13
Sterilization

Def

Sterilization is the process of killing or removing bacteria and all other forms of living microorganisms and their spores from preparations or articles. A product is said to be sterile when it is free from all living microorganisms and passes the sterility tests.

13.3 Thermal Resistance of Microorganisms

The microorganisms show varying resistance to sterilization procedures. The degree of resistance varies with the specific organisms particularly with spores of microorganisms which are more resistant than vegetative forms of the organism. Therefore before planning the sterilization process it must be ensured that the method and its conditions must be lethal to the resistant spores and the following points should be taken into consideration:

(a) Thermal death time

The thermal death time may be defined as the time required to kill a specific type of microorganism at a given temperature under specified conditions. It not only depends on controllable factors like temperature, pH, presence of bactericide etc but also depends on uncontrollable factors such as number of contaminating microorganisms and their resistance to heat.

The table 13.1 shows approximate values of thermal death times of different spores to moist heat and dry heat.

Table 13.1 Approximate thermal death times of different spores

	Time in minutes					
	Moist heat			Dry heat		
Organism	100°C	110°C	121°C	120°C	140°C	170°C
1. B.anthracis	5-15	-	-	-	180	-
2. Cl.welchii	5-10	-	-	50	5	-
3. Cl.tetani	5-15	-	-	-	15	-
4. Cl.botulinum	330	90	10	120	60	15
5. Soil bacilli	>1020	120	6	-	-	15

It will be seen from the above table that there is a considerable variation in thermal death times between different types of bacterial spores therefore an adequate margin of safety should be kept to kill the most resistant species of microorganisms and spores expected to be present by exceeding temperature and time for which it is applied than the known thermal death times of most of the spores. Commonly the thermal death time indicated is increased by 50 percent.

(b) Death rate of microorganisms

By direct method it is not possible to determine that when the sterility is first achieved because shortly before sterility is reached the number of living organisms is so small that accurate determination of it becomes impossible due to very high errors in taking the samples. Therefore reliable method is to plot a graph of log survivors against time of exposure.

(c) Decimal reduction time (D value)

It is one of the functions to indicate the efficiency of sterilization process. This is the time in minutes required to reduce the number of viable organisms by 90 percent i.e. the time corresponding to one log cycle on the survivor/time curve. The order of death of microorganisms can be calculated from the equation:

$$K = 1/t (\log No - \log N)$$

where K is constant depending on the organism, temperature, medium and assuming logarithms to the base 10; it is the time of exposure in minutes; No is the number of organisms viable at the beginning of the time interval and N is the number of organisms viable at the end of the time interval.

It was noted that after 90% reduction in microorganisms the following equation was obtained:

$$\begin{aligned} K &= 1/t (\log No - \log 0.1\ No) \\ &= 1/t (\log No - \log 10^{-1}\ No) \\ &= 1/t [\log No - (\log 10^{-1} + \log No)] \\ &= 1/t [\log No - (-1) \log 10 - \log No] \\ &= 1/t\ (1) \log 10 \\ &= 1/t \end{aligned}$$

$$t = 1/k$$

Time t was defined as the decimal reduction time which is called the D value.

$$D = 1/k$$

The value of D can be found out by calculating K from the graph of logarithm of the number of surviving organisms against time of exposure.

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(a) Dry Heat Sterilization

Substances which get destroyed by moist heat or due to their physical characteristics cannot be sterilized by moist

heat may be sterilized by dry heat in ovens designed specially for this purpose which are electrically heated and thermostatically controlled.

Substances which are sterilized by dry heat include fixed oils, glycerin, liquid paraffin, petrolatum, propylene glycol and powders such as talc or zinc oxide. In addition, dry heat sterilization is the method of choice for sterilization of glassware, many surgical instruments and surgical catgut. Preparations containing water, alcohol or other volatile substances and surgical dressings cannot be sterilized by this method because at high temperature liquids may evaporate and dressing may char.

During dry heat sterilization the microorganisms and bacterial spores are killed by oxidation. Since dry heat is less effective than moist heat, higher temperatures and longer periods of exposure are required. Exposure at 160°C for 1 hour is required for dry heat sterilization. The exposure time depends on packaging of the material, thickness of glass, volume of container etc. for example syringes and needles may be sterilized at 160°C for 1 hour but glycerin or liquid paraffin must be sterilized at 160°C for 2 hour or at 170°C for 1 hour. Consequently higher temperatures require shorter exposure time for a given substance and on the other hand lower temperatures require longer exposure time. A substance which gets decomposed at a higher temperature may be sterilized at low temperature exposed for long period of time. Dry heat sterilization may be done by means of direct flame (flaming) or by hot air oven.

(a) Flaming

Flaming is the simplest method of dry heat sterilization in which the material to be sterilized is kept in the hot part of Bunsen burner's flame for a few seconds and the process is repeated several times. This method is generally used for those articles which are to be used immediately e.g. forceps, needles, knives, blades, scalpels, metal spatulas, the mouth of culture tubes and bottles, and platinum loops. This method is not reliable for sterilizing greasy or oily materials.

(b) Hot-air Oven

Hot air oven or dry heat sterilizer consists of a metallic chamber of aluminium or stainless steel, which is electrically heated and thermostatically controlled. There are two types of ovens (1) in which air is circulated by gravity convection to all parts of the chamber (2) "mechanical convection type" in which air is circulated by a fan. The latter type is more satisfactory because the sterilizing temperature is more readily controlled.

The chamber of the oven has double walls which are separated from each other by thick layer of glass-fibre insulation. The hollow flanged door is also filled with glass fibre insulation. The inner side of the door is fitted with asbestos gasket that provides a tight seal to prevent heat loss. Depending on the size of the oven 3-4 perforated shelves are provided in the chamber which can be removed as and when desired. A good quality thermometer is fitted in front of the chamber for noting the temperature during the process. A fan is provided for air circulation in the oven. A vent is fitted at the top of the oven. An on-off switch is provided along with green and red indicators. The heating elements are fitted on the lower side of chamber. Heat is transferred from the source to the articles by conduction, convection and radiation.

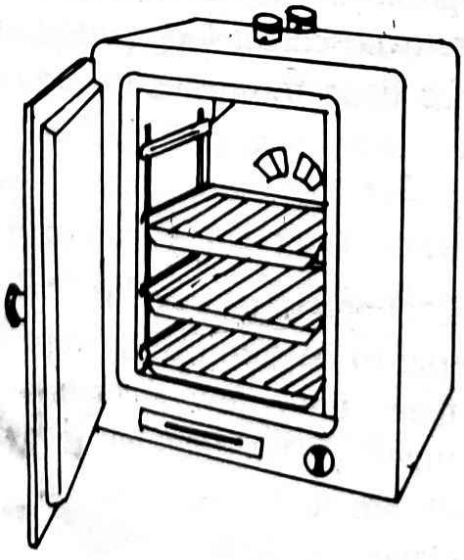


Fig. 13.1 Hot-air oven

For getting good results the oven should be properly loaded so that all the articles are exposed to uniform heat for required time. Care should be taken that the oven is not opened in between the sterilization operation. Glasswares (thoroughly cleaned and dried) like conical flasks, test tubes, pipettes etc. should be plugged with non-absorbent cotton wool because absorbent cotton wool becomes saturated during sterilization and the plugs act as inefficient seals because the motile bacteria can swim through the attached moisture into the tubes.

Advantages of Dry-Heat Sterilization

1. It is most suitable method of sterilization for substances which are destroyed by moisture e.g. oily substances and dry powders.
2. Glasswares like flasks, test tubes, pipettes, all glass syringes etc. can be easily and thoroughly sterilized which may not be possible in moist heat sterilization.
3. It is less damaging to glass and metal equipment than moist heat.

Disadvantages of Dry-Heat Sterilization

1. It requires very long heating up times, high temperature and long exposure time.
2. Most medicaments, rubber and plastic articles which are thermolabile get destroyed by this method.
3. Preparations containing water, alcohol or other volatile substances cannot be sterilized by this method because the liquids may evaporate at high temperature.
4. It is unsuitable for surgical dressings because the natural moisture of the fibres quickly vaporises which leads to deterioration and ultimately charring may take place.

(b) *Moist Heat Sterilization*

Moist heat sterilization is also known as steam sterilization. It is done in an autoclave but on small scale a pressure cooker can be used, in which steam under pressure is used. It is the most reliable method of sterilization because in the presence

of moisture bacteria are destroyed at a considerably lower temperature rather than when moisture is absent. In fact, bacterial cells with a large percentage of water are killed easily. Spores, which contain relatively low percentage of water are comparatively difficult to kill. By this method the microorganisms are destroyed by denaturation and coagulation of some of the essential proteins present in the microorganisms. Moist heat sterilization is more powerful than dry heat sterilization because (a) the penetrating power of steam is much more than that of dry heat (b) the thermal capacity of steam is much greater than that of dry heat (c) in presence of moisture, denaturation or coagulation of essential proteins present in microorganisms takes place at lower temperature.

(1) **Autoclaving** Autoclaving is the process of heating in an autoclave in which saturated steam under pressure is allowed to penetrate through the materials for at least 15 minutes at a minimum temperature of 121°C. The measurement of time begins when the temperature of the material being sterilized reaches 121°C. It should be noted that it is the temperature which destroyes the micro-organisms and not the pressure, the pressure helps in increasing the temperature of the system.

The following table shows the relationship between pressure and temperature and the exposure times commonly employed for sterilization by steam under pressure.

Pressure	*Temperature*	*Time*
10 pounds	115.5°C	30 minutes
15 pounds	121.5°	20 minutes
20 pounds	126.5°	15 minutes

From the above table it is clear that greater the pressure applied, higher the temperature obtained and lesser the time required for sterilization. Generally the sterilization in an autoclave is done at a temperature of 121°C for 15 minutes.

Autoclave is an apparatus used for sterilization by steam under pressure. A portable or bench autoclave is quite similar to pressure cooker. It is a hollow cylindrical vessel of about 15 litres capacity made up of aluminium or stainless steel, fitted with a lid which can be firmly secured. In one type of

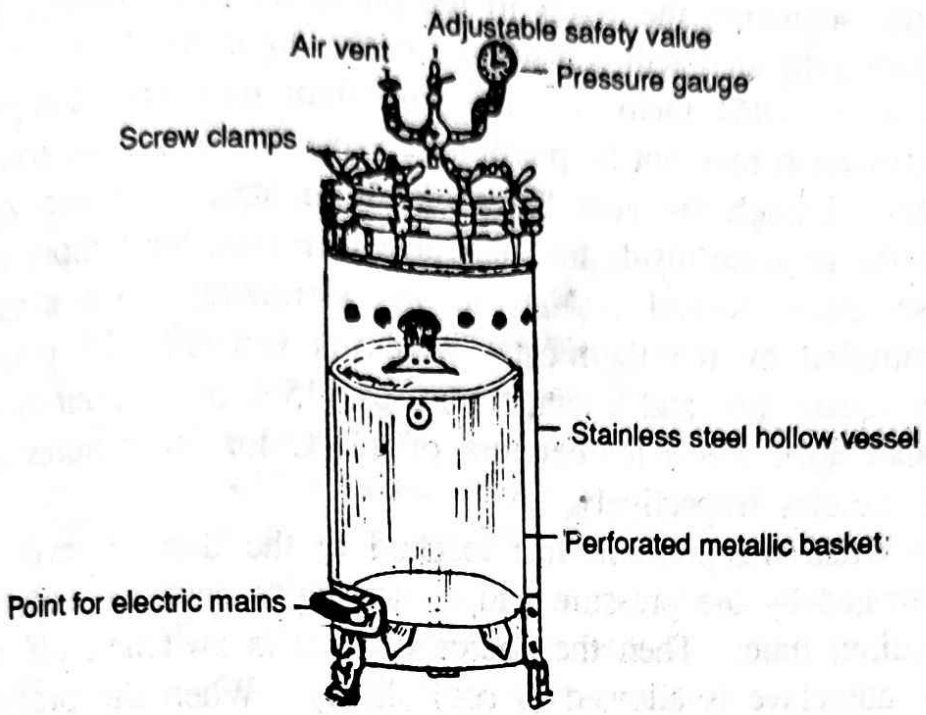


Fig. 13.2 Autoclave

autoclave the lid is fitted with eight screw clamps, a pressure gauge, an air vent and an adjustable safety valve. The externally fitted lid has the advantage that whole of the capacity of the vessel can be used but at the same time it has disadvantage also that even if one clamp is damaged or left loose, the pressure imposed on others may lead to explosion. Therefore it is essential that all the clamps should be firmly secured and should be carefully maintained. The autoclave is electrically heated, the electric elements are fitted at the bottom of the autoclave. It is provided with a perforated metallic basket fitted with legs, in which the material to be sterilized is placed.

Working

The working of this type of autoclave is very simple. The perforated metallic basket is taken out of the vessel and a bucket full of water is put in the vessel so that the heating elements get completely immersed in water. The material to be sterilized is loosely packed in the basket which is then kept in the autoclave. Care should be taken that the basket should not touch the water. The lid is tightly fitted in position and the source of heat switched on, air vent it kept open.

After sometime the water in the autoclave starts boiling and steam generated will replace the entire air in the body of the autoclave (this factor is very important otherwise complete sterilization may not be possible). When the steam has passed freely through the vent for about 5 minutes, close the vent. As the pressure inside the autoclave increases, the temperature also increases and reaches to the sterilizing point already controlled by the thermostat which is generally 10 pounds per square inch and a temperature of 115°C or 15 pounds per square inch and a temperature of 121°C for 30 minutes and 20 minutes respectively.

When the pressure has reached to the desired level, as indicated by the pressure gauge, heating is continued for the required time. Then the source of heat is switched off and the autoclave is allowed to cool slowly. When the pressure inside and outside the autoclave equals or drops to zero level, the steam vent is opened and lid removed to take out the sterilized material.

(2) **Horizontal Large Scale Autoclave** The portable autoclaves described above can only be used for small number of articles or for a few transfusion bottles. On larger scale e.g. In hospitals and industries horizontal autoclaves are used which may measure upto 20 ft in length and 12 inch to 6 ft in diameter. In pharmaceutical industries, double door autoclaves are used in which the substances to be sterilized are introduced through one door and taken out through the other door. The construction and working of horizontal autoclaves are basically the same as that of portable autoclaves but steam may be introduced from an outer source.

Advantages of Moist Heat Sterilization

1. Because of high penetration power of steam under pressure, microorganisms are killed more efficiently and in lesser time at low temperatures than dry heat.
2. In large size autoclaves large quantities of materials can be sterilised in one batch.
3. Solutions packed in sealed containers, as ampoules, are readily sterilized by this method.

4. Bulk solutions, glassware, surgical dressings, rubber gloves and surgical instruments are effectively sterilized by this method.

Disadvantages of Moist Heat Sterilization

1. This method is unsuitable for materials which cannot withstand the heating at 115°C or more.
2. This method is not useful for oils, fats, ointments, powders, oily injections; and other preparations through which steam cannot penetrate.

(3) Heating with a Bactericid

properities of the vaccines are protected whereas the bacteria are killed.

(c) Sterilization by Radiations

Sterilization by radiations is also known as "cold sterilization" because no heat is used in this method. The microorganisms are very susceptible to the lethal effects of ionizing radiations. The exact mechanism by which the microorganisms are destroyed is not clear. According to one theory alteration of chemicals presents in microorganisms takes place with the formation of new compounds which destroy the microorganisms. According to another theory the vital structures of cells, such as nucleoproteins are destroyed by which the microorganisms are killed.

Radiations may be classified as :

1. Electromagnetic waves which include infra-red radiations, ultraviolet light, X-ray and gamma rays.
2. Stream of minute particles of matter which includes alpha radiations and beta radiations also known as alpha particles and beta particles respectively.

Out of the above mentioned radiations only the infra-red radiations, ultraviolet light, gamma rays and high velocity electrons are used for sterilization. The other radiations are not used for sterilization purposes.

(1) **Ultra-violet light** Direct sunlight is quite harmful to the microorganisms, it can destroy them due to the presence of ultra violet rays in it. U.V. rays of shorter wavelengths are

more destructive than rays of longer wavelengths. These two types of rays are emitted by the sun. The rays of shorter wavelength are absorbed by the atmosphere where as rays of longer wavelength which are less harmful reach to the earth .

The penetration power of U.V. rays is very less, they are effective only to the exposed surface. Therefore they are commonly employed to reduce airborne contamination and sterilization of aseptic rooms or areas where the pharmaceutical processing is to be carried out. It is of little value as a sterilizing agent.

The most common source of artificial U.V. rays is the U.V. lamps by which U.V. radiations in the region of 2537 Å are produced which has germicidal activities. They are often used in pharmaceutical industries for sterilization of aseptic rooms and for naked surfaces such as table tops etc; for this purpose the lamps may be fitted at the top of the surface to be sterilized.

U.V. rays are very harmful to the skin and eyes therefore these organs must be properly protected by wearing hoods, gowns with long sleeves and rubber gloves. Eyes should be protected by wearing eyeshields e.g. plastic face masks.

(2) **Gamma Rays** Gamma rays are generally obtained from radio-active isotopes of cobalt 60. When the unstable atoms of this isotope disintegrate, they emit two gamma rays in succession. They kill microorganisms by ionization of atoms of essential substances present in the living cells of microorganisms.

Gamma rays are similar in nature to X-rays of short wavelength. Being electromagnetic radiations both of them have high penetration power, the fact which is used in sterilization.

Advantages of gamma radiation sterilization

1. Because of high penetration power these radiations are used in the preservation of foods. In pharmaceutical industries they are a satisfactory method of sterilization for parenteral preparations containing antibiotics like benzyl penicillin, streptomycin sulphate, polymixin

sulphate; vitamins like ascorbic acid; surphonamides such as sulphapyridine and sulphathiazole etc.

2. These radiations are used for sterilization of some bacterial and viral vaccines e.g. influenza, poliomyelitis and rabies vaccines.
3. There is no significant rise in temperature.
4. The process is continuous because short exposure time is required and a large quantity of material can be sterilized at once.
5. No aseptic handling is required because sterilization can be done after packing the material in final containers.
6. This method is quite reliable.

Disadvantages

1. Because of high cost involved, all the industries cannot afford to instal the plant.
2. These radiations are harmful to the persons engaged in this work so they must by protected and kept under constant attention.
3. They may lead to change in colour, solubility and texture of the preparation and may also lead to decomposition of certain medicaments.

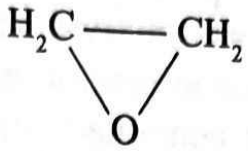
2. Chemical Methods

(a) Gaseous Sterilization

Gaseous sterilization is a special type of chemical sterilization in which the chemicals used are gases or vapours and not the liquids or solids dissolved in a solution. Many gases like, sulphur dioxide, chlorine, ozone, formaldehyde, beta-propiolactone and ethylene oxide have bactericidal effects. Although formaldehyde was extensively used as a fumigant but now its use has found limited acceptance. Now a days ethylene oxide has become the most widely used gaseous sterilizing agent in pharmacy and medicine.

The gases used for chemical sterilization are as follows:

(1) **Ethylene oxide** Ethylene oxide is a colourless gas at ordinary temperature. It is a simple cyclic ether having the formula



It is highly inflammable when mixed with air in concentrations more than 3% but when properly diluted with an inert gas such as carbon dioxide or a suitable flourinated hydrocarbon it becomes non-inflammable and can be safely used for sterilization purpose. A mixture of 90% carbon dioxide and 10% ethylene oxide are non-explosive and are commercially available.

The mode of action of ethylene oxide to kill the microorganisms is based on the process of alkylation of essential substances present in a protein molecule.

Sterilization by ethylene oxide is a complex process as compared to dry heat and moist heat sterilization because it requires greater precautions with regard to ethylene oxide concentration, temperature, humidity and time. Concentrations of ethylene oxide used for sterilization range from 200 to 1000 mg/litre. If the concentration is doubled the exposure time is reduced to half. Similarly with slight rise in temperature the sterilizing efficiency of ethylene oxide is increased which helps in the reduction of exposure time. In general the concentration of ethylene oxide used should be 450 mg/litre of sterilizer chamber space and must be exposed from 6 to 16 hours at temperatures of 49 to 60°C. However, if the materials to be sterilized are unable to withstand this slight rise in temperature, they should be sterilized at room temperature but exposed for longer periods.

Table 13.2

Ethylene oxide concentration	*Exposure time at 25°C*
88 mg/litre	10 hours
442 mg/litre	4 hours
884 mg/litre	2 hours

Gas sterilization requires specialized equipment which resembles autoclaves. The sterilizing chambers are fitted with an efficient vacuum pump, a control system to regulate the introduction of the gas mixture and to maintain the desired gas pressure, a device to control the humidity in the chamber and thermostatically controlled heating elements.

Advantages of Ethylene Oxide Sterilization

1. Thermolabile substances can be sterilized at room temperature or at a slightly raised temperature.
2. It has great penetrating power therefore quite useful for sterilizing surgical instruments such as catheters, needles and plastic disposable syringes.
3. It do not damage the moisture sensitive substances and equipments, rather, it needs moisture for killing the microorganisms. In anhydrous conditions it is not effective.
4. Powders packed in polythene bags can be sterilized by it.

Disadvantages of Ethylene Oxide Sterilization

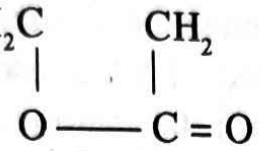
1. Since it is a slow process therefore it requires long exposures, hence, unsuitable in emergencies.
2. Costly equipment is required for sterilization.
3. Since it is highly inflammable therefore requires special precautions.

Ethylene oxide sterilization is more expensive but less reliable than moist heat sterilization therefore it should not be used when the latter is practicable. For thermolabile substances ionizing radiations should be preferred than ethylene oxide for sterilization of articles required in bulk e.g. disposable syringes, needles, gloves, catheters etc.

(2) **Formaldehyde** It has been quite commonly used for fumigating the rooms and blankets used in the hospitals. It is quite effective bactericidal agent and kills all bacteria including spores. It is quite irritant and pungent in nature and has low penetrating power. Formaldehyde has been used in an alcoholic solution for disinfection of instruments.

Formaldehyde as sterilizing agent has disadvantages of low penetrating power through covered surfaces and it is difficult to expel the gas from the sterilizing area.

(3) **Beta-propiolactone (BPL)** It is a heterocyclic ring compound having the following formula



It is quite active at low concentrations hence used in concentrations of 2-5 mg/litre of space at 25°C. The BPL vapours are 5 times more active than formaldehyde vapours and 4000 times more active than ethylene oxide. It has low penetrating power, therefore used for sterilizing large areas such as laboratories and aseptic rooms. It is not used in pharmaceutical applications.

(b) Sterilization by Disinfectants

Disinfectants are mainly used for sterilizing the surfaces used for aseptic work. In emergency they may be used for sterilizing the surgical instruments like forceps, scissors, knives, blades etc. For this purpose the required instruments may be dipped in the disinfectant and afterwards washed with sterilized water. The commonly used disinfectants include: alcohol, iodine, isopropyl alcohol , chlorine, cresol with soap solution, phenol and formaldehyde.

3. Mechanical Methods

(a) Sterilization by filtration

Sterilization by filtration is one of the oldest methods of sterilization used in pharmacutical industries for small scale filtration operations. In this method the solutions to be sterilized are passed through bacteria proof filters which include Berkefeld, Pasteur-Chamberland, Seitz and Millipore filters. This method is very useful for thermolabile solutions and can also be used for other solutions. The microorganisms are physically removed by adsorption on the filter medium or by a sieving mechanism. The bacterias are entrapped in the pores of the filters and are

removed from the solution. Since the filtration through these pores is very slow, vacuum and/or pressure are employed to enhance the filtration. In practice, the filter, the accessories, and the receiving vessels must be sterilized by suitable means and kept sterile throughout the operation. This method requires, that aseptic conditions must be maintained. The apparatus should be thoroughly inspected before use for cracks or breakage which may render it unfit for sterilization purposes. After passing the solution through bacteria proof filters it is distributed into sterile containers, under aseptic conditions. The containers are then sealed.

Although all the processes i.e. filtration, filling and sealing are done under aseptic conditions but still the microorganisms may enter into the solution from atmosphere or containers, therefore sterility tests must be performed on the filled containers.

13.6 Types of Filters

Various types of filters used for sterilizing the solutions by filtration are:

1. Seitz filter.
2. Sintered glass filters.
3. Berkefeld and Mandler filters.
4. Pasteur-Chamberland filters.
5. Millipore filters.
6. Membrane filters.

1. Seitz Filter

Seitz filter was developed in Germany and marketed under the trade name Seitz. They are usually round but occasionally square. These filters consist of two parts. The lower part is fitted with a perforated plate over which a compressed asbestos pad is placed which acts as a filtering media. The asbestos filter pads are made in several porosities out of which grade E.K. is used for bacterial filtration. The upper part has a valve through which pressure can be applied. The two parts i.e. upper and lower are joined together by means of winged nuts. The solution to be filtered is filled in the apparatus,

pressure is applied through the valve and filtered solution is collected at the bottom in sterilized containers.

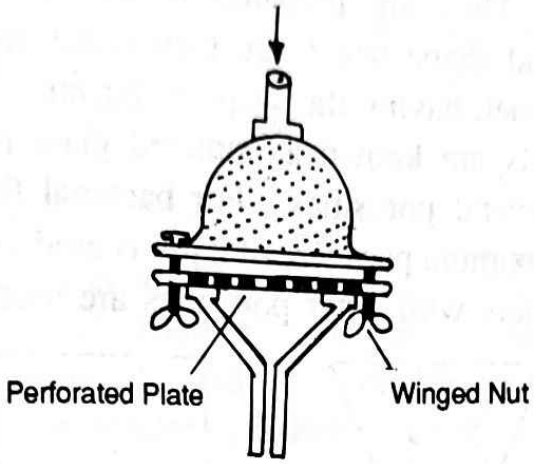


Fig. 13.3 Seitz filter

Advantages

1. As the pads are meant for single use , a new pad is to be used each time and there is no risk of contaminating the filtrate.
2. The apparatus is very simple to use.
3. For viscous solutions they are more suitable than ceramic or glass filters.

Disadvantages

1. Asbestos pads may shed loose fibres which makes the solutions unsuitable for injections.
2. It imparts alkalinity to the filtrate which may be sufficient to precipitate the alkaloids from solutions of their salts.
3. The pads may adsorb sufficient amount of medicament which may result in loss of volume specially when the quantity of solution is small.

2. *Sintered Glass Filters*

Sintered glass filters consist of ground glass particles which are fused together by heating to its sintering point (it is that temperature at which the glass particles are fused together to

become solid, without melting). The fused particles have interstices between themselves which form a suitable system for filtration. They are prepared in the from of discs of suitable size and shape which are then sealed by heat in to a Pyrex glass funnel, having the shape of buchner funnel. These so fused funnels are known as sintered glass funnels, which are made in several porosities. For bacterial filtration Grade 5 having the maximum pore size of 2 μm is used, for c'arification of solutions filters with other porosities are used.

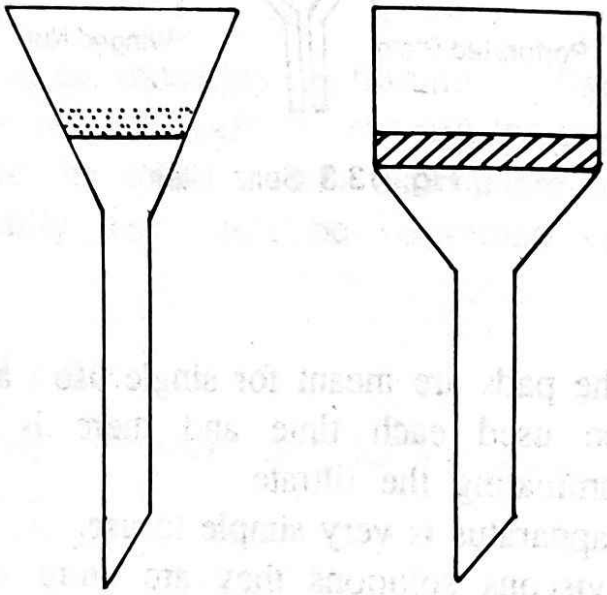


Fig. 13.4 Sintered glass filter

These filters are very fragile, so must be handled carefully. After use they must be cleaned thoroughly. For cleaning they must be washed by suction with hot hydrochloric acid and then with distilled water, until the medium is free from acid.

Advantages

1. If properly cleaned, nothing can enter into the filtrate therefore they are generally used for the filtration of solutions to be injected.
2. They are useful for filtering small as well as large volumes.
3. Very little amount of medicament may be absorbed.
4. Volume of filtrate retained in the medium is negligible.

Disadvantages

1. They are very costly.
2. The medium is unsuitable for large volume filtration because for this purpose large discs are required which are mechanically weak.

3. *Berkefeld Filters*

Berkefeld filters are test tube shaped filters called "filter candles" or "ceramic candles". They are made up of unglazed porcelain or kieselguhr and are available in various porosity grades. They are hollow cylinders mounted on metallic joints. One end of the candle is closed and the other is fitted with a narrow opening which is attached to a vacuum pump at the time of its use. These candles can be sterilized by moist heat sterilization at 121°C for 20 minutes.

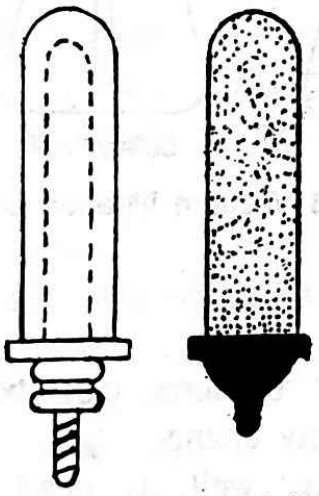


Fig. 13.5 Berkefeld filter

For filtration, the candle is placed in the solution to be sterilized. The narrow opening is attached to the vacuum pump. When the vacuum is applied and pressure inside the candle is decreased, the solution is forced to move inside the candle from where it is collected in large size sterilized containers. The solution so filtered is distributed in final containers which are sealed immediately. The whole process of filtration is carried out under strict aseptic conditions.

By the repeated use of filtration candles, they may get clogged and can be easily cleaned by scrubbing the outer surface of the filter with a brush and passing the water under

pressure from inside to outside direction which will remove the entangled particles from the interstices.

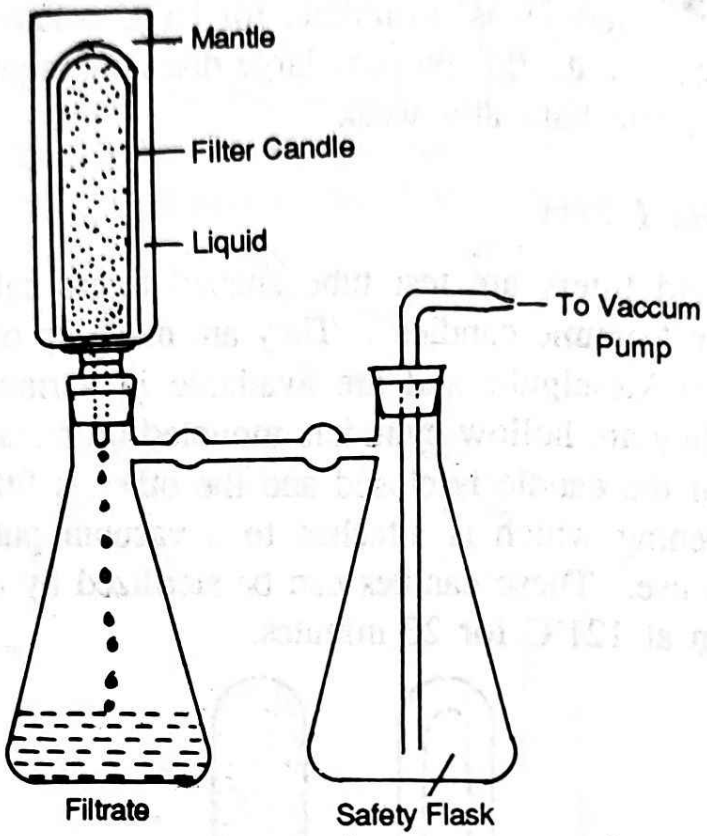


Fig. 13.6 Vacuum filtration assembly

Advantages

1. Themolabile solutions can be sterilized without undergoing any change.
2. All, living as well as dead microorganisms are removed.

Disadvantages

1. The main disadvantage of such filters is that the pores get blocked which require thorough cleaning before the process is repeated.
2. As compared to other filtration medias these candles are little difficult to fit into the filtration units.

4. Millipore Filters

They are porous structures made up of pure and biologically inert cellulose ester. These filters posses high degree of uniform

pore size, high flow and high thermal stability. They do not absorb the solution and are resistant to chemicals. Millipore filters are available in pore size ranging from a high of 8 μ to a low of 0.01 μ. Generally a grade with pore size of 0.22 ± 0.02 μ is used for bacterial filtration. Among the various bacterial filters available, the millipore filters are the most suitable effective method. Small volumes and large volumes of solutions can be filtered easily.

5. *Membrane Filters*

Membrane filters have become very common among ultrafiltration methods because the membranes used have been refined to a great extent. They are made up of cellulose, polyvinyl chloride, nylon and other cellulose derivatives. They are very fine having a wide range of pore size from 8 μ down to 0.22 μ. However for bacterial filtration, membranes with pore size of 0.22 to 0.45 μ are recommended. For use these membranes are fixed in a funnel of desired size and shape as is done in the case of sintered glass funnels.

Advantages

1. Bacteria are removed by sieving.
2. Because the membranes used are very thin therefore adsorption of medicament is negligible.
3. A new disc is used for every new operation.
4. Filtration is quite rapid.
5. They do not liberate particles or chemical substances to the filtrate.

Disadvantages

1. Fine pores may get clogged easily for which a prefilter may be used to remove colloidal matter.
2. Chemically they are less reistant and are soluble in certain organic solvents e.g. ketones and esters.
3. They are very brittle when dry and in this condition they can be stored for years together.

Membrane filters are extensively used for filtration and sterilization of a large number of pharmaceutical preparations