plastic bags and other single use equipment, glass containers , surgical dressings and more .Sterilization can also be achieved in a dry heating . Much higher temperatures are required for this method however temperatures are not suitable for most drug products . Dry heating is also not appropriate for aqueous solutions and is most commonly used to sterilize glassware metal and other surfaces . Exposure to sterilization is another sterilization method used through the industry.

Gamma radiation is the most common ultra violet radiation and high velocity electrons . Radiation is typically used for the sterilization of single use components systems but it can be used for packaged drug products . Treatment with gases is also alternative .

## 2. Importance of sterilization to pharmaceutical industry;

Terminal sterilization is the process of sterilizing a product on its final containers . It is an important process to ensure product remain sterile . All medical and parenteral equipments are sterilized in batches and usually sterilized using heat . The products themselves however are not thermally sterilized as the heat may damage it . Sterilization ensures the microbial growth is killed effectively. Any microbial growth that occurred while the

products are in storage can affect the quality of the product and must be prevented.

method of terminal sterilization  
ethylene oxide : for predilection  
syringes and medical devices  
unable to tolerate high  
temperatures

irradiation : also for prefilled  
syringe and medical devices  
unable to tolerate high  
temperatures.

moist heat sterilization: for  
large and small parenteral  
devices and ophthalmic  
products

3. Gaseous sterilization: it is the process of using ethylene oxide sterilization . Alternatively pure ethylene oxide gas can be used below atmospheric pressure in sterilizer chamber from which all air has been removed .The sterilized action is based on alkylation reaction . This gas is highly explosive in a mixture of

less than 3.5 u.v in air  
sterilized design and operation :  
An ethyl oxide sterilizer consists of a leak proof and explosion proof steel chamber normally of 100-300 liter capacity. 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 and conditioning of the load by passage of sub atmospheric pressure steam .  
Forced gas circulation is often employed to minimize variations in conditions throughout the sterilizer chamber  
After treatment, the gases are evacuated either directly to the outside atmosphere or through the special exhaust system.  
in this way safe removal of the ethylene oxide is achieved reducing the toxic hazards to

the operator

4. Radiation sterilization: it utilizes ionizing radiation to sterilize medical devices . It's usage has grown in descent decades .there are two 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 microganism . This radiation can come in the form of gamma or x rays that react to dna resulting damage of the cell .

Non ionizing radiation uses longer wavelength and lower energy. As a result it loses the ability to penetrate substances and can be used in sterilizing surfaces . The most common non ionizing radiation is ultraviolet light which is used in a variety of manner through industry .