**Lecture -2-**

**Sterilization and Disinfection**

**Sterilization concept**

Sterilization is essential concept in the preparation of sterile pharmaceutical products .

Its aim is to provide a product that is safe and eliminates the possibility of introducing

Sterilization

Sterilization –a process that by which all viable M.O are removed or destroyed , based on a probability function .

Method of inactivating M.O may be classified as either :
*1.Physical*

A. moist heat

b. dry heat

c. irradiation

d. sterile filtration is another process , but it only removes , not inactivates M.O

**Method of inactivating M.O may be classified as either :**

a. Gaseous

b. Liquid sterilants

**Sterilization methods**

|  |  |
| --- | --- |
| Method | Equipment |
| *Thermal* |
| Moist heat sterilization | * Saturated steam autoclaves
* Superheated water autoclaves
* Air over steam autoclaves
 |
| Dry heat sterilization | * Batch sterilizers
* Continuous tunnel sterilizers
 |
| Non- thermal |
| Chemical cold sterilization | * Ethylene oxide
* Vaporized hydrogen peroxide
* Hydrogen peroxide/steam
* Other gases
 |
| Radiation sterilization | * Electromagnetic
* Particulate
 |
| Filtration | Membranes  |

**Thermal sterilization**

Involves the use of either moist or dry heat.

Moist –heat sterilization is the most widely used and reliable sterilization method.

Dry – heat sterilization is appropriate for materials that cannot withstand moist – heat sterilization

1-Moist –heat sterilization

Microorganism are destroyed by cellular protein coagulation .

The objects to be sterilized are exposed to saturated steam under 1 atmosphere pressure at a minimum temperature of 121°C for at least 20-60 minutes.

An autoclave is commonly used for moist – heat sterilization .

Because it does not require as high a temperature, moist – heat sterilization cause less product and equipment damage compared to dry – heat sterilization .

Autoclaves

Is a device to sterilize equipment and supplies by subjecting them to high pressure saturated steam at 121 °C or more, typically for 15-20 minutes

**Autoclaves types**

Portable autoclave (bench autoclave)

Stationary autoclave (large steriliser)

For porous loads e.g., dressing

For bottled fluids

**Main features of autoclave ( \* )**

Lid(door) fitted with clamps and asbestos jacket , stationary autoclave may be double doors at both ends one for loading and one for unloading.

**Pressure gauge**

Thermocouple for measurement of temp. usually located within the discharge channel in dummy article .

Air vent to remove air before sterilization .

**Main features of autoclave**

1-Lid(door) fitted with clamps and asbestos jacket , stationary autoclave may be double doors at both ends one for loading and one for unloading.

2-Pressure gauge

3-Thermocouple for measurement of temp. usually located within the discharge channel in dummy article .

4-Air vent to remove air before sterilization .

5. Safety valve to permit escape of excess steam to prevent explosion .

6. Modern autoclaves are recording (record pressure, temp during the whole process ) supplied with timer and are automatically controlled .