

METHODS OF PACKAGE STERILIZATION, IMPORTANCE AND PRINCIPLES

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Characteristics of Good Sterilant / Sterilizing Agent

1. Rapid sporicidal activity
2. Ease of application and compatibility with packaging machinery.
3. Compatibility with packaging material
4. Ease of removal of residues
5. No detrimental effects of residues on the package/ product
6. Should be economical
7. Easy to Handle.

Methods of Package Sterilization

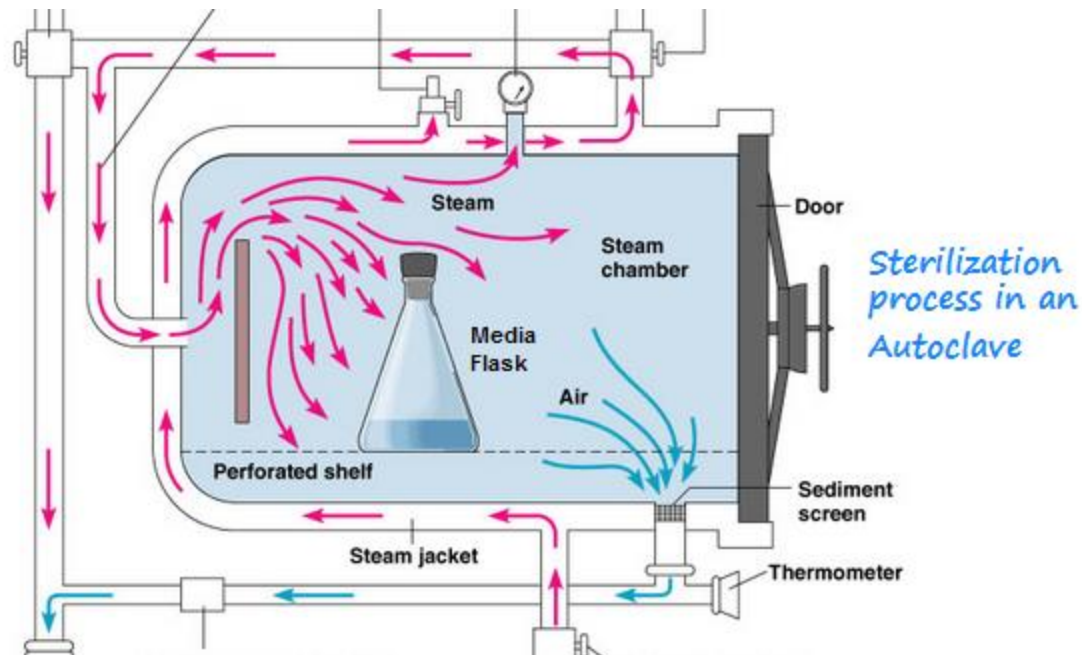
Dry heat

- The packaging material is heated in a hot air oven for a specified minimum temperature for a stated time.
- Various combinations of temperature and time are recommended depending on the type of the material being sterilized.
- The usual recommended minimum holding times and temperatures are 180°C for 30 minutes for glassware.



Super heated steam systems

- Metal containers were the first used in aseptic operations.
- In this system, sterilization of the metal container and its closure is accomplished by the application of heat using super heated steam.
- The advantage of this system is that it can achieve high temperatures at atmospheric pressure; however micro organisms are more resistant to superheated steam than saturated steam.



Hydrogen peroxide systems

- In this system, the packaging material is not metal and it comes in rolls rather than in preformed containers.
- The rolls are continuously fed into a vertical machine which sterilizes, forms, fills, and seals the package.
- Sterilization is accomplished with a combination of hydrogen peroxide and heat.

- A second system is similar to the above method. The main difference is in how the heat is applied to the package surface.
- This system provides the heat necessary for sterilization by means of a heated stainless steel drum.
- A thin film of peroxide is applied to the product contact surface. This surface is then rolled over the heated drum.
- Contact with the drum heats the peroxide and effects sterilization.

- A third system also uses packaging material which comes in rolls. The rolls are continuously fed into the machine which forms, fills, and seals the package. Sterilization is accomplished with a **combination of hydrogen peroxide and heat**. The packaging material **travels through a bath of hot hydrogen peroxide** which softens the material for forming. Cups are then formed, filled and sealed with a lid which also travels through a hydrogen peroxide bath.
- A fourth system utilizes preformed cups to which a **lid foil is heat-sealed after filling**. The cups are fed into the machine where they are sterilized by applying a **spray of peroxide followed by heating**. The lid material is sterilized by being passed through a bath of hydrogen peroxide
- Another system which can utilize preformed carton **sprays low concentration hydrogen peroxide solution on the inside of the carton**. This sprayed carton then **passes under a UV light** source which acts synergistically with the hydrogen peroxide in destroying micro organisms.

Low-Temperature hydrogen peroxide gas plasma (LTHPGP) sterilization

- Low-temperature hydrogen peroxide gas plasma (LTHPGP) sterilization is a relatively new technology, marketed under the trade name Sterrad® by ASP is used mainly for rapid sterilization of medical instruments without leaving toxic residues.



Exposure to gaseous ethylene oxide

- Some material which cannot be sterilized by dry heat or autoclaving may be sterilized by exposure to gaseous ethylene oxide.
- The method can be carried out at low temperatures and damages relatively few materials.
- It is however difficult to control and use of ethylene oxide.
- Compared to other methods of sterilization, the bactericidal efficiency of ethylene oxide is low.

Sterilization by chemicals

Per-acetic acid

- Per-acetic acid is a liquid sterilant which is effective against spores of aerobic and anaerobic bacteria and is effective at low temperatures than hydrogen Peroxide.
- But it is toxic. Hence this is used in pre-sterilization of packaging materials.

Ethyl alcohol

- At 80% concentration, ethyl alcohol is effective in sterilization of packaging materials.
- However, it is ineffective against spores. Hence it is not generally used.

Sterilization by irradiation

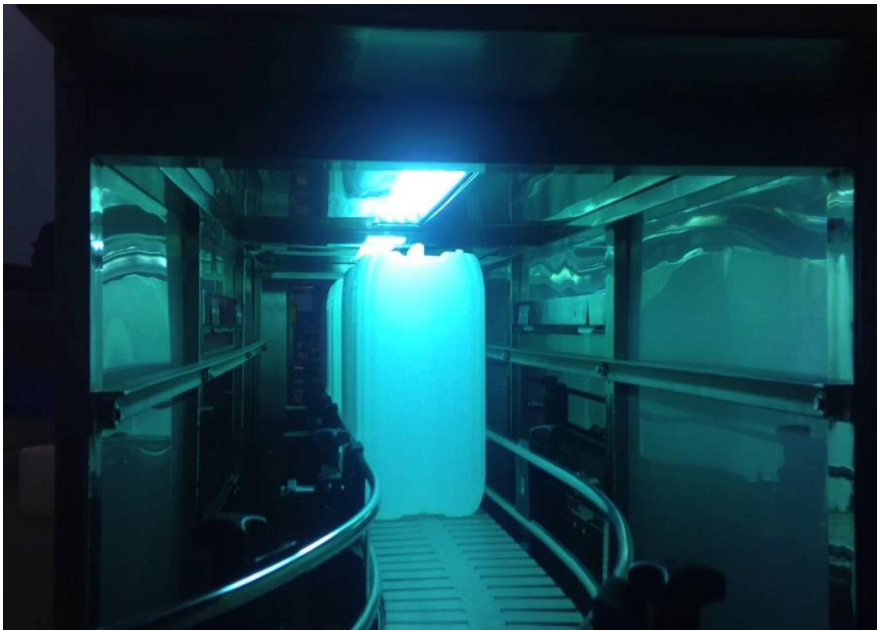
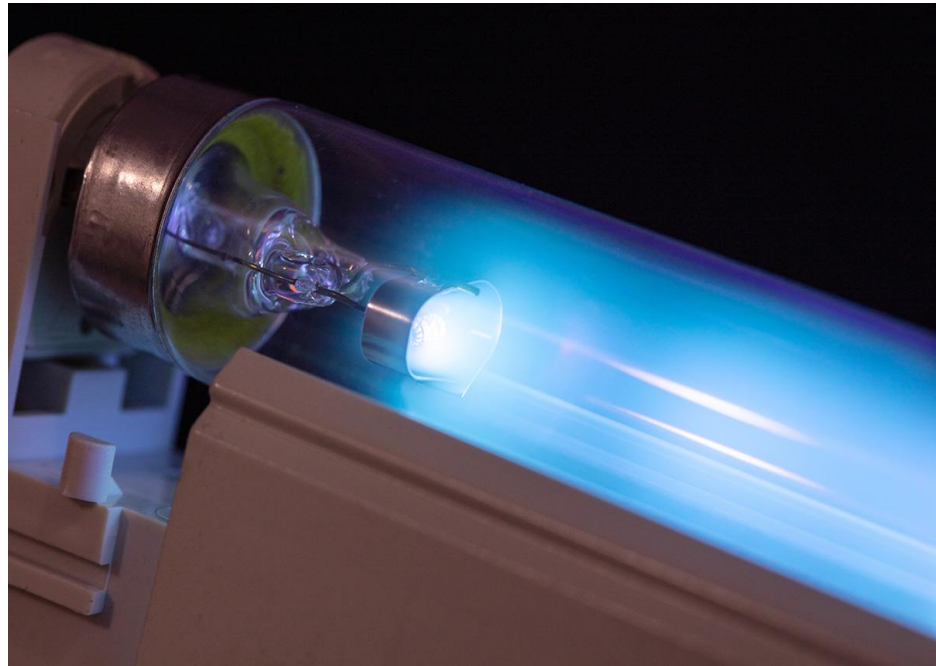
In irradiation sterilization, radiations of energies well below 10 Mev are usually employed and hence no radioactivity is induced in the material so sterilized.

Advantages

- It is a single process.
- It is a clean process – No residual chemicals
- It is a reliable process.
- It is a cold process and hence less damage to packaging materials occurs.
- It is an energy saving process.
- It is a cost effective and economic process

1. Irradiation with ultra - violet rays

- They are generally recommended for use with sterilization of contaminated surfaces and disinfection of aseptic handling rooms or boxes.
- The disinfection capacity of UV rays in air is affected by moisture, dust concentration etc.
- UV radiation is a powerful disinfectant.
- Its sterilizing power arises from its capacity to get selectively or reasonably absorbed at 228 nm and 265 nm wavelength by the peptide bonds of nucleic acid in the cells of microbial organisms.
- UV rays are produced by mercury discharge tubes fitted with quartz windows for transmission of UV rays with minimum absorption. These units are relatively inexpensive.
- UV radiation is harmful to man particularly to the skin. Direct exposure to UV rays must be avoided.



2. Irradiation with gamma rays

- Gamma radiation is the most widely used form of ionizing radiation sterilization
- Gamma irradiation has become the industry standard for high-energy sterilization due to the convenience, low cost, and good sterilization results.
- Gamma irradiation involves the bombardment of photons from a ^{60}Co source.
- Because of the excellent penetrating ability of gamma rays, a wide range of packaging materials may be gamma-sterilized including those composed of multiple resins.
- Pre-packaged articles may also be gamma-sterilized since many materials such as cellophane, polyethylene, and nylon can be penetrated by gamma rays.
- Gamma rays have five times the penetration capability than electron beam radiation.
- Gamma radiation sterilization usually employs ^{60}Co as the radioisotope source with a dosage of generally 2.5 megarads, although higher levels are sometimes used, and maximum temperatures usually are in the range of 30°C – 40°C .



3. Electron beam (E-beam)

- Electron beam irradiation is the bombardment of high-energy electrons.
- Sterilization is quick but with limited penetration.
- Less is known about the e-beam sterilization effects on the physical properties and colour stability of thermoplastics compared with gamma sterilization.
- Doses for e-beam irradiation for the sterilization of medical disposable items are in the 1–6 megarad range.

There are several differences between e-beam and gamma sterilization.

1. The e-beam process uses no radioactive source and employs lower energy radiation than gamma sterilization.
2. It is claimed that electron beam sterilization causes less material degradation than gamma, thus reducing the risk of product damage.
3. Exposure time for e-beam is shorter than exposure in gamma radiation.
4. Plastic parts sterilized by electron beam are only exposed for minutes versus hours or days with gamma rays.
5. However, the penetration capability of e-beams is poor, resulting in the need for many e-beam sterilized pieces to be irradiated from multiple sides to ensure complete sterilization.

Packaging Materials / Forms Sterilized by Different Methods

Packaging material/form	Sterilization method
Milk pouch film	UV rays
UHT packaging film	Chemical – H ₂ O ₂
Metal cans	Heat
Plastic bottles, cups	Chemical – H ₂ O ₂