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

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.

Discuss the importance of sterilization in the production of Pharmaceutical products.

1. To reduce the risk of

contamination on surgical apparatus.

Sterilization is required for any medical and surgical material to be used under strict aseptic conditions. Physical methods (use of heat, dry or wet, use of ultraviolet radiation, gamma or accelerated electrons) or chemical methods (application of a liquid or gaseous chemical) are used.

2. To minimize the growth of organisms on culture medium. In the environment the use of sterilization techniques decreases the growth of bacteria on surfaces, which leads to the decrease in transmission of organisms among the population.

3. Control diseases by killing some germs like deadly bacteria, fungi and viruses.

4. It also minimizes some

biological changes on organisms.

Explain Gaseous Sterilization, its Sterilizer design, and operation.
Gaseous **sterilization** is a sterilization by means of a bactericidal gas, frequently used for items that are heat and moisture sensitive. Ethylene oxide is the gas most often used; it is highly explosive and flammable in the presence of air, but these hazards are reduced by diluting it with carbon dioxide or fluorinated hydrocarbons. Gas sterilization is a chemical process resulting from reaction of chemical groups in the bacterial cell with the gas. Factors influencing gas sterilization include time of exposure, gas concentration, penetration of the gas, and temperature and humidity in

the sterilizing chamber. Automatically controlled ethylene oxide sterilizers are usually heated to a temperature of 54°C (130°F). A humidity level of 35 to 70 per cent is recommended.

STERILIZER DESIGN AND OPERATION

An ethylene oxide sterilizer consists of a leak proof and explosion proof steel chamber normally of 100-300l capacity. This can be surrounded by a hot water jacket to provide uniform chamber temperature. Successful operation of the chamber requires removal of air from the chamber by evaporation, humidification and conditioning of the load of passage of sub atmospheric pressure steam. Forced gas circulation is often employed to minimize variations in conditions throughout the

sterilizer chamber. Absorption of ethylene oxide by the load is enhanced by the introduction of excess gas at the beginning or addition of more gas as the pressure drops during the sterilization process. After treatment, the gases are evacuated either through the special exhaust system or directly to the outside atmosphere. Filtered sterile air is then admitted either for a repeat of the vacuum or for air purging until the chamber is opened. In this way, safe removal of ethylene oxide is achieved reducing the toxic hazards to the operator.

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 healthcare-related fields. For example, radiation sterilization is readily applied during tissue allograft preparation, pharmaceutical packaging and medical device manufacturing.