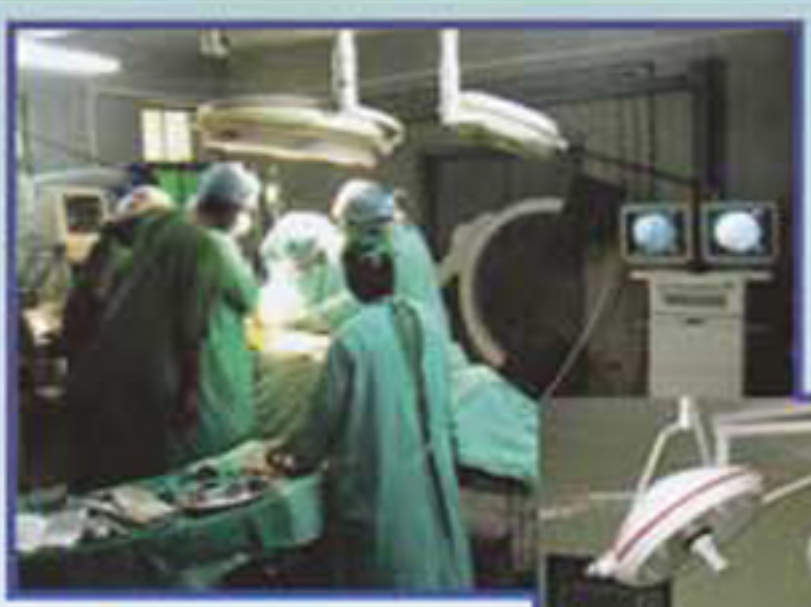
PRACTICAL HOSPITAL AND CLINICAL PHARMACY

SECOND YEAR DIPLOMA IN PHARMACY



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NIRALI PRAKASHAN
ADVANCEMENT OF KNOWLEDGE

PRACTICAL HOSPITAL AND CLINICAL PHARMACY

SECOND YEAR DIPLOMA IN PHARMACY

As Per E.R. 1991

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Preface to Fourteenth Edition

We are pleased to present this revised New Edition of **"Practical Hospital and Clinical Pharmacy"** in a short tenure.

This was possible only due to the overwhelming response from the colleagues, friends and students.

Taking into consideration that minimum 25 practicals in a year, enough number of experiments have been added to this edition. The entire contents of the practical book have been re-arranged suitably.

We hope the teachers and students will co-operate us whole-heartedly as in the past.

February, 2013 **Authors**

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Preface to the First Edition

It is an exclusive pleasure to introduce first edition of Practical Hospital and Clinical Pharmacy book for Second Year Diploma in Pharmacy according to Education Regulations 1991.

The book encompasses the different solutions of the curriculum of Practical Hospital and Clinical Pharmacy designed for Second Year Diploma in Pharmacy.

The book covers different techniques in sterilization of surgical dressings and large volume parenteral preparation. Computers are increasingly used in hospitals and a practical is introduced on introduction to computers.

This book would not see completion without the suggestions and criticisms from our colleagues, teachers and educational authorities.

We shall welcome suggestions and criticisms from all the strata of profession to make improvements in the next edition.

We thank our publishers Shri. Dineshbhai Furia and Jignesh Furia of Nirali Prakashan, for their kind co-operation.

Authors acknowledge the assistance given by Shri. A. B. Mahadik in Computer Programming.

14th January, 1995 **Authors**

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Syllabus

HOSPITAL AND CLINICAL PHARMACY PRACTICALS

No. of hours of practical : 50 **Marks : 100**

1. Preparation of Transfusion Fluids.

2. Testing of Raw Materials used in Chapter 1.

3. Evaluation of Surgical Dressings.

4. Sterilization of Surgical Instruments, Glass-ware and other Hospital Supplies.

5. Handling and Use of Data Processing Equipments.

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Contents

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INTRODUCTION

Hospital Pharmacy is that department in the hospital from where drugs and pharmaceutical preparations are distributed to various other departments within the hospital.

Prescriptions to inpatients, discharged patients and out-patients are also dispensed from here. It is in this department that manufacturing and storage of pharmaceutical preparations take place. Any injectables (parenteral) that may be manufactured are sterilized and stored here only. In some hospitals, this department may also store and dispense accessories like surgical dressings, cotton gauze bandages, and gloves etc. The department is headed by a legally qualified, registered pharmacist.

The first hospital, that we know, was started in Pennsylvania in North America in 1752. The first person to be appointed, to the position of a 'Hospital Pharmacist' was at this very hospital. The latter half of the twentieth century has seen rapid advances in the so called developed countries (western countries). The formation of Associations of Hospital Pharmacists has seen to the needs of the professional working in this area and has enabled them to form clear cut objectives and purpose for the betterment of the profession as a whole. In our country, leading stalwarts in this field have been Miss Gaitonde S.N. and Dr. B.D. Miglani.

Rapid advances in science and technology has led to specialisation in different fields. Similar phenomenon, have been observed in case of hospital pharmacy. As pharmacists has proved their capabilities, the medical profession has come to rely on them for their knowledge of drugs with regard to composition, action, interactions, dosage and toxic effects. Consequently, some pharmacists have specialised in clinical studies of drugs, leading to a section of professionals, known as 'Clinical Pharmacists.'

Hospitals are considered to be the location of choice, where a medical practitioner or a drug company, may wish to carry out testing and trials of new drugs, or drugs which may exhibit more than one beneficial pharmacological action. It is in this area of work, that a clinical pharmacist gives support as/he is knowledgeable about different factors involved in absorption, distribution, metabolism and excretion of drugs and their metabolites.

The magnitude and responsibility of the work being undertaken by hospital and clinical pharmacists has made us aware that it is essential for a pharmacy student to be knowledgeable about the basic techniques involved in the manufacture and sterilization of parenterals.

The following chapters will educate the students in different methods used for sterilization, techniques of aseptic transfer, cleaning of glassware and instruments to be sterilized, preparation of few transfusion fluids, surgical dressing, their evaluation. Some assay procedures to determine the quality of the product as required by official compendia have also been discussed.

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I . . .

STERILIZATION IN HOSPITALS

Sterilization is the process in which all living micro-organisms are totally destroyed or removed from a liquid or an object. The different methods used for sterilization can be broadly classified into two main groups :

1. Physical and
2. Chemical.

The different physical methods used include :

(i) Sterilization by heat (dry or moist)

(ii) Radiation and

(iii) Filtration.

The chemical methods, used are (i) gases or (ii) liquids.

There is no single procedure that can be used to sterilize all drugs and medical devices. The nature of the product will be the decisive factor, as which method is most suitable for that particular product, whereby sterility is achieved without any degradation in the product.

STERILIZATION

Physical	Chemical	Mechanical
(A) Dry heat (B) Moist heat (C) Radiation	(a) Gases (b) Liquids	Filtrations : 1. Berkefeld filter 2. Seitz – filter 3. Sintered – glass filter 4. Membrane filter

PHYSICAL METHODS

(A) DRY HEAT :

It is one of the oldest known methods of sterilization. Heat destroys all micro-organisms, including bacterial spores. The chief cause of death of micro-organisms when dry heat is used is due to coagulation and oxidation. The time required to kill the micro-organisms is inversely proportional to the temperature employed.

Sterilization by dry heat is usually carried out in hot air ovens. They may be of the natural convection type or the forced convection type. The ovens usually consist of an aluminium or stainless steel chamber, separated from the outer case by a thick layer of glass fibre insulation. The hollow flanged door is also filled with insulation and carries an asbestos gasket to provide a tight seal. Heaters are usually fixed to the outside of the chamber. Heat is transferred from the source to the load by radiation, convection and to a lesser extent by conduction. The ovens designed should be such that every article should receive correct exposure, where it is placed and the sterilizing temperature must be reached quickly and maintained with minimum variation. In natural convection type ovens, circulation depends upon the currents produced by the rise of hot air and fall of cool air. Containers placed in the oven may block the circulation, resulting in poor heat distribution. In forced convection type ovens, a blower or a fan is provided to circulate the heated air around the object placed in the oven. This greatly improves the efficiency. The temperature differences at various locations on the shelves may be reduced to as low as ±1°C.

The sterilization operating cycle includes lag time, sterilizing hold time and cooling. *Lag time* is the time required to heat up the whole load to the required sterilizing temperature. *Sterilizing hold time* is the time for which the whole load is held at, or above, the required sterilizing temperature. The load should be allowed to cool in the oven without any disturbance for some time, before it is removed to storage in a dust-free atmosphere until cold.

Generally, dry heat is less efficient than moist heat, hence it requires higher temperature and longer exposure time. Some time-temperature figures commonly used in sterilization of hospital supplies are as follows :

170°C - 1 hour

160°C - 2 hours

150°C - 2.5 hours

140°C - 3 hours

Some of the materials that are sterilized by this method are talc, starch, lactose, petroleum jelly, mineral oils, greases and waxes, glassware, porcelain mortars and pestles, evaporating basins and tiles, metal beakers, stainless steel dishes, scissors and scalpels.

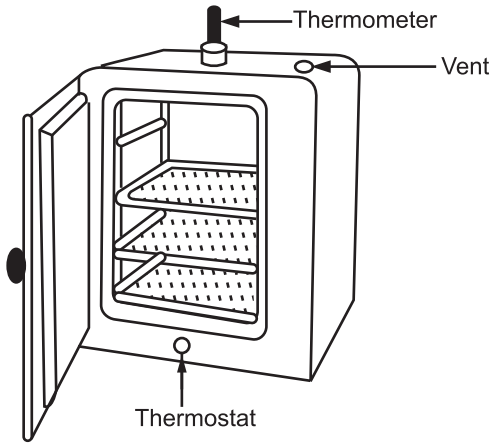

Fig. 1 : Hot Air-Oven

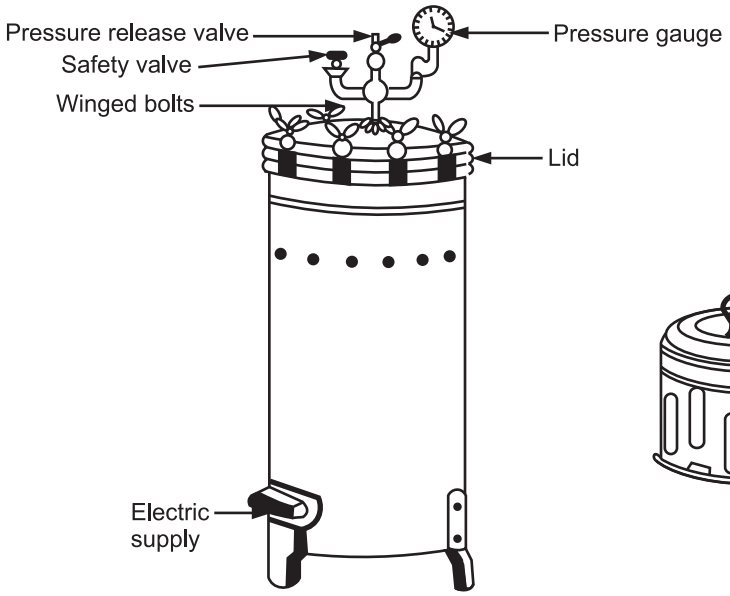

Fig. 2 : Autoclave

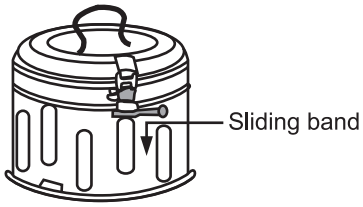

Fig. 3 : Drum for Sterile Dressings

(B) MOIST HEAT :

Moist heat in the form of steam under pressure is a widely used method for sterilization. It causes coagulation of cell protein leading to the destruction of the micro-organisms. The thermal capacity of steam is much greater than that of hot air. When steam condenses, it liberates thermal energy equal to its heat of evaporization. This amounts to approximately 540 cals per g at 100°C and 524 cals per g at 121°C. The heat energy liberated by hot air is approximately 1 cal per g of air for each degree centrigrade of cooling. Thus, when saturated steam strikes a cool object and condenses, it liberates approximately 500 times more the amount of heat energy than that liberated by an equal weight of hot air. As a result, the object is heated much more rapidly by steam. This method is suitable only for water-wettable materials and aqueous solutions and is usually carried out in autoclaves.

AUTOCLAVE

An autoclave is a strong cylindrical body made of an aluminium alloy with handles. Around the rim are eight bolts that swing up into slots and the lid, where they are held in position by winged nuts. The curved lid, concave on the side exposed to the steam pressure, carries a recessed rubber gasket, that gives a tight seal. On the lid are three controls, a vent through which air is expelled, a pressure gauge that records steam pressure and vacuum and a safety valve. The density of steam is lower than that of air, so steam enters the autoclave and rises to the top and displaces the air downward. Objects should be so placed that there is adequate circulation space for steam around it and the air displaced downward can be removed out of the exhaust line from the chamber. To be effective, air pockets must be eliminated. This requires that the items be wet when placed in an autoclave.

An autoclaving cycle is a sequence of operations, comprising of air removal, lag time, sterilizing hold time and cooling. Lag time is the time required to heat up the whole load to the required sterilizing temperature. Sterilizing hold time, is the time for which the whole load is held at the required sterilizing temperature. Exposure to saturated steam under pressure for 15 minutes at a temperature of 121°C in a pressurized vessel (autoclave) is said to achieve effective sterilization.

Wrappings for equipment and supplies, subject to moist heat sterilization, must permit easy penetration of steam and escape of air. Some of the disposable wrapping materials used are 20 lb kraft paper, special parchment paper and Tyvek. Reusable types include close-weave nylon and dacron.

Indicators like wax or chemical pellets that melt at 121°C or paper strips impregnated with chemicals that change colour under the influence of moisture and heat are used for evaluating the sterilization process.

Moist heat sterilization is applicable to bottled fluids, ampoules, rubber closures, glassware and other equipment with rubber attachments, surgical gauze and dressing, surgical gowns and gloves.

(C) RADIATION :

Two types of radiations are used for sterilization - electromagnetic (UV and γ radiation) and particulate (high energy electrons).

(i) UV radiation : It has limited use. Artificially produced UV radiation by mercury vapour lamps, in the region of 253.7 milli-microns is used in the pharmaceutical industry for maintenance of aseptic areas and room. UV light has poor penetrating power, as it is extensively absorbed by substances like glass, plastics and turbid liquids. Its efficiency is affected by dust and is therefore suitable for sterilization of air and water in thin layers and of hard impermeable surfaces. Operators need to protect themselves, especially the skin and eyes from the effect of radiation.

(ii) Gamma radiation : Radiations emitted from radioactive materials such as cobalt-60 or cesium-137 are used for sterilization. These radiations are very reliable, but their source is relatively expensive and emission cannot be shut off once started. When gamma radiations are absorbed within the cell, disorganization of enzymes and DNA of the nucleus takes place, leading to cell death.

A dose of 2 to 2.5 megarads is considered adequate to ensure sterility.

(iii) Particulate radiation : The only one currently being employed for sterilization is the β particles of electron. The β particles are accelerated to a high energy level by the application of high voltage potential, with which, articles to be sterilized are bombarded. The sterilizing dose of 2.5 megarads can be achieved very rapidly (2 to 3 seconds) and the operation can be discontinued.

In the pharmaceutical industry some of the materials sterilized, using the above methods are vitamins, antibiotics, steroids, hormones, hospital supplies, plastic syringes, needles, plastic tubing, catheters, prostheris and so on.

(D) FILTRATION :

Sterilization by filtration is essentially a means by which the micro-organisms are physically removed from a solution, thus rendering it sterile. The filters may be made up of porcelain, plastic polymers like cellulose acetate and nitrate, nylon, polyvinyl chloride, polycarbonate, polysulfone and teflon. Sometimes sintered metals such as stainless steel and silver are used when highly durable characteristics are required. Filters vary considerably in pore size - those having a maximum pore size of 2.5 μm or less are suitable for sterilization. The micro-organisms are removed from the solution, by sieving, surface, adsorption, deposition in the system of interlocking pores formed by the materials that go to make up the filter and retention in capillary film. Some pharmaceuticals, may be readily absorbed by one type of filter and not by another, hence the need of having filters made up of different materials. Since the process of gravity filtration is slow, sometimes vacuum or pressure or both may be employed to increase the filtration rate.

A pre-requisite for sterilization operation is that the entire assembly, with the exception of the solution to be sterilized, should first be sterilized before use. Most filters may be sterilized by steam and/or dry heat, either separately or as a complete assembled unit. Aqueous solutions may be sterilized by filtration through a suitable bacteria-proof filter. This method is rapid and can be carried out at any temperature and is therefore suitable for solutions containing thermo-labile ingredients.

CHEMICAL METHODS

(A) Gaseous : Gases such as **formaldehyde** and **sulphur dioxide** have been used for sterilization for many years. Other gases like **ethylene dioxide, propylene oxide, ozone, chloropicrin and methyl bromide** have been shown to possess germicidal properties, but only ethylene oxide is widely used for sterilization of medical products.

Ethylene oxide, at room temperature is highly flammable, alone and when mixed with air. However, when mixed with inert gases, such as carbon dioxide or fluorinated hydrocarbons (Freons), it is rendered non-inflammable and safe to handle. Being gaseous in nature, it readily penetrates materials such as

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