CBS Confident Pharmacy Series

Fourth Edition

Hospital and Clinical Pharmacy

Course Code: **ER20-25T**

for **Second Year Diploma in Pharmacy**

As per new syllabus prescribed by Pharmacy Council of India



VN Raje

CBSPD Dedicated to Education
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Salient Features

- Lucid and easy language
- To the point answers
- Remembering the concepts in the simplest way
- Infusing confidence in the reader to appear in the board examinations

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Preface to the Fourth Edition

This edition of the book under the CBS Confident Pharmacy Series builds self-confidence in students which helps to get success in the examinations. The book has been written to meet the requirements of students of Diploma in Pharmacy (DPharm) in accordance with the new revised syllabus ER-2020 prescribed by Pharmacy Council of India.

This book is small and humble effort has been put in for compiling necessary information on the subject. An attempt has been made to demystify and simplify the basic concepts for the students of pharmacy and to enable them get an evergreen success in MSBTE examinations and all other qualifying examinations throughout India.

The salient features of the present book are:

- Lucid and easy language
- To the point answers
- Remembering facts in the simplest way
- Infusing confidence in the reader to appear in the board examinations.

Hence, the series is named

CBS Confident Pharmacy Series

I am confident that this book will be useful to both the students and the teachers of Diploma in Pharmacy as well as the candidates desiring to succeed in competitive examinations for better job opportunities in pharmacy profession such as hospital pharmacists in PHCs, civil hospitals, etc.

Vijay N Raje

to
my beloved family

Acknowledgements

I express my heartfelt thanks to Prof Madan Jagtap, Chairman, Gourishankar Education Society, Satara, Maharashtra, for consistent encouragement and inspiration for writing this book.

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I am also thankful to Shri Satish Kumar Jain, Chairman and Managing Director, and Shri Shantanu Sarkar, Assistant General Manager, Mumbai Branch, CBS Publishers & Distributors Pvt Ltd, for their sustained efforts and keen interest in the publication of this book.

I wish all my beloved students to have a great success in the board examinations.

Vijay N Raje

Syllabus

(As per PCI New ER 2020)

Hospital and Clinical Pharmacy

Course Code: ER20-25T **75 Hours (3 Hours/week)**

1. **Hospital pharmacy**
   - Definition, scope, national and international scenario.
   - Organisation structure.
   - Professional responsibilities, qualification and experience requirements, job specifications, work load requirements and inter professional relationships.
   - Good pharmacy practice (GPP) in hospital
   - Hospital pharmacy standards (FIP basel statements, AHSP)
2. **Different committees in the hospital**
   - Pharmacy and Therapeutics Committee—objectives, composition and functions.
   - Hospital formulary—definition, procedure for development and use of hospital formulary.
   - Infection Control Committee—role of pharmacist in preventing antimicrobial resistance.
3. **Supply chain and inventory control**
   - Preparation of drug lists—high risk drugs, emergency drugs, Schedule H1 drugs, NDPS drugs, reserved antibiotics.
   - Procedures of drug purchases—drug selection, short-term, long-term and tender/e-tender process, quotations, etc.
   - Inventory control techniques—economic order quantity, reorder quantity level, inventory turnover, etc.
   - Inventory management of central drugstore—storage conditions, methods of storage, distribution, maintaining cold chain, devices used for cold storage (refrigerator, ILR, walk-in-cold rooms).
   - FEFO, FIFO methods.
   - Expiry drug removal and their disposal methods, e.g. narcotics.
   - Documentation—purchase and inventory.
4. **Drug distribution**
   - Drug distribution (inpatients and outpatients): Definition, advantages and disadvantages of individual prescription order method, floor stock method, unit dose drug distribution method, drug basket method.
   - Distribution of drugs to ICCU/ICU/NICU/emergency wards.
   - Automated drug dispensing systems and devices.
   - Distribution of narcotic and psychotropic substances and their storage.

5. **Compounding in hospitals:** Bulk compounding, IV admixture, services and incompatibilities, total parenteral nutrition.
6. **Radio pharmaceuticals:** Storage, dispensing and disposal of radio-pharmaceuticals.
7. Application of computers in hospital pharmacy practice, electronic health records softwares used in hospital pharmacy.
8. **Clinical pharmacy:** Definition, scope and development—in India and other countries technical definitions, common terminologies used in clinical settings and their significance as paediatrics, geriatric, anti-natal care, post-natal care, etc.

   Daily activities of clinical pharmacist: Definition, goal and procedure of:
   - Ward round participation.
   - Treatment chart review.
   - Adverse drug reaction monitoring.
   - Drug information and poisons information.
   - Medication history.
   - Patient counseling.
   - Interprofessional collaboration.

   Pharmaceutical care: Definition, classification of drug related problems, principles and procedure to provide pharmaceutical care, medication therapy management, home medication review.
9. **Clinical laboratory tests** used in the evaluation of disease states—significance and interpretation of test results:
   - Haematological, liver function, renal function, thyroid function tests.
   - Tests associated with cardiac disorders.
   - Fluid and electrolyte balance.
   - Pulmonary function test.
10. **Poisoning: Types of poisoning:** Clinical manifestations and antidotes. Drugs and poison information centre and their services: Definition, requirements, information resources with examples, and their advantages and disadvantages.
11. **Pharmacovigilance**
    - Definition, aim and scope.
    - Overview of pharmacovigilance.
12. **Medication errors:** Definition, types, consequences, and strategies to minimize mediation errors, LASA drugs and tall man lettering as per ISMP.
13. **Drug interactions:** Definition, types, clinical significance of drug interactions.

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Chapter 1

Hospital Pharmacy

Q1. Define hospital. State the functions of hospital.

Hospital

According to WHO, "hospital is an organization of governing body which makes the use of complicated but specialized scientific equipments and functioning through a team of trained staff".

Hospital is an organization which provides a special facility and working for care of patient through the trained persons.

Functions of Hospital

1. To take a care of sick and injured patients.
2. Restoring and keeping up good health of community.
3. To promote good services to patient for getting relief from diseases and pains.
4. To lower the incidences of diseases through early detection and treatment.
5. To make trained and skilled physicians and nurses.
6. To maintain and distribute hospital formulary.
7. To promote research in medical, pharmaceutical and other related fields.
8. To take care of patient by using advanced knowledge and instruments.
9. To rise general standard of medicine for increasing quality of patient care.
10. To contribute in prevention of spreading of disease in the community.
11. To run the programmes like public education and vaccination.
12. It serves as a link between community and official health agencies to improve community health.
13. The bigger hospitals co-operate with smaller hospitals. Thus, hospital performs co-operative work.
14. Primary function is to take care of inpatients and outpatients.

Q2. Give the classification of hospital.

Hospital

A. On Clinical Basis

1. **Types of disease**
   - i. TB hospitals.
   - ii. Mental hospitals.
   - iii. Leprosy hospitals.
   - iv. Cancer hospitals.
2. **Types of patient**
   - i. Gynaecological hospitals.
   - ii. Maternity hospitals.
   - iii. Pediatric hospitals.
3. **Types of medicine**
   - i. Allopathic hospitals.
   - ii. Ayurvedic hospitals.
   - iii. Homeopathic hospitals.
   - iv. Unani hospitals.
   - v. Nature-cure centers
   - vi. Physiotherapy centers.
4. **Types of organ**
   - i. ENT hospitals.
   - ii. Eye hospitals.
   - iii. Orthopaedic hospitals.
   - iv. Kidney hospitals

B. On Non-Clinical Basis

1. **On the basis of ownership**
   - a. *Government:*
     - i. Central government: Railway and defence hospitals.
     - ii. State government: Civil hospitals.
     - iii. Local government: Municipality hospitals.
   - b. *Non-government:*
     - i. Run by trust.
     - ii. Run by limited company.
     - iii. Run by religious body.
     - iv. Other private hospitals/nursing homes.
2. **On the basis of size (bed capacity)**
   - i. Large hospitals: > 1000 beds, e.g. KEM hospital (1600 beds).

ii. Medium hospitals: 500 to 1000 beds, e.g. Bombay hospital (700 beds).
iii. Small hospitals: 100 to 500 beds, e.g. Hinduja hospital (175 beds).
iv. Very small hospitals: Less than 100 beds, e.g. PMD hospital (75 beds).

3. On the basis of cost

i. Elite hospitals: Hospitalisation rates vary between ₹500–1200 per day.
(Like five-star hotels with facilities like TV, telephone, fridge, etc.), e.g. Jaslok and Hinduja Hospitals.
ii. Low budget hospitals: Civil hospitals, corporation hospitals.

C. Miscellaneous Hospitals

1. **Accredited hospitals:** These hospitals provide facilities which are decided by council about the healthcare. In United States such hospitals are present.
2. **Others**
   i. Teaching hospitals.
   ii. General hospitals, e.g. Civil hospital.
   iii. Hospitals for non-profit purpose, e.g. Ramakrishna Mission hospital, Kolkata.
   iv. Hospitals for profit purpose.

Q3. Write a note on 'organization of hospital'.

- The hospital is run by the governing body or by the board of trustee or by society, trust or association.
- The governing body members are having experience, knowledge and qualification from several fields.
- The governing body/board of trustee is legally responsible for the specific activities run by the trust.
- For smooth functioning of hospital, governing body appoints the qualified and experienced person as the head of particular institution of hospital.
- Head of the hospital is called hospital administrator/director/dean of the hospital. He is the experienced and qualified person from clinical field. Mainly he/she should be having master degree from medical field and minimum 6 to 10 years experience.
- Hospital administrator is selected or appointed by governing body and is appointed by governing body as its member.

- The heads of all departments are the assistants of administrator.
- The department heads are having minimum master degree from their fields and they are assisted by other staff.
- The departments are classified as clinical and non-clinical departments.
- *Clinical departments:* Gynaecological department, paediatric department, ophthalmic department, surgery department.
  Non-clinical departments: Pharmacy department, nursing department, laundry department, radiology department, maintenance department, etc.
- The staff pattern of each department is different and dependent on the type of services given by the department. The heads of departments are assisted by assistant heads and staff of that department.
- For radiology department, head is assisted by assistant head and other two or three technicians.
- For nursing department, the staff pattern is large. The head of nursing department is assisted by concerned assistant heads and nurses. Generally, one nurse should be made available for maximum 3 patients only. Therefore, on the basis of bed capacity of department, staff pattern of nursing department, pharmacy department is to be decided.
- For taking decision in emergency conditions and other complicated conditions the committees were prepared such as:
  i. Temporary committees, e.g. building construction committee, joint conference committee.
  ii. Permanent committees, e.g. executive committee, PTC, finance committee.
- Thus, the organisation of hospital is dependant on type of services offered by hospital, bed capacity of hospital (Fig. 1.1).

Q4. Write the constitution and functions of governing body of the hospital.

- Governing body is organization having legal authority about the functioning of hospital.
- It is prepared by trust/association/society.
- It is prepared to control over the functioning of hospital.

Constitution

- It is generally constituted by persons from medical, pharmacy, nursing and other fields.

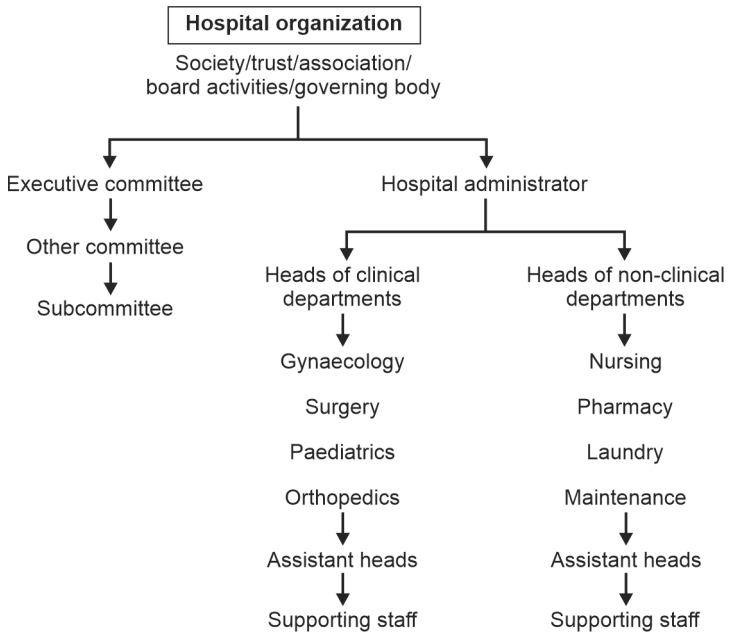


Fig. 1.1: Organisation of hospital

- The governing body appoints some persons which are well known in specific fields, e.g. social workers and advocates.
- The members of this committee should have an interest in social and legal functioning of the hospital. These members should indirectly increase the status of hospital in community.

Functions of Governing Body

1. To appoint hospital administrator.
2. To establish objectives of hospitals.
3. To answer about queries asked by the court regarding court matters.
4. It is a responsible legal authority, therefore, it should guide to staff of the hospital about the requirements of legal documents and papers.
5. To sanction the plans and budget of hospitals.
6. To give suggestions to hospital administrator about management and administration.
7. To select the members of executive committee.
8. To inspect overall activity of hospitals.
9. To conduct the programs through hospital in community for keeping up good health of community.

Q5. Who is the administrator of a hospital? What are his responsibilities/functions?

Administrator of Hospital

"The head/dean/director of the hospital is an administrator of the hospital".

- He is a member of governing body.
- He is the head of PTC.
- He is the secretary of joint and executive committees.
- He is a qualified and experienced person from medical field.
- He is having minimum master degree in medical field and 6 to 10 years experience.

Functions/Responsibility/Role of Hospital Administrator

1. To implement the policies of the governing body.
2. To decide the subcommittees, their members and functions.
3. To decide scientific programmes for the development of knowledge of staff.
4. To manage routine activities by considering main purpose of patient care.
5. To appoint heads of department by taking consideration of governing body.
6. To attend seminars, meetings arranged by other hospitals.
7. To arrange the programmes for keeping good health of the community and to increase the status of hospital.
8. To decide the programmes for training of physicians, nurses and volunteers and control over such programmes and activities.
9. To communicate with hospital staff and to discuss about problems of staff.
10. To attend the meetings of the governing body and to discuss about budget of hospital, finance and other problems of hospital.
11. To take sanctions or approvals of governing body for hospital budget.
12. To check the documents and activities done in hospitals.
13. He should plan for the expansion of a hospital.
14. He should coordinates the work of various section heads of the hospital.
15. He has to provide facilities, equipment and assistance to clinical department.

Q6. What are different type of services provided by hospital?

- The services provided by hospital are divided into two categories:

Clinical services	Non-clinical services (supportive services)
i. General surgery and orthopaedic ii. Gynaecologic and obstetrics iii. ENT iv. Ophthalmologic v. Anaesthesia vi. Psychiatric and nervous diseases vii. Tuberculosis viii. Communical diseases ix. Paediatric x. Medical services (staff pattern)	i. Nursing services ii. Dietary services iii. Pharmacy iv. Housekeeping services v. Pathological services vi. Blood bank vii. Anaesthesia service viii. Account keeping services

1. Clinical Services

Clinical services are completely governed by medically trained and qualified doctors who diagnose and treat the patient.

i. **General surgery:** Surgical services are offered by surgical department and useful for better care and easy to overcome symptoms of diseases. These services are provided by professionally trained and experienced doctors. They are assisted by a number of physicians, nurses and compounders.

ii. **Medical services (staff pattern):** The staff pattern is dependent on type of patient. The staff is classified as:
   a. ***Honorary staff:*** It consists of physicians who are active in hospital during their working years and having interest to work after retirement and having their outstanding performance and experience.
   b. ***Consulting staff:*** These are specialized from specific faculty and available for specified time only.
   c. ***Active staff:*** These are active and full time employees of the hospital. These are having involvement to increase the standard of hospitals.
   d. ***Associated medical staff:*** These are junior and less experienced physicians.
   e. ***Residential medical staff:*** These are the group of physicians who are employees of hospital and living in campus of hospitals.
   f. ***Courtesy medical staff:*** It is the group of physicians who had decided to attend the private patient but refuse the membership of hospital.

2. Non-clinical Services (Supportive Services)

a. Nursing services: This service provides the total healthcare to patient. It is a therapeutic and preventive service. The emotional support to the patient is also provided by this department. The in-charge of this department is a coordinator between medical and nursing staff. The head of this department should perform the following functions:

i. Select the procedure and policies of nursing.
ii. To keep the nursing records.
iii. To prepare required budget.
iv. To provide nursing supplies to nurses.
v. To discuss about nursing problems with the director of hospital.
vi. To adjust departmental duties of nurses.
vii. To take part in seminars for getting the recent knowledge.
viii. To train the nursing staff.

b. Dietary services: It is a supportive service offered by the hospital. The food is offered on scientific basis to each inpatient and suggestions are given about the diet by the food manager. The head of this department is called dietitian.

The duties of head of this department are:

i. To perform the plan for the type of diet for the patient by considering his food allergies and dietary histories.
ii. Selection and purchasing of food materials.
iii. Maintenance of record about purchasing and utilization of food material.
iv. To act as authority for preparation and distribution of diet to each patient.
v. To train and to supervise over the staff of the department.
vi. To follow the specific precautions about the storage of food material.
vii. To help in research studies.

The head of this department should have master degree and at least 2 years experience, the staff of this department should be at least 12% of the total hospital staff. The prepared food is transferred to nursing department for distribution.

c. Pharmacy services: This department is governed by head of department of pharmacology. It stores and dispenses medications and other supplies to inpatients as well as the outpatients.

d. Housekeeping services: It provides cleaned and clear hospital and bed making services. The head of this department is called housekeeper. Housekeeper is well known and educated person. He is having the knowledge of cleansing agents, detergents, disinfectants, soaps, etc.

His duties are:

i. To coordinate with other departmental staff.
ii. To keep records about the utilization of cleansing agents, beds, pillow covers, bed sheets, etc.
iii. To adjust the duties of department staff.
iv. To train the unskilled workers.

e. Pathological services: Head of this department is a medical person with special training in pathology. It provides services, such as checking of blood, urine, stool samples of the patients.

f. Blood bank: Most of the hospitals operate blood bank facilities under department of pathology.

g. Anaesthesia services: Head of this department is a specially qualified and trained medical person also known as anaesthetist. They provide anaesthesia services required during surgery.

h. Account keeping services: This department controls over intake and the utilization of money. This department manages purchasing medicines, instruments and other hospital supply and expenses over maintenance of hospital, payments of employees, etc.

Q7. Define Hospital Pharmacy. Give the objectives and functions of Hospital Pharmacy.

Hospital Pharmacy

Definition: Hospital pharmacy is the department, service or a domain in the hospital organization, managed under the direction of professionally competent legally qualified person.

- Hospital pharmacy is the actual practice of pharmacy in hospital.
- Hospital pharmacist was the first recognised representative of the pharmaceutical profession.
- The first North American Hospital, Pennsylvania. Hospital started functioning in 1752 and Jonathan Roberts worked in it as a hospital pharmacist.
- Hospital pharmacy is the practice of pharmacy within the hospital under supervision of professionally competent and legally qualified pharmacist.

Objectives of Hospital Pharmacy

1. To provide the right medicine to right patient at right time, in right quantity with minimum cost.
2. To plan, organize and implement the policies of pharmacy.
3. To implement the decision of PTC.
4. To participate in research work.
5. To act as profit centre of the hospital.
6. To act as a counselling centre to the patient.
7. To act as an information centre about drugs.
8. To manufacture large volume parenterals or suitable dosage forms.

Functions of Hospital Pharmacy

1. To participate in patient care system by dispensing medicine and monitoring the patient.
2. Dispensing of narcotics, medicines and pharmaceutical preparations.
3. Dispensing of radiopharmaceuticals and alcohol-containing drugs.
4. Dispensing of surgical dressing and related products.
5. Packaging of medicines, drugs and labelling of containers.
6. It acts as a profit centre of the hospital.
7. Checking and maintaining of records of drugs about utilization, distribution, etc.
8. Maintenance of inventory control, purchasing methods, book keeping and record keeping.
9. To check sources of drugs and medicines.
10. To check the received materials for their standards.
11. To implement decision of PTC and maintain the distribution system of drugs.
12. To furnish the information about drugs to the patients and clarify queries asked by patients and thus it acts as information and counselling centre.
13. Manufacturing of sterile and nonsterile products and checking of prepared products.
14. To take part in research study and to cooperate with other departments.
15. To take part in various programmes arranged by hospital for better community health.

Q8. Give the location and layout of hospital pharmacy department.

Location

- Hospital pharmacy department should be located at ground floor or at first floor of the hospital.
- It should be away from inpatient department.
- It should be near to outpatient department, hospital library, drug information centre and should be attached to the manufacturing unit of hospital pharmacy.
- The space for hospital pharmacy department should be minimum 250 sq. feet as per schedule N.
- Depending upon the bed capacity of the hospital the area for hospital pharmacy department is as follows:
  i. For 100 beds hospital, 10 sq. feet per bed.
  ii. For 200 beds hospital 6 to 8 sq. feet per bed.
- According to bed capacity of hospital, type of work and workload norms, the requirement of pharmacist is fulfilled.
- At least 3 pharmacists should be appointed for any small hospital.
- According to bed capacity the number of pharmacists required are:

Up to 50 beds	–	3 pharmacists
Up to 100 beds	–	5 pharmacists
Up to 200 beds	–	8 pharmacists
Up to 300 beds	–	10 pharmacists
Up to 500 beds	–	15 pharmacists

- Generally, outpatient attendance and bed strength ratio is 3:1. One pharmacist can be recommended for maximum 10 patients (Fig. 1.2).
- Due to location of hospital pharmacy at ground floor, easy dispensing to the outpatient and to other departments is possible.
- Hospital pharmacy should have adequate space separately for cold storage, storage of narcotic drugs, radiopharmaceuticals, manufacturing section, for outpatient dispensing, for labelling, packing, weighing and compounding, for central sterile supply, for officer in-charge of hospital pharmacy and for hospital library.
- The hospital pharmacy department should have pleasant look and enough space and furniture.
- The educative posters, informative hanging charts should be adjusted on walls, to fill up the waiting time.
- The light literatures, newspapers, educative magazines should be provided in waiting rooms.

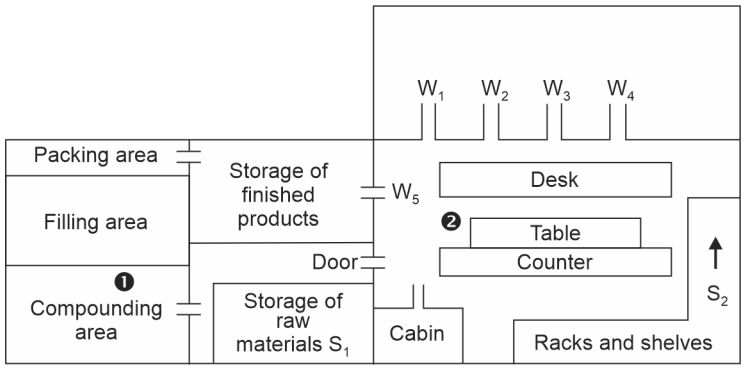


Fig. 1.2: Layout of hospital pharmacy department

Section 1. = Manufacturing department

2. = Hospital pharmacy

W_1 and W_2 = Dispensing to outpatients

W_3 = For dispensing to inpatients

W_4 = Dispensing to emergency patients

W_5 = Forgetting medicines to dispensing from manufacturing section

S_1 = Storage of raw materials

S_2 = Storage of drugs and medicines

- The floors and walls should be clean.
- The floor should be acid-resistant and wall should be painted by light colour and should have smooth surface.
- If manufacturing section is started in hospital, it should be attached to main pharmacy department.
- In large hospitals separate pharmacy substations are located at each floor. Such substations are in vertical manner, therefore, stair way connection can be adjusted.

Q9. Give the flowchart of materials in hospital pharmacy.

- Hospital pharmacy receives its supply of materials either from outside manufacturing units or manufacturing units present inside the hospitals (Fig. 1.3).

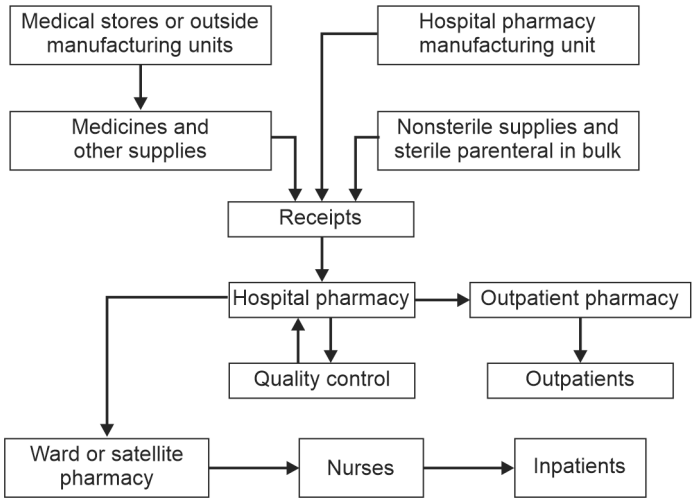


Fig. 1.3: Flowchart of materials

- These supplies are stored and dispensed according to the need to the inpatients or outpatients ultimately.
- It keeps quality control over the receipts.
- For inpatients the supplies are provided to nurses through the ward pharmacies.
- Outpatients medications are supplied through the outpatient pharmacy.

Q10. What are the requirements of space and equipment for smooth working of hospital pharmacy?

The type of hospital, bed capacity of hospital decide the space for pharmacy department. As per schedule N the space for pharmacy department should be minimum 250 sq. feet.

The separate area should be provided to dispensing and distribution, for drugstore, for subdepartments of pharmacy. If manufacturing section is also opened in hospital, separate equipments and space should be provided to that section as per the norms.

Facilities and Equipment Required for Dispensing and Distribution

i. Prescription cabinet
ii. Storage cabinet
iii. Working table
iv. Counters

v. Cabinet for storage of mortars and pastles
vi. Refrigerator, oven
vii. Sterilizers
viii. Cabinet for keeping glasswares
ix. Office desk
x. Filling cabinet
xi. Cupboard for keeping journals and books
xii. Minimum windows for dispensing
xiii. Fluorescent lamps
xiv. Sink with adequate drainage facility
xv. Separate cupboard for narcotics
xvi. Adequate facility for light and water
xvii. Shelves racks
xviii. Book cases
xix. Lockers
xx. Notice boards.

For Manufacturing Section

i. Containers for manufacturing
ii. Containers and closures
iii. Packaging material
iv. Balances for weighing
v. Machineries required for manufacturing and packing
vi. Water distillation stills.

For Sterile Products/Section

i. UV lamps
ii. Laminar flow
iii. Bacteria-proof filters
iv. Aseptic cabinet, etc.

Requirement of Pharmacists/Personnel

The pharmacist should be engaged with maximum 10 patients. The number of pharmacists required is:

Up to 50 beds – 3 Pharmacists
Up to 100 beds – 5 Pharmacists
Up to 200 beds – 8 Pharmacists
Up to 300 beds – 10 Pharmacists
Up to 500 beds – 15 Pharmacists

Separate pharmacist for the dispensing, distribution, drugstore, manufacturing section, clinical pharmacy, drug information centre, quality control should be available.

Q11. Describe the qualification requirements and abilities required for hospital pharmacists (head of hospital pharmacy)

The head of hospital pharmacy department should be at least MPharm in pharmacology. Clinical pharmacist should have a degree such as master in clinical pharmacy. Quality control incharge should be MPharm (analytical chemistry) and assistants should be BPharm or DPharm. The head of hospital pharmacy should have the following abilities:

i. Administrative ability.
ii. Technical ability.
iii. Academic ability.
iv. Ability to develop manufacturing section.
v. Ability to control.

i. Administrative Ability

- He should have an ability to plan, organize, direct and to control over various activities and functions of hospital pharmacy department.
- He should have an ability to select the staff for pharmacy department and to train and guide them.
- He should prepare proper work schedule, purchasing, budget and should develop better pricing system for costing of prescription.
- He should have an ability to interact properly with other departments.
- He should motivate his staff for achieving greater heights in functioning of pharmacy.
- He should have an ability to make pharmacy department as economical viable unit.
- He should have information about the government rules and regulations for proper record-keeping related with drug distribution, purchasing, utilization, etc.

ii. Technical Ability

- He should have adequate knowledge about the storage of drugs, drug interactions, precautions, dose of drugs.
- He should develop proper drug distribution system, proper way of dispensing and good pricing system of medicines.
- He should know pharmacokinetic, pharmacodynamic, pharmacological and pharmacotherapeutic aspects of drugs.
- He should clarify the queries asked by the assistants or physicians.

iii. Academic Ability

- He is the head of department, therefore, he is also responsible for better manufacturing, dispensing procedures.
- He should have ability to develop suitable training programmes for pharmacist.
- He should have an ability to guide pharmacy staff to conduct active research useful for development of product, dispensing and pricing system.
- He should motivate his staff for medical and pharmaceutical research.
- He should provide research and training material to the staff.
- He should take part in seminars and programmes arranged by the hospital.
- He should know about research methodology.
- He should provide motivation to the staff in taking patient care and to perform better functioning of the departments.
- He should have an ability to train the staff of the department.

iv. Ability to Develop Manufacturing Section

- He should have knowledge about the pharmaceutics.
- He should have an ability to prepare the estimate for starting manufacturing section.
- He should know the standards required for manufacturing of particular dosage forms.
- He should know about the instruments and machinery, apparatus required for the manufacturing of dosage forms.
- He should have an ability to attract a suitable person as the head of manufacturing section.

v. Ability to Control

- He should have control over the inventory of drugs and over the money expenditure.
- He should have an ability to develop suitable procedure for purchasing of drugs, costing of prescription, etc.
- He should have an ability to control over the staff of his department.
- He should be able to inspect any subpharmacy department at any time.
- He should maintain smooth functioning of pharmacy department.

Q12. Write in brief about organization of hospital pharmacy department.

The organization pattern of hospital pharmacy department depends upon the duties and functions carried out by the hospital pharmacy department.

Separate pharmacist should be engaged as the head of the department.

In large hospitals the separate in-charge for each department is appointed.

- The head of hospital pharmacy department should be MPharm in pharmacology with adequate abilities like administrative ability, technical ability, etc.

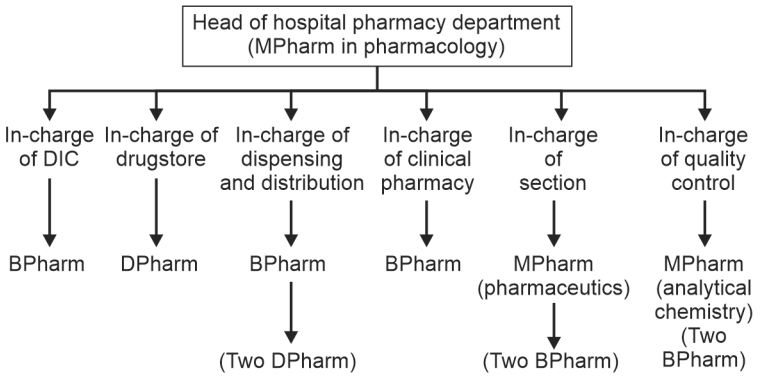


Fig. 1.4: Head of hospital pharmacy department

- The head of hospital pharmacy department is assisted by heads of dispensing and distribution and also of DIC, drugstore, clinical pharmacy, quality control and manufacturing unit.
- The head of drugstore should be DPharm and that of manufacturing section, MPharm in pharmaceutics. The heads from other subdepartments should be at least BPharm.
- Only quality control department should have a head from analytical chemistry and at least a master degree in pharmacy (MPharm).
- In-charge of manufacturing section is assisted by two bachelors in pharmacy, in-charge of quality control section is assisted by two BPharms.
- In-charge of dispensing and distribution is assisted by two DPharms.
- As per workload the staff pattern may be changed.
- In manufacturing section, helpers and other assistants are more as compared to sections such as DIC, etc.

- The quality control department requires assistants for performing analysis and checking of every incoming material and finished products.

Q13. Explain the job specifications and professional responsibilities of hospital pharmacist (chief hospital pharmacist).

JOB SPECIFICATIONS AND PROFESSIONAL RESPONSIBILITIES of HOSPITAL PHARMACIST

Following are the job specifications for the position of chief pharmacist,

1. Plans, organizes, and directs pharmacy policies and procedures in accordance with specified policies of hospital.
2. Compounds and dispenses medicines and preparations according to prescriptions noted by physician.
3. Manufactures sterile and non-sterile preparations in hospitals.
4. Implements decision of PTC of which he is a member.
5. Provides information regarding medications to physicians, interns and nurses.

Responsibilities

1. Specifications for purchase of all drugs, chemicals and pharmaceutical preparations used in treatment of patients.
2. Forecasting the demand of the department.
3. It decides to manufacture or purchase medicine from the industry.
4. Selection of reliable supplier.
5. Purchasing of drug products from reliable suppliers and maintaining a record of the purchased drug.
6. Purchasing raw material for drug manufacturing and maintaining a record of purchased raw material.
7. Manufacturing of sterile and non-sterile preparation and maintaining manufactured records.
8. Quality control of the manufactured products and maintaining the record of quality control of the manufactured products.
9. Storage of drugs.
10. Dispensing of drugs and maintaining a record of dispensed drugs.
11. Dispensing of all narcotic drugs and alcohol and maintenance of a perpetual inventory of them.
12. Maintenance of an approved stock of antidote and other emergency drugs.
13. Manufacturing of drugs and maintaining manufactured product records.

14. Quality control of manufactured products and maintaining the quality control of manufactured products.
15. Providing drug information services.
16. Providing patient counselling.
17. Inspection of all pharmaceutical supplies on all services.
18. Providing information regarding medications to physicians, interns and nurses.
19. Planning, organizing, and directing pharmacy policies and procedures in accordance with specified policies of the hospital.
20. Implementing decision of PTC.
21. Preparation of periodic reports on the progress of the department.

Q14. What is the workload/number of pharmacist required to run hospital pharmacy? Mention Interprofessional relationship of hospital pharmacist.

According to Workload Requirement of Pharmacists

- The manpower trained in pharmacy varies with the size of the hospital, and the services it offers.
- The number of pharmacists required for a hospital is calculated on the basis of some workload norm like the number of prescriptions received and dispensed or the number of beds available in the hospital and its occupancy rate.
- As a rule of thumb, it can be said that there must be minimum 3 pharmacists in a very small hospital. For a 100-bed hospital there can be 5 pharmacists, as the number of beds increases, the number of pharmacists also increases, but not proportionately.
- The following is the suggested staff pattern of pharmacists as recommended by the study group of hospitals (Table 1.1).

Table 1.1: Pharmacist requirement

Bed strength	Number of pharmacists required
Up to 50 beds	3
Up to 100 beds	5
Up to 200 beds	8
Up to 300 beds	10
Up to 500 beds	15

- While calculating the number in very large hospitals (1000 beds, 2000 beds, 3000 beds), the service points available for dispensing to the inpatients and outpatients are considered.

- The outpatient attendance as compared to bed strength in hospitals is usually in the ratio of 3:1 for larger hospitals, one pharmacist has been recommended for 133 patients.

INTERPROFESSIONAL RELATIONSHIPS OF HOSPITAL PHARMACIST

1. Interdepartmental communication is largely a formal affair between different departments of an organization.
2. Interdepartmental communication is effective when it is supported by good infrastructural facilities.
3. Pharmacy department must interconnect with physician and nursing unit.
4. Co-ordination ensures the availability and requirements of day-to-day necessities and emergency medicines.
5. Pharmacists should always check the physician order and the patient history before dispensing the prescription and in case of any doubt, should consult the doctors.
6. While prescribing the medicines, the physicians should always write the patients age and diagnosis, as it will be helpful to pharmacists to take a note of this while dispensing medicines.

Q15. Discuss the "Concept of Good Pharmacy Practice (GPP)".

OR

What is GPP? Give its requirements, elements and guidelines.

Good Pharmacy Practice (GPP)

Definition: Good pharmacy practice is a practice of pharmacy that responds to the needs of the people, who use the pharmacist's services to provide optimal, evidence-based care.

- International Pharmaceutical Federation (FIP) developed standards for pharmacy services under the heading of "Good Pharmacy Practices" in community and hospital pharmacy settings.
- The mission of GPP is to provide medication and healthcare products and services to people and society to achieve good outcomes from treatment.
- GPP guidelines are based on the pharmaceutical care given by pharmacists
- The GPP guidelines recommended that National Standards should be for the pormotion of health, the supply of medicines, medical devices, patient selfcare and improving prescribing and medicine use by pharmacists activities.
- WHO has made certain recommendations about GPP that clarify and meet that obligations to ensure that to provide quality service to the patient.

- In order to satisfy these requirements WHO recommended that:
  a. Professional responsibility should be main philosophy underlying the practice.
  b. Pharmacist's input is essential component in decisions on medicine use.
  c. Professional interactions particularly with physicians should be seen as therapeutic partnership involving mutual trust and confidence.
  d. Relationship with other pharmacists should be as colleagues and should favour improvement in pharmacy services and not as a competitor.
  e. Pharmacist must be aware of importance of providing information to patient and to ensure this, patient's medication profile be generated and maintained.
  f. Pharmacist should try to gather and use comprehensive, objective and current information about therapeutics and medicines in use.
  g. Pharmacist should continually try to maintain professional competence throughout his professional life.
  h. It is necessary to have national standards of GPP, that should be adhered to by the practitioners.

Elements of GPP

GPP addresses the following elements.

1. Promoting good health, avoiding ill health and achieving health objectives.
2. Supply of medicines and their rational use.
3. Self-care activities involving advice and where appropriate supply of medications for self treatment.
4. Activities influencing prescribing and medicine use.
5. In collaboration with other healthcare professional's health promotion activities for community at large, prevention of abuse, misuse, etc.
6. Involvement in all stages of clinical trials.

Good pharmacy practice (GPP) organizes the following major roles for pharmacists

1. To prepare, obtain, store, secure, distribute, administer, dispense and dispose the medical products.
2. To provide effective medication therapy.
3. To maintain and improve professional performance.
4. Contribute to improve effectiveness of healthcare system and public health.

Requirements for the Good Pharmacy Practice (GPP)

1. Premises/layout/furniture
2. Equipment
3. Manpower
4. Storage
5. Inventory control
6. Services
7. Documentation

I. Requirements of Premises/Layout/Furniture

- The location of pharmacy should be such that it is easily identified by the public.
- The environment in the pharmacy should be neat and clean.
- It should have clearly and marked word "Pharmacy"
- The pharmacy should also be accessible to disabled people or peoples using wheelchairs
- It should have display counter, shelves for medicine storage, counselling area, waiting area, billing area, adequate space for movement and waste collection boxes

Counselling area should have furniture (table and chairs) and cabinets for keeping Patients Medication Records (PMR).

2. Requirements of Equipments

- The pharmacy should be equipped with refrigerator for storage of medicine in cold temperature and validated from time to time.
- Counselling area should be equipped with demonstration chart, patient information leaflets, reference materials, etc
- It should contain basic equipments such as thermometer, sphygmomanometer, glucometer, stethoscope, weight and height scale
- It should have telephone, computer software facilities.

3. Requirements of Manpower

- The pharmacy should be managed under the supervision of pharmacist and other personnel working in pharmacy should be well trained.
- The pharmacy should have well-documented guidelines and procedures for personnel set by management with pharmacist consultation.
- The personnel in the pharmacy should wear neat apron/coat and wear a badge displaying his name and designation. ·
- All pharmacy personnel should be medically examined and adequately immunized periodically.

- The chief pharmacist must be bachelor/master in pharmacy.
- Assistant pharmacist must be at least diploma in pharmacy.

4. Requirements for Storage

- All the medicines coming into the pharmacy should initially be quarantined and then checked for quantity, batch number, expiry, integrity, etc. After checking they should be transferred to their respective storage location.
- All the medicines should be stored at appropriate temperature protecting from excessive light, dust and humidity.
- The medicines and shelves should be clean and dust free following Standard Operating Procedures (SOPs).
- Narcotics and psychotropic should be stored and labelled as per norms.
- Shelves should be checked periodically for expiry of medicines and expired medicines should be kept separately labeling a "Expired Goods" "Not for Sale".
- Expired medicines unused and unopened medicines are either returned to the supplier or destroyed as per in-house protocol.

5. Requirements for Inventory Control

- The pharmacy should develop and maintain safe, effective, operational and socio-economically acceptable procurement and inventory management.
- Pharmacist should ensure medicines and healthcare products readily available in the pharmacy in sufficient quantities.

6. Requirements of Services

- Service strategies include home delivery of medicine, special care and attention to patients like elderly patients, regular patients, etc.
- Service manual should state in detail service offered, service time and pharmacy operation schedule.

7. Requirements of Documentation

- Documentation is one of the activities for maintaining and achieving quality.
- Pharmacist shall maintain all necessary documents like registration, permissions, etc.
- All operational documents like purchase invoices, sales invoices, etc.

Q16. Write a note on "hospital pharmacy standards" (FIP Basel statements.)

Hospital Pharmacy Standards (FIP Basel Statements)

- The FIP Congress held in Tokyo in 1993 adopted and FIP/GPP text under Tokyo declaration on standards for quality of pharmacy services, in which it is stated that standards are important part in measurement of quality services to the consumers.
- The FIP believes that standards based on these guidelines should be used by National Pharmaceutical Organizations.
- The guidelines recommended that national standards are set for the promotion of health, the supply of medicines, medical devices, patient self-care and improving prescribing and medicine used by pharmacist activities.
- In 2014, "Revised FIP Basel Statement on the future of hospital pharmacy was adopted as "Hospital Pharmacy Practice Standards" as revisions of initial 2008 version.
- The document consists of total 65 statements, of which first 19 statements are concerned with 'Overarching and Governance Statements" and the remaining statements are grouped in six different themes as follows:

  Theme 1: Procurement
  Theme 2: Influencing on prescribing
  Theme 3: Preparation and delivery of medications
  Theme 4: Medication administration
  Theme 5: Monitoring of medication
  Theme 6: Human resources and training

Theme 1: Procurement

- Hospital pharmacists should be involved in the complex process of procurement of medicines and health products promoting equity and access. They should ensure transparent procurement processes are in place in line with the best practice and national legislation, are free from conflict of interest, and are based on the principles of safety, quality and efficacy.

Theme 2: Influences on Prescribing

- Hospitals should utilize a medicine formulary system (local, regional, and/or national) linked to standard treatment guidelines, protocols, and treatment pathways based on the best available evidence.

- Hospital pharmacists should be key members of pharmacy and therapeutics committees to oversee all medicines management policies and procedures, including those related to off-label use and investigational medicines.

Theme 3: Preparation and Delivery

- Hospital pharmacists should assume responsibility for storage, preparation, dispensing, and distribution of all medicines, including investigational medicines. Hospital pharmacists should assume responsibility for the appropriate labeling and control of medicines stored throughout the facility.
- Hospital pharmacists should be involved in determining which medicines are included in ward stock and standardizing the storage and handling of ward medicines.

Theme 4: Administration

- Hospital pharmacists should ensure that the information resources needed for safe medicines preparation and administration are accessible at the point of care. Hospital pharmacists should ensure that clinically relevant allergies, drug interactions, contraindications, past adverse events and other relevant medication history details are accurately recorded in a standard location in patient records and evaluated prior to medicine use.
- Hospital pharmacists should ensure that medicines are packaged and labeled to ensure identification and to maintain integrity until immediately prior to administration to the individual patient.
- Medication labels should be clear and have sufficient information to ensure safe administration, including at least 2 patient identifiers, the name of the medicine, prescribed route, dose in mass and, where appropriate, volume and rate of administration.

Theme 5: Monitoring of Medicines Use

- An easily accessible reporting system for defective medicines should be established and maintained.
- Reports of defective or substandard medicines should be reviewed internally and sent in a timely manner to regional or national pharmacovigilance or regulatory reporting programs, and the manufacturer.
- An easily accessible reporting system for adverse drug reactions should be established and maintained.

- Reports of reactions should be reviewed internally and sent in a timely manner to regional or national pharmacovigilance or regulatory reporting programs.
- These data should be regularly reviewed to improve the quality and safety of medicines use practices.

Theme 6: Human Resources, Training and Development

- At a national level, competency frameworks are defined, established and regularly assessed.
- At a national level, hospital pharmacists should engage health authorities to bring together stakeholders to collaboratively develop evidence-based hospital pharmacy human resource plans, to support responsible use of medicines including those in rural and remote areas.
- Hospital pharmacists should work with key stakeholders to ensure that workforce education, training, competency, size, and capacity are appropriate to the scope of services, coverage, and responsibilities of all cadres providing pharmacy services.

Q17. What are ASHP guidelines for minimum standards for pharmacies in hospitals?

ASHP guidelines: Minimum standards for pharmacies in hospitals.

- American Society of Health-System Pharmacist (ASHP) guidelines are intended to serve as a basic guide for the provision of pharmacy services in hospitals.
- These guidelines have been developed considering safe, effective and cost-conscious medication use. Accordingly nine standards have been identified as follows:

1. **Standards I:** Practice management
2. **Standards II:** Medication use policy development
3. **Standards III:** Optimizing medication therapy
4. **Standards IV:** Drug product procurement and inventory management
5. **Standards V:** Preparing, packing and labeling medications
6. **Standards VI:** Medication dispensing and delivery
7. **Standards VII:** Monitoring medication use
8. **Standards VIII:** Evaluating effectiveness of the medication use system
9. **Standards IX:** Research

Q18. What is NABH? Enlist various programs under NABH. Give the benefits of NABH.

NABH stands for National Accreditation Board for Hospitals and Health providers.

Definition: NABH is a part of the Quality Council of India which was established to offer accreditation to healthcare providers and hospitals on their adherence to quality guidelines.

Objective: The objective of establishing NABH is enhancing health system and promoting continuous quality improvement and patient safety.

- NABH currently considers the following accreditation, certification and empanelment programs:

1. Accreditation Programs

i. Hospitals
ii. Small healthcare organizations
iii. Blood banks
iv. Medical imaging services
v. Dental facilities/Dental clinics
vi. Allopathic clinics
vii. AYUSH hospitals
viii. Primary health centres
ix. Clinical trial
x. Panchakarma clinics
xi. Eye care organizations

2. Certification Programs

i. Entry level hospital
ii. Entry level small healthcare organizations
iii. Entry level AYUSH centre
iv. Entry level AYUSH hospital
v. Nursing excellence
vi. Medical laboratory program
vii. Emergency department
viii. MVTF empanelment certification

Benefits of Accreditation

1. Benefits for patients:

- Accreditation results in high quality of care and patient safety.

- Patients receive services by credentialed medical staff.
- Rights of patients are respected and protected.

2. Benefits for organization:

- It enables continuous improvement in healthcare organization.
- It ensures organization's commitment to quality care, patient safety and best clinical outcomes.
- It raises community confidence in services provided by the hospital.
- It provides opportunity to healthcare unit to benchmark with the best.
- It provides marketing advantage in a competitive healthcare.
- It gives international recognition to organization which helps to promote medical tourism.
- It provides objective system of empanelment by insurance and other third parties.

3. Benefits for staff:

- Staff gets satisfaction as it provides for continuous learning, good working environment and leadership.
- Efficiencies and competencies of staff gets improved.
- It improves overall professional development, knowledge and competencies.

Q19. Give the difference between "hospital pharmacy and community pharmacy".

Difference between hospital pharmacy and community pharmacy:

Sr. No	Hospital pharmacy	Community pharmacy
1.	Hospital pharmacy is defined as the actual practice of pharmacy in hospital.	Community pharmacy is a practice of pharmacy under the supervision of a pharmacist where prescription orders are compounded and dispensed other than a hospital pharmacy.
2.	Hospital pharmacy is one of the departments of hospital, dispensing medications to inpatients and out-patients.	Community pharmacy is also known as retail pharmacy.
3.	Location in the hospital, should be such that it is convenient for providing services to all departments of hospital and personnel who make daily use of such services.	Location of community pharmacy shall be based on ease and convenience of customers, the patients and other factors like near hospital, market, etc.

Contd.

Contd.

Sr. No	Hospital pharmacy	Community pharmacy
4.	Co-ordination with other departments of hospital is essential.	Co-ordination with prescribing physicians is essential.
5.	Activities are interrelated such that physician–pharmacist–nurse–patient relationship is involved.	Activities are not so extensive and physician–pharmacist–patient relationship is enough.
6.	In addition to internal, external forces influence on standards of practice, e.g. accreditation agencies.	No such influence from external forces on standards of practice.
7.	Responsibility to meet the needs of many other departments of hospital.	No such responsibilities.
8.	Beyond patient care other responsibilities such as education, research, public health.	Beyond patient care, limited other responsibilities.
9.	Opportunity to interact with clinical practitioners, nursing staff, pathologist.	Limited opportunity to interact with other healthcare professionals.

Q20. Enlist NABH standards for hospitals (ten chapters of hospital standards). Explain accreditation process of hospitals.

NABH Standards for Hospitals (Ten Chapters):

Ten chapters of hospital standards are:

1. Access, Assessment and Continuity of Care (AAC)
2. Care of Patients (COP)
3. Management of Medication (MOM)
4. Patient Rights and Education (PRE)
5. Hospital Infection Control (HIC)
6. Patient Safety and Quality Improvement (PSQ)
7. Responsibilities of Management (ROM)
8. Facility Management and Safety (FMS)
9. Human Resource Management (HRM)
10. Information Management System (IMS)

NABH Accreditation Procedure

1. **Preparation of policies and manuals:** Hospital shall prepare quality manual, policies and procedures required as per NABH standards.
2. **Application for accreditation:** Fill in the details in the application as per the instructions given in the online application portal and submit application online.

3. **Scrutiny of application:** NABH officer shall scrutinize the application for its completeness.
4. **Notification of principal assessor and assessment team:** NABH shall appoint principal assessor and a team of other members. The principal assessor shall evaluate the adequacy of all documents (quality manual, policies, procedures, departmental manuals) as mandated by the standards.
5. **Types of assessments conducted by NABH:** NABH in co-ordination with the hospital may choose to follow one of the following methods for conduction of assessment:
   a. *Onsite assessment:* Here the assessors visit the healthcare organization for predefined mandays based on bed strength of hospital. Assessors verified the documents, facilities and conducts interviews in person at HCO.
   b. *Desktop assessment:* Here the organization will submit information and documents as per checklist and the same shall be reviewed by NABH assessor. Based on review the assessor shall give recommendations.
   c. *Remote assessment:* Here the assessor does not go to the HCO in person but conducts entire assessment from a remote location through use of virtual platforms. Hospital needs to provide the online platform.
   d. *Hybrid assessment:* Here one of the assessors may be physically present at the HCO during assessment and the others will be doing the audit from remote location through the use of virtual platform.
6. **Pre-Assessment (optional):** It is optional and those organizations who do not desire to undergo pre-assessment shall communicate in the remark column of application form. However, who desire to undergo pre-assessment, NABH shall conduct such assessment. Principal· assessor along with others in the team are assigned the job of preassessment. The principal assessor shall submit report of assessment online. The hospital shall take corrective actions on the non-conformities pointed by the assessors.
7. **Final assessment:** After the corrective actions taken by organization on the non-conformities pointed in pre-assessment, NABH shall constitute a team for final assessment. The size of assessment team shall depend on bed capacity of hospital and scope of services provided. The date of final assessment shall be mutually agreed upon by hospital management and assessors. The team

shall review the hospitals documented management system with reference to the compliance to NABH standards. Documents, policies, procedures shall be assessed for their implementation and effectiveness. The assessment report is prepared and uploaded by principal assessor in the online portal.

8. **Review of assessment report:** The non-conformities observed are visible to hospital organization, once the report is uploaded by principal assessor. The hospital shall take corrective action on such non-conformities and upload the requisite documentary evidence of action taken. The principal assessor shall review the corrective action taken by the hospital. The hospital organization can avail only two cycles of corrective actions on non-conformities.

   After satisfactory corrective action is taken by hospital, the accreditation committee examines the assessment report, additional information received from the hospital and consequent verifications. Accreditation committee shall make appropriate recommendations regarding accreditation of HCO.
9. **Issue of accreditation certificate:** NABH shall issue an accreditation certificate with a validity of four years. The certificate has unique number and date of validity.
10. **Surveillance and reassessment:** Accreditation shall be valid for four years but within 20–24 months of date of accreditation, the NABH shall conduct surveillance. NABH may call for unannounced visit, based on any concern or any serious incident reported by individual, organization or media.
11. **Focus assessment:** When there are any significant changes in accredited hospital, e.g. change in scope of activities, operations, change of location, change in key technical personnel, etc. the focus assessment shall be conducted.
12. **Surprise assessment:** NABH may conduct surprise assessment in accredited hospitals periodically to evaluate the compliance to the standards. Hospitals are expected to adhere to the NABH standards at any point of time, once it is accredited.

Objective Questions with Answers in Bold Letters

1. ASHP stands for **American Society of Health-System Pharmacists**.
2. GPP stands for **Good Pharmacy Practices**.
3. NABH stands for **National Accreditation Board of Hospitals and Healthcare Providers.**
4. NQAS stands for **National Quality Assurance Standards**.

5. The practice of pharmacy that responds to the needs of the people who use the pharmacists services to provide optimal, evidence-based care is known as **GPP**.
6. The FIP Basel statements can be split into 6 themes
7. GLP stands for **Good Laboratory practices**.
8. The number of pharmacists required for 50 bed size hospital are **3**.
9. NABH started the hospital accreditation program in the year **2005**.
10. The minimum qualification required for registered pharmacists is **D. Pharmacy**.
11. The current hospital standards 5th edition is launched in **February 2020**.
12. NABH provides guidelines for the benefits of **patients, employees and hospitals**.
13. Number of beds in medium size hospitals are **500–1000**.
14. For 300 bed hospital, number of pharmacists required are **10**.
15. The minimum area required for hospital pharmacy is **250 sq.ft**.
16. A prescription for Schedule II and Schedule III controlled drug is valid for **14 days**.
17. The head of the hospital is an **administrator** of the hospital.
18. Prescription is dispensed by **pharmacists**.
19. Pharmacy comes under **non-clinical services** of the hospital.
20. The first North American Hospital, Pennsylvania hospital, started function in 1752 and **Jonathan Roberts** worked in it as a hospital pharmacist.

Chapter 2

Different Committees in the Hospitals

Different committees in the hospitals are

- Pharmacy and Therapeutic Committee (PTC)
- Hospital Formulary (HF) System (HFS)
- Infection Control Committee (ICC)

Q1. What is pharmacy and therapeutic committee (PTC)? Give the objectives/purpose and composition of PTC.

PTC

PTC is a policy framing and recommending body on matters related to rational use of drugs in the hospital and consists of members from various departments of the hospital.

Composition of PTC

PTC consists of:

i. At least 3 physicians
ii. One nursing staff
iii. One pharmacist (secretary)
iv. Hospital administrator (chairman)
    - Chairman is appointed from the physicians.
    - Pharmacist is usually the secretary.
    - There are approximately six meetings per year of the PTC.
    - Secretary is responsible for preparation of agenda for meeting which should be submitted to all members well in advance.
    - Secretary is also responsible for preparing minutes of the meeting.
    - PTC is appointed by governing body/board of trustees.
    - PTC is appointed for better control over routine services provided by hospital.

OBJECTIVES OF THE PHARMACY AND THERAPEUTIC COMMITTEE

1. Advisory objectives:

- To assists in the formulation of policies regarding evaluation, selection and therapeutic use of drugs in the Hospital
- To advise medical staff and hospital administrator about all matters regarding drug use including investigational drugs.
- To advise pharmacist about effective drug distribution and control procedures.
- To give recommendations about the drugs to be stocked in patient care areas.

2. Educational objectives:

- To assist in the formulation of policies to meet the needs of professional staff for getting complete current knowledge about the drugs and their use.
- To review adverse drug reactions and also provide hospital formulary system.
- To look after arrangement of training programs for the professional staff involved in drug use.

Q2. Describe the functions and scope of PTC.

Functions and scope of PTC:

1. It develops policies regarding drug safety.
2. It develops hospital formulary system.
3. It promotes rational use of drugs without wastage and duplication of drugs.
4. It takes review of hospital formulary.
5. It provides training to physicians, nurses, volunteers.
6. It develops policies and procedures for the purchasing, distribution, selection and storage and uses of drugs.
7. It manages the educational programmes for hospital staff.
8. It gives advice to pharmacy department about the purchasing, storage of the drugs and medicinal products.
9. It plays an effective role in hospital management and can prepare subcommittee for purchasing, maintenance, etc.
10. It inspects over the routine activities of the hospital.
11. It partly controls over the hospital library.
12. It gives different suggestions to manufacturing department of the hospital.
13. It can also take decisions about 'automatic stop order' for the dangerous drugs or for the drugs showing unwanted effects.

14. It makes the list of emergency drugs, dangerous drugs, narcotic drugs, alcohol containing and other drugs.
15. It interacts with FDA department.
16. It promotes rational use of drugs.
17. It gives guidelines regarding addition and deletion of drugs in hospital.
18. It helps to review ADR in hospital.
19. It decides quality norms for distribution, administration and use of medication.
20. It advises the pharmacy in procedures for effective drug distribution and control procedures.

Q3. Explain the role of PTC in drug safety. OR How does PTC ensure drug safety in hospital?

Drug safety is one of the major responsibilities of the hospital pharmacist.

The PTC can play an effective role in ensuring drug safety on a continuous basis, by creating safety awareness in all departments of the hospital.

For drug safety in hospital, PTC should consider the following points during its administration.

1. Employment of qualified person as a 'chief pharmacist' (BPharm) and rest are diploma holders.
2. Takes care that the medicines are dispensed only by pharmacists.
3. Sufficient number of pharmacists are employed to cover full day in different shifts of 8 hours.
4. Proper adequate storage facilities are to be provided in pharmacy.
5. Drugs classified under poisons are stored separately from non-poisonous drugs.
6. Stock and issue of narcotic and psychotropic substances shall confirm to legal requirements.
7. Follow of GMP effectively in manufacturing section.
8. External preparations are kept separately and dispensed in special containers, which are distinctively different from the liquid orals like syrups and mixtures.
9. Empty infusion glass bottles (saline bottles) should never be permitted for other uses like collection to urine, vomits, bringing coffee and storing of antiseptic solutions.
10. Providing a library and documentation facility.

Q4. What is hospital formulary? What is the aim or need of hospital formulary system?

Hospital Formulary

It is continuously revised collected information of pharmaceutical dosage forms which gives current clinical judgement to the medical staff.

It is continuously revised compilation of pharmaceutical dosage forms.

Aims/Needs of Hospital Formulary

1. To provide best possible treatment to the patients in lowest possible cost is the ultimate aim served by a hospital formulary.
2. It informs the physicians, nurses and pharmacists about the new and more potent drugs available in the hospital.
3. It avoids the use of brand and therapeutic duplication of drugs.
4. It promotes rational use of drugs.
5. To provide guidelines for 'procuring, prescribing, dispensing and administering of drugs in a hospital'.
6. It informs about availability of medicines, dosage forms and their quantity in the hospital.
7. To inform the staff about standard dosage regimen, adverse effects of the drugs.
8. It provides guidelines regarding emergency drugs in a hospital.
9. It contains list of physicians, their address, phone numbers; qualification and available timings in the hospital which is useful for reference or in emergency conditions.
10. It informs the staff about reported ADRS in the hospital.

Q5. Write guidelines for hospital formulary system. OR Explain guiding principles of HFS.

1. It provides policies, procedures for purchasing and distribution of medicines.
2. It provides information to nursing staff about doses, uses, route of administration of the drugs.
3. It provides information and guidelines about dispensing of medicines and maintenance of documents to pharmacist.
4. It provides information about manufacturing, repacking and labelling of medicines.
5. lt provides information to the physicians about available drugs in the hospital along with their quantity.

6. It provides guidelines regarding maintenance of stock of medicine for the pharmacist.
7. It is useful for preparation of purchase list, purchase order, checking of stock to the pharmacist.

Q6. Explain the significance/functions/importance/role of hospital formulary system.

1. It provides greatest benefits to the patients and physicians (therapeutic).
2. It eliminates duplication of drugs, thus reducing inventory duplication.
3. It gives prescribing tips and additional drug information.
4. It provides current and modern developments in medicines.
5. It helps in evaluating and selecting drugs in the hospitals.
6. It gives guidelines regarding prescribing, procuring, dispensing and administering of a drug in hospital.
7. The information in the hospital formulary is useful for physicians, nurses, pharmacists in the hospital.
8. It provides availability of stock of drugs in the hospital.
9. It gives information about reported adverse reactions in the hospital and hence staff should take care to avoid further possibilities of ADRs.
10. It also contains list of emergency drugs, poisonous drugs, etc.
11. It contains aims and objectives of the hospital.
12. It contains list of physician,s, qualification and their available timings so that other staff and patients may get benefited.
13. HFS also informs about use of drug, precautions, contraindication of the drugs and doses of drugs.

Q7. Give the format of hospital formulary/what is the nature of hospital formulary/give the format and contents of HFS.

Contents of Hospital Formulary System (HFS)

It contains:

1. Pharmacological index
2. Alphabetical index of drugs.
3. List of emergency drugs.
4. List of narcotic drugs, dangerous drugs, etc.
5. List of drugs with their uses, doses and dosage forms, route of administration, precautions, contraindications, and adverse reactions, etc.
6. List of physicians with their address, phone numbers, qualification and available timings at the hospital.

7. Current developments, research in pharmacy and medical field.
8. Information about addition and deletion of drugs.
9. Reported ADRs in the hospital.

Format of HFS

- Format of hospital formulary is decided by PTC.
- Generally, it should be in binded form.
- The size of HF is decided by PTC.
- It should be light in weight, easy to carry.
- It should contain minimum but essential information.
- The coloured pages are not allowed.
- It should not contain any advertisement.
- Only white paper and black ink is allowed for preparation of HF.

Q8. How is hospital formulary prepared?

Hospital formulary is prepared by pharmacy and therapeutic committee.

- Pharmacist is an important member of this committee.
- PTC takes decision about addition and deletions of drugs.
- After that, pharmacist edit the information and undertakes the production, printing and compilation, etc. of formulary.
- Once it is decided to have formulary, the contents other than drugs included are also to be decided, e.g. prescription writing, use of drugs, diagnostic agents, toxicology section, posology, useful tables/data.
- The pharmacist is informed of all these decisions. The preparation of a formulary is then a routine production function.

Q9. How are entry (addition) and deletion of drugs in the hospital formulary done?

The decisions of addition and deletion of drugs in HF are taken by PTC.

Addition/Entry of a Drug into HF

For addition of any drug into hospital following things should be considered:

1. The drug should be well accepted in market or otherwise should have 'No objection certificate' from FDA under the Drugs and Cosmetics Act.
2. The drug should have sufficient 'margin of safety', i.e. minimum side effects and good pharmacological action with minimum dose.

3. Marketed products should mention their license no., registration no., address of registered office of the company and essential information about the medicine.
4. PTC checks the information about drug and the effects of drugs should be monitored and then through discussions and seminars. PTC informs the physicians about the use of drugs.
5. After confirming effectivity of drug PTC permits the particular drug to enter into the hospital pharmacy.

Deletion of the Drugs from HF

The ADR/drug interaction/unwanted side effect if observed with patient, then it should be reported by physicians to PTC.

The information regarding ADRs should be reported to PTC by the following type of form:

ADRs

Date: Time
Dosage form: Name of the drug:
Patient's name: Age: Sex:
Type of disease:
Observed side effects/ADR/Interaction:
Other information:

Signature of Applicant

The PTC calls meeting and the physicians should show the ADRs of the drug through seminar and discussion. After that PTC decides the deletion of a particular drug.

Q10. What is Infection control committee? Give objectives, constitution/composition and functions/Importance of infection control committes.

Infection Control

- It is a process by which healthcare facilities develop and implement specific policies and procedures to prevent the spread of infection among the healthcare staff and patients.
- Nosocomial infection is an infection acquired by a patient or staff member while in a hospital or healthcare facility which is also called healthcare associated infection (HCAI).
- Infection control committee (ICC) is a multidisciplinary committee responsible for establishing and maintaining infection prevention and control, its monitoring, surveillance, reporting, research and education.

Objectives Infection Control Committee

- To understand the causes of nosocomial infection and basic infection control concept.
- To minimize the risk of infection to patients, healthcare workers and visitors.
- To formulate local guidelines and standard operating procedures (SOPs) for prevention and control of infection.
- To educate and train healthcare workers.
- To recommend rational antimicrobial policy for the hospital and formulate antimicrobial stewardship programme.
- To ensure implementation and monitoring of the programme.
- To prevent the resistance to antibiotics.

Composition/Constitution of ICC/Members of ICC

Members of ICC

- Infection control officer (Chairman-Medical Superintendent)
- Infection control nurse (Secretory)
- HODs from
  - Microbiology department
  - Pathology department
  - Pharmacy department
  - Surgery department
  - Medicine department
  - Paediatric department
  - Nursing department

Principle Responsibilities/Role/Functions/Importance of Infection Control Committee (ICC)

- To develop a manual of policies and procedures for aseptic, isolation and antiseptic techniques.
- To carry out targeted surveillance of HAIs, data analysis for presentation in HICC meeting and take corrective steps.
- To advise staff on all aspects of infection control and maintain a safe environment for patients and staff.
- To supervise and monitor cleanliness and hygienic practices.
- To oversee sterilization and disinfection and monitor the use and quality control for disinfectants.
- To advise management of at risk patients and supervision of isolation procedures.
- To investigate outbreaks of infection and take corrective measures for control and prevention of outbreak.

- Waste management.
- To provide relevant information on infection problems to management.
- To assist in training of all new employees as to the importance of infection control and the relevant policies and procedures.
- To organize regular training programme for the staff to ensure implementation of infection control practices.
- To audit infection control procedures and antimicrobial usage.
- To monitor healthcare workers safety programme.

Q11. Explain the role of pharmacist in preventing antimicrobial resistance.

Role of Pharmacist in Preventing Antimicrobial Resistance

- Antimicrobial resistance is a natural process. It occurs when microorganisms are able to resist the drug that has been used to fight them.
- The American Society of Health-system Pharmacist (ASHP) believes that pharmacists have a responsibility to take a prominent role in prevention and control of antimicrobial resistance in health systems.
- Hospital pharmacists play a key role in preventing antimicrobial resistance in the following ways.
  1. Educate and vaccinate the patients
  2. By dispensing antibiotics in safe and rational manner
  3. Spreading awareness about the danger of inappropriate use of antibiotics.
  4. Promoting optimal use of antimicrobial agents.
  5. Reducing the transmission of infection.
  6. Educating health professionals, patients and public
  7. Obtaining and storing vaccines and making them available as appropriate.
  8. Maintaining records of antibiotics distributed to the medical departments.
  9. The hospital pharmacist may also participate in the hospital sterilization and disinfection practices.
  10. The pharmacist also participate in monitoring of patients laboratory reports of microbial sensitivity and advise prescribers if microbial resistance is suspected.
  11. Pharmacist helps to evaluate trends in antibiotic prescribing relative to change in microbial resistance patterns, and assist

in developing prescribing patterns to help to minimize the development of resistance.

12. He should develop and conduct relevant continuing education programmes for hospital staff concerning antimicrobial drug products and their use.

Objective Questions with Answers in Bold Letters

1. PTC stands for **Pharmacy and Therapeutic Committee.**
2. HFS stands for **Hospital Formulary System**.
3. ICC stands for **Infection Control Committee**.
4. HICC stands for **Hospital Infection Control Committee**.
5. MDROs stand for **Multi-Drug Resistant Organisms**.
6. HAIs stand for **Hospital Acquired Infections**.
7. The Pharmacy and Therapeutics Committee play dual role of **advisory and education**.
8. The **Pharmacist** is a secretary of PTC.
9. **Infection Control Nurse** is a secretary of Infection Control Committee.
10. AMR stands for **Anti-Microbial Resistance**.

Chapter 3

Supply Chain and Inventory Control

Q1. Define supply chain. What are the main steps of effective management of medicine supply? What are different categories of drug lists?

Supply chain: Supply chain is the activity required by the organisation to deliver the goods and services to the consumers.

A supply chain includes

i. Supplier
ii. Transporters
iii. Warehouses
iv. Retailer
v. Consumer

The main steps of effective management of medicines supply are:

1. Preparation of drug list.
2. Procedure for drug purchases (procurement), storage, dispensing
3. Inventory control techniques
4. Inventory management

Categories of Drug Lists

Hospital pharmacist prepares the different categories of drug lists:

- **High risk drugs:** These are the drugs which not needed but are harmful if given. Examples: Adrenaline, Chemotherapy, Potassium chloride injection. These are marked in RED during storage, billing and issuing.
- **Emergency drugs:** These are the life saving drugs kept in emergency box to meet any accident or exigency. Examples: Avil, dexamethasone injection, anti-snakebite injection, adrenaline, atropine, etc.
- **Schedule H1 drugs:** These are the medicines required to sell on prescription only and record for certain drugs is to be maintained for 3 years. Example: All medicines other than OTC brands.
- **NDPS drugs:** These are the narcotics and psychotropic substances which have the potential for abuse and addiction. Examples: Opioids, alprazolam, diazepam, codeine, tramadol.

Q2. Define high risk drugs. What are the strategies used to reduce errors using high risk drugs?

OR

Write a note or "high risk drugs".

High Risk Drugs (High Alert Medication)

- High risk drugs are the drugs that have a high risk of causing harm to patient when misused.
- The following high risk medicine classes are recommended by Australian Commission for Safety and Quality in Healthcare.
  i. Antimicrobials
  ii. Potassium and other electrolytes, psychotropic medications
  iii. Insulin
  iv. Chemotherapeutic agents
  v. Heparin and anticoagulants
  vi. Safer systems of administration

Methods/Strategies to Reduce Errors using High Risk Drugs

- Improving access to information about these drugs.
- Limiting access to high risk medications.
- Using tall man lettering to differentiate high risk medications
- Using auxiliary label and automated alerts
- Standardising the prescribing, storage, preparation and administration of these products.

List of High Risk Medications/Drugs

- Epinephrine
- Nor-epinephrine
- Phenylephrine
- Propranolol
- Metaprolol
- Labetalol
- Propofol
- Ketamine
- Lignocaine
- Warfarin
- Dabigatron
- Altepase
- Succinyl choline
- Glimepiride
- Glyburide
- Glipizide
- Tolbutamide
- Magnesium sulphate injection
- Nitro pruisside sodium injection
- Opium tincture
- Oxytocin IV
- Potassium chloride injection
- Potassium phosphate injection
- Promethazine injection

- Digoxin
- Amphotericin-β
- Lorazepam
- Chloral hydrate
- Vasopressin IV
- Insulin

Q3. What are emergency drugs? Enlist emergency drug list.

Emergency Drugs

Definition: Emergency drugs are the medications which may be essential to receive the immediate therapeutic requirements of patients and which are not available from any other approved source in necessary time to prevent risk of harm to the patients.

- These are life-saving drugs kept in emergency box to meet any accident.
- Emergency drugs are important to manage patients in the hospital emergency department and intensive care units (ICU).
- The absence of emergency drugs may cause mortality and morbidity. Hence the availability of emergency drugs shall be important in a designated department.

List of Emergency Drugs

• Oxygen (Medical) • Normal saline • Glucose saline • Epinephrine (Adrenaline) • Atropine • Calcium gluconate • Dextrose 10% • Diphenhydramine • Dopamine • Salbutamol • Calcium chloride • Aspirin	• Fentanyl • Hydralazine • Lorazepam • Naloxone • Phenobarbital • Sodium bicarbonate • Vecuronium • Volume expanders • RBCs • Insulin • Frusemide

Q4. Write a note on schedule H1 drugs.

Schedule H1 Drugs

- These are the drugs which are dispensed on the prescription of medical practitioner only.

- Schedule H1 includes sensitive antibiotics habit forming drugs and drugs having severe side effects, if taken without supervision and prescription by registered medical practitioner.
- Schedule H1 Drug warning:
  a. "It is dangerous to take this preparation except in accordance without the medical advice".
  b. "Not to be sold by retail with the prescription of registered medical practitioner.

List of Schedule H1 Drugs

- Alprazolam
- Balofloxacin
- Buprenorphine
- Capreomycin
- Cefdinir
- Cefditoren
- Cefepime
- Cefetamate
- Cefixime
- Cefoperazone
- Cefotaxime
- Cefpirome
- Cefpodoxime
- Ceftazidime
- Ceftibuten
- Ceftizoxime
- Ceftriaxone
- Chlordiazepoxide
- Clofazimine sodium
- Codeine
- Cycloserine
- Diazepam
- Diphenoxylate
- Deripenam
- Ertapenem
- Ethambutol hydrochloride
- Ethionamide
- Feropenam
- Gemifloxacin
- Imipenem
- Isoniazide
- Levofloxacin
- Meropenem
- Midazolam
- Moxifloxacin
- Nitrazepam
- Para-amino salicylate
- Pentazocine
- Pralifloxacin
- Pyrazinamide
- Rifampicin
- Sparfloxacin
- Thiacetazone
- Tramadol
- Zolpidem

Q5. Write in brief about list of NDPS drugs.

NDPS Drugs

The Narcotic Drugs and Psychotropic Substances (NDPS) are the drugs which have the potential for abuse and addiction.

Narcotic Drugs and Psychotropic Substances Act 1985, is an Act of Parliament of India that prohibits the production/manufacture/

cultivation, possession, sale, purchasing, transport, storage or consumption of any narcotic drugs or psychotropic substances.

Opioids are plant alkaloids derived from opium poppy are considered as narcotic drugs.

Narcotic drugs and psychotropic substances are the habit forming substances and at higher concentrations prove to be toxic. Hence, the operations related to narcotic drugs and psychotropic substances are prohibited to control their misuse.

- Special attention is given for prescribing NDPS drugs.
- These medicines have a red line and NRx written on it.
- Selling these drugs without prescription is crime and records are maintained for 3 years and periodically submitted to the government.
- Following are the six essential narcotic drugs available at hospital by taking prior permission.
  1. Morphine
  2. Codeine
  3. Dihydroxycodeinone (hydroxycodone)
  4. Dihydroxycodeinone (oxycodone)
  5. Fentanyl
  6. Methadone

  Other NDPS drugs are
  - Heroine
  - Carfentanil
  - Tramadol
  - Hydromorphone

Q6. Write a note on "reserved antibiotics".

Reserved Antibiotics

- Reserved antibiotics are reserve for the treatment of confirmed or suspected infections due to multi-drug resistant organisms.
- This concept is designated "restricted antibiotics" or "high end antibiotics".
- Reserve group of antibiotics should be used as "Last resort" options.
- These antibiotics should be available, but their use should be in highly specific patients or when all antibiotic options have failed or are not suitable.
- The newly added antibiotics are classified as reserve antibiotics under WHO's AWARE (Access, Watch and Reserve) designation by the agency in 2017, to guide responsible antibiotic prescribing, curb development of resistance and ensure that antibiotics remain effective and are available when needed.

- Based on recommendations from an expert committee WHO added ceftazidime-avibactam, meropenem-vaborbactam and plazomicin to its essential medicine list.

List of "reserve antibiotics" identified by WHO includes:

1. Ceftazidime-avibactam
2. Meropeneum-vaborbactam
3. Plazomicin
4. Linezoid
5. Colistin
6. Fosfomycin
7. Polymyxin-β

Q7. Define purchase and purchasing. Give the objectives of purchasing.

Purchase

Purchase is the process of procurement of goods or materials.

Purchasing

"Purchasing means the buying of right type of material in right quantity at the right time and at the right place."

Objectives of Purchasing

i. Right quality
ii. Right quantity
iii. Right source
iv. Right price
v. Right time
vi. Right place
vii. Right mode of transportation
viii. Right packaging

i. *Right quality:* The quality of the material is important in building reputation of business.
   Before placing any purchase order, a small quantity of product is obtained and quality is judged and then only final purchase order is placed.
ii. *Right quantity:* Many of the times the purchase quantity depends upon price structure, discounts, free gifts to attract the customers. Thus, the quantity purchased should not be excess than our requirement.

iii. *Right source:* The right source may be the manufacturer, C and F or authorised wholesaler.

He should provide the materials continuously along with right quality.

iv. *Right price:* The price depends upon quality and quantity of the purchase material.

Right price does not indicate the lowest price. The right quality with comparative minimum price is the right price.

v. *Right time:* The materials should be purchased as and when they are required to maintain a regular supply. This is known as right time.

vi. *Right place:* Generally, the items are expected to deliver in the premise of the customers, is the right place.

vii. *Right mode of transportation:* The mode of transportation depends upon distance and time.

Q8. What do you mean by 'centralized and de-centralized purchasing?

The purchasing involves two modern methods.

a. Centralized purchasing method

In this system, purchases are done for the entire hospital. All the items are purchased through a purchase committee at a time. Hence, called centralized purchasing.

For this purpose requirement of each department of hospital is listed by head of every department and forwarded to purchasing committee.

The in-charge of this committee prepares consolidated and comparative statements. Further these statements are forwarded towards executive committee or governing body. This committee sanctions items which are to be purchased and such sanctioned items are listed by purchasing committee which were prepared in 7 copies. These copies are required for purchasing committee, audit department, vendor, store, hospital administrator, governing body and related department.

b. Decentralized purchasing method

If the purchases are done by individual department, it is called decentralized purchasing, e.g. nursing department, catering department, clinical department, stationary department, etc.

Decentralized purchase is either done by junior medical officer or pharmacist.

Q9. What is procurement? Describe the procedure of procurement of goods for hospital pharmacy.

OR

What is purchase procedure? Explain various steps involved in purchase procedure (procurement).

Procurement

Procurement is a process of purchase adapted as per the policy of organization.

Purchase Procedure (process of procurement)

The following steps are involved in the purchase (procurement process)

1. Purchase requisition
2. Selection of suppliers (vendors)
3. Purchase order
4. Receipt of the goods
5. Release of payment to the supplier.

1. Purchase Requisition

- The materials to be purchased for a particular period are well planned for the purpose of their regular and continuous use.
- The departmental head prepares purchase requisition slip according to the specification of products required and send it to administrative head of the concern department.
- The purchase requisition form includes
  - i. Type of material to be purchased
  - ii. Time of requirement
  - iii. Quantity to be purchased
- Once the requisition slip is approved, then it is send to purchasing officer and one copy retained by pharmacist.

2. Selection of Supplier (vendors)

The supplier (vendors) should be selected for the procurement/purchase of the materials for the hospital from the following ways:

a. By inviting tenders from wholesalers and manufacturers
b. By direct purchase from wholesalers and manufacturers
c. Emergency purchase from a local retail drugstore
d. By a contract purchase arrangement with the manufacturer.

- The list of items to be purchased is sent to various suppliers or tender is invited.

- On receiving the quotations (competitive rates) from different suppliers, the comparative statement of all the quotations received is prepared.
- The supplier (vender) which has quoted the lowest rate is generally selected without compromising quality at the materials.
- If the items are not available in stock, the emergency purchase can be done from local market. For this, purchase form is prepared in duplicate, one copy is sent to the department and the other copy is retained in the pharmacy.

3. Purchase Order (PO)

- Purchase order may be defined as an offer to buy a specific drug products from the selected supplier (vendor).
- After selecting the supplier, purchase officer or chief pharmacist prepares purchase order (PO)
- Purchase order includes detailed description, specification packaging, price and quantity needed, etc.
- The purchase order is in written form evidence of agreement between the buyer and the supplier.
- The seven copies of purchase order (PO) are prepared and are send to various sections as follows:

  1st copy: Sent to supplier by post or hand delivering for supplier.
  2nd copy: Sent to accounts department where it will be retaining for accounting.
  3rd copy: Retained by purchasing officer for his department
  4th copy: Sent to the department from where request form is received.
  5th copy: Completion of 5th copy is done if articles are received and sent to the account department.
  6th copy: It is utilized only when goods are back ordered.
  7th copy: It is a specific copy kept by purchase officer for other use.

4. Receipt of the Goods

- When the ordered goods received in the department, the quantities and prices are checked.
- The invoice of the supplier is compared with the purchase order.
- Bills of the received goods are sent to the account section where the bills are entered in purchase record form.
- If part of order is returned to the supplier, good return note must be prepared. One copy is given to supplier and another is retained in the department.

5. Release of payment to the supplier

After confirmation of the correct quantity of good received as per the given specification the payment is done to the supplier as the conditions of agreement.

Q10. Define "tender". Explain various types of tenders.

Tender

A tender is the procedure of inviting prices of materials and terms and conditions of supply from the suppliers.

Types of Tenders

a. *Oral tenders:* In this type, the suppliers are requested to visit the purchasing organisation and inform the prices of products. On receiving the information purchase orders are placed.

b. *Single tender:* It this type, the purchase department appoints a person to enquire prices of the product in the market and to record the information.
- The supplier is selected who offers lowest price.
- This method is followed when the material is of a little use.

c. *Limited tender:* In this type, the tenders are invited from "approved suppliers" only.
- The purhaser has to make contact with suppliers. Generally, contact is done by written fashion. This method is used for purchasing proprietary products.

d. *Open tender/public tender/advertise tender*

- This method is followed when there are a large number of suppliers and the requirement of materials is also large.
- In this type, purchaser gives advertisement in papers and trade journals. The suppliers are expected to prepare and deliver the price list or the quotations.
- The suppliers are also expected to send the price list in a sealed envelop and also send some small samples of the product.
- Sealed envelops are opened on a decided date and suitable supplier is selected. The order is placed to the supplier offering lowest prices.

Q11. What is E-tender? Explain E-tender process.

E-tender

Definition: It is the process for sending and getting tenders by electronic means, instead of old paper-based technique.

E-tendering Process

1. The tenders are invited from suppliers by electronic means (e-procurement system)
2. The bids are sent by suppliers through online e-procurement system before the due date.
3. Received e-tenders were downloaded by purchase officer.
4. E-tenders were evaluated by purchase officer and the result of an award of contract is uploaded on e-procurement system.
5. The order is placed to supplier which has quoted lowest rate. However, factors like quality, period of supply, other expenses like freight, sales tax, packaging and forwarding charges are also to be considered.

Q12. What do you mean by quotation? Explain the procedure for request for quotations.

Quotation

A quotation is a document that a seller provides to buyer to offer goods or services at a stated price under specified conditions.

Request for Quotation (RFQ)

A request for quotation (RFQ) is a competitive bid document used when inviting suppliers has to submit a price of supplying products or services where the requirements are standardized or produced in repetitive quantities.

Request for quotation (RFQ) is method of procurement is used particularly where:

i. The cost of a material to be produced is less than the cost involved in invitation of competitive bids.
ii. There is an established market for the goods to be produced.
iii. Goods or works or services to be produced are urgently required for maintenance or urgent repairs.

Procedure for request of quotation shall include the following

1. Quotations shall be invited from as many potential suppliers as practicable.
2. Each supplier shall be permitted to give only one quotation supplier.
3. The successful quotation shall be the lowest priced quotation meeting the needs of procuring entity.

Q13. What is inventory control? Give objectives of inventory control.

Inventory Control

"Inventory control is an effective way to keep a watch over losses from misappropriation, damage, deterioration and carelessness and proper control over maintenance of stock."

Objectives of Inventory Control

1. To have a regular and uniform supply of materials.
2. To reduce or minimise investment in inventory.
3. To minimise wastage of raw material during storage.
4. To minimise misappropriation of materials.
5. To minimise thefts.
6. To obtain regular information about availability of product.
7. To maintain control over maintenance of stock.
8. To increase efficiency and smooth functioning of organisation.
9. To maintain proper utilisation of funds available.

Q14. Give the functions and importance of inventory control.

1. To keep the inventories as low as possible as per market conditions.
2. To remove "out of stock" or "excessive stock" conditions.
3. To maintain a sufficient stock of finished products to meet the market requirements.
4. To maintain proper records to estimate correct purchases.
5. To forecast the market and economic conditions of supply.
6. To take care of materials during storage period.
7. To provide a safety stock against strikes, transports, delays, etc.
8. To maintain proper leadtime during procurement of materials.

Q15. What are the different methods/tools/techniques used in inventory control?

Methods of Inventory Control

1. ABC analysis
2. VED analysis
3. EOQ method
4. Recorder quantity level
5. Inventory turnover
6. Setting of various levels
7. Perpetual inventory control system

8. Input–output ratio analysis
9. Effective purchase procedure
10. Review of slow-moving and non-moving items

Q16. What is economic order quantity (EOQ)? Explain methods of calculation of EOQ. Mention advantages of EOQ.

Economic order quantity (EOQ)

Economic order quantity prescribes the size of the order at which, the ordering cost and inventory carrying cost will be minimum.

- It is the balance between "ordering cost" and "inventory carrying cost".
- "It is the number of units per order to be purchased which will minimize both inventory carrying cost and ordering cost".
- The correct quantity to buy is the quantity at which ordering cost and inventory carrying cost will be minimum.
- There are two major components of EOQ:

a. Inventory carrying cost

It includes:

i. Rent/cost of storage
ii. Storage facilities provided
iii. Cost of handling materials
iv. Special facilities like refrigerator, air conditioning
v. Amount of interest payable
vi. Salary of storekeeper and other staff.

b. Ordering cost: It is the cost of placing order.

i. Cost of stationary
ii. Cost of postage, telephone, fax, e-mail, etc.

Methods of calculating EOQ

There are three methods of calculating EOQ

a. Graphical method
b. Algebraic method
c. Tabulation method

a. Graphical method

In this method a graph is plotted between order quantity and cost to order and carry (total cost)

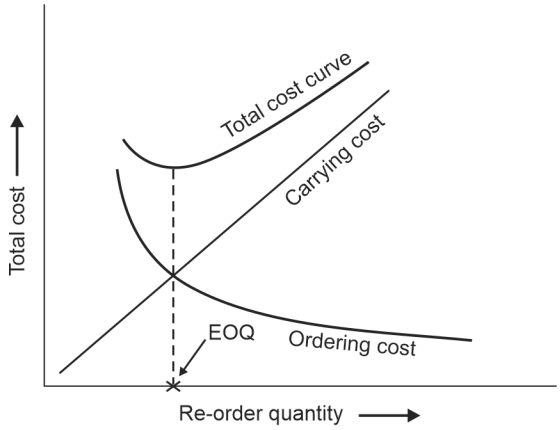


Fig. 3.1: Determination of EOQ

- In order to determine EOQ graphically, re-order quantity is plotted against the annual cost (total cost).
- The EOQ is the point where the ordering cost and carrying cost are at minimum.

b. Algebraic Method

- This method assumes that demand, ordering and holding costs all remain constant.
- The formula to calculate EOQ using this method is:

$$EOQ = \sqrt{\frac{2ab}{cs}}$$

Where,

a: Annual consumption

b: Buying cost per order

c: Cost per unit of material

s: Storage and other inventory carrying cost

c. Tabulation Method

- Tabulation method is normally used when by increase in the quantity of purchases, there is a change in the price.
- In this method carrying cost is calculated on average.
- The least of ordering cost and carrying cost taken together will be the EOQ.

EOQ = Least ordering cost + Least carrying cost

Advantages of EOQ

1. Simple method
2. Widely used
3. Number or orders to be placed in a given period of time can be calculated.
4. Purchase schedule can be prepared.
5. Maintains minimum inventory

Q17. Explain the terms "lead time" and "buffer stock".

1. Lead Time

- The time taken between placing an order and receipt of drugs to the department.
- The longer lead time requires longer storage of drugs stock in the hospital.
- Therefore, efforts should be taken to reduce the lead time for effective inventory control.
- The lead time has two components:
  - **a. Administrative lead time:** It includes the time taken by organisation to complete the purchase procedure, calling price lists, analysis of price list, making enquiries and negotiations, etc.
  - **b. Suppliers lead time**
    - – It includes time required for communication and transportation of materials.
    - – It includes collection, packaging of order, transportation.
    - – If delivery is by post, then postal delays may increase lead time.

2. Buffer Stock (Safety Stock)

- Buffer stock means the minimum quantity of a specific items which must be kept in the store of all time.
- Buffer stock is utilized in emergency periods like strikes or unseen demands.
- The quantities of stock below the minimum stock levels are considered as buffer stock/safety stock.
- Buffer stock can be calculated as:

$$\text{Buffer stock} = (\text{Maximum consumption rate per day} - \text{Consumption rate per day}) \times \text{Lead time}$$

- For maintaining buffer stock the following factors to be taken into consideration.
  - i. Lead time

ii. Nature of item and rate of consumption.
iii. Availability of substitutes.
iv. Re-order level
v. Stock out cost.

Q18. Write a note on 'reorder quantity level'.

Reorder Quantity Level

- It is the level of stock of any item at which next purchase procedure is started.
- Reorder quantity level is the level in between maximum and minimum stock level.
- Reorder quantity level maintains buffer stock, otherwise there will be stock out situation.
- For reorder level the time between placing order and receiving goods should be considered.
- For re-ordering, attention must be given to unavailable large consumption and expiry date of the product.
- Reorder level can be calculated as
  1. Reorder level = (Average daily usage rate × Average lead time in days) + Safety level
  2. Reorder level = Maximum lead time × Maximum consumption rate.
- Reorder level gives a signal regarding when to place a new order for fresh supply of an inventory items.
- The main risk factor in reorder level is being out of stock and some other risk factors are disruption in production and foregone sales.
- The internal factors involved in reorder level are:
  i. Maximum usage during the lead time.
  ii. Safety level
  iii. Replenishment period.
- The external factor involved in reorder level is the lead time taken by the supplier.

Q19. Write a note on 'inventory turnover' and 'inventory turnover' ratio.

Inventory Turnover

- Inventory turnover refers to the amount of time that passes from the day an item is purchased by a company until it is sold.

- One complete turnover of inventory means the company sold the stock that it purchased, less any items lost to damage or shrinkage.
- Inventory includes all goods, raw or finished that a company has in stock with the intent to sell.
- Inventory turnover is the rate that inventory stock is sold, or used and replaced.
- The inventory turnover ratio is calculated by dividing the cost of goods by average inventory for the same period

$$\text{Inventory turnover ratio} = \frac{\text{Cost of goods}}{\text{Average value of inventory}}$$

- Inventory turnover ratio is the number of times a company has sold and replenished its inventory over a specific amount of time.
- The formula can also be used to calculate the number of days it will take to sell the inventory on hand.
- A high ratio is more desirable than a low one as a high ratio tends to point to strong sales.
- Calculating and tracking inventory turnover helps businesses make smarter decisions in a variety of areas, including pricing, manufacturing, marketing, purchasing and warehouse management.

Advantages of Inventory Turnover Ratio

- The patient will be able to obtain the fresh and new inventory.
- It will minimize the risk of inventory expired due to long storage.
- The ratio tells how efficiently the department manages the inventory.

Disadvantages of Inventory Turnover Ratio

- It can be manipulated.
- It hides slow moving items.

Q20. What are various storage conditions of the drugs?

OR

Write a note on the ideal conditions for storage of drugs.

Storage Conditions of Drugs

- Drugstores are used to store all kinds of products and materials like capsules, tablets, liquid dosage forms, injectables, antibiotics, narcotic and psychotropic substances, biologicals, medical devices, etc.
- Storage of drug is an important aspect of the total drug control system.

- Proper environmental control must be maintained wherever the drugs and supplies are stored.
- Store keeping is directly concerned with the physical storage of goods.
- Proper storage offers protection against fire, damage, deterioration, theft, losses, etc.
- Storage helps in identifying and locating drugs through indexing, labels and identification marks.
- Proper storage helps in effective inventory control.
- Safety of storage drugs is also important and poisons and inflammable compounds must be stored safely.
- Since the quality of medicines is affected by physiochemical and environmental factors, the appropriate storage conditions are essential for maintaining potency, physical and chemical integrity, preventing deterioration and maintain quality throughout their shelf-life.
- Storage conditions or pharmaceuticals should possess the following:
  1. Adequate temperature
  2. Sufficient lighting
  3. Clean conditions
  4. Humidity control
  5. Cold storage facilities
  6. Adequate shelving to ensure the integrity of the stored drugs.
- India being a tropical country with varied climatic conditions in terms of temperature. Hence it is important to store the products at their labelled storage conditions as recommended by the manufacturers
- Some of these labelling conditions are:
  1. Keep in cool, dry place.
  2. Keep in cool, dark place
  3. Store in dark at 2°C to 8°C
  4. Do not store above 25°C
  5. Store at room temperature
  6. Store below 4°C (do not freeze)
  7. Store below 30°C. Do not freeze
  8. Keep in dry place, not exceeding 30°C
  9. Keep in cool dry place protected from light
  10. Store below 30°C, protected from moisture (Table 3.1)

Table 3.1: Storage conditions as per Indian pharmacopeia	
Storage conditions	Indian standards as per IP-1996
Cold	Temperature not exceeding 8°C (between 2°C–8°C)
Cool	Any temperature between 8°C–25°C
Warm	Any temperature between 30°C–40°C
Excessive heat	Any temperature between 40°C
Freezer	Temperature between –25°C to –10°C
Room temperature	temperature prevailing at working area.
Dry place	Average relative humidity not exceeding 40%

Methods of Storage of Pharmacopeia

Sufficient number of racks should be provided for storage of drugs and essential supplies.

1. Capsules, tablets, liquid dosage forms and injections, etc. are stored in a specific shelves/racks.
2. Biologicals, antibiotics are stored properly in refrigerator.
3. Vaccines and thermolabile drugs are essential to be stored at cold store 2–8°C
4. Liver preparations, antibiotics, vitamins, etc. should be kept at cool temperature 8°–25°C.
5. Alcohol and alcohol containing preparations should be stored as per the norms.
6. Narcotic and psychotropic substance are kept under lock and key.
7. To prevent theft of costly drugs and prescribed schedule X-drugs should be stored separately under lock and key.
8. Poisons are stored in independent closed racks and labelled as "POISION".
9. Large bulk items are stored at bottom.

Q21. What is cold chain? Write in brief about cold chain management of pharmaceuticals.

Cold Chain

The cold chain is the system used for storage and distribution of temperature controlled medications that require specific temperature until it reaches to the user.

- The cold chain contains all of the materials, equipment and procedures used to maintain the needed temperature range.
- Cold chain is required to protect the integrity, usability and procedures used to maintain the needed temperature range.
- Cold chain is required to protect the integrity, usability and efficacy of the pharmaceutical product.
- Cold chain pharmaceutical products include modern biological therapeutics such as monoclonal antibodies, cellular and gene therapies, vaccines, certain types of insulin and some cancer treatments.
- Pharmaceutical cold chain management refers to the logistic and planning of pharmaceutical supply chain that is kept within a range of specific low temperature.
- The cold chain involves three important elements
  1. Men
  2. Equipment (both storage and transportation)
  3. Monitoring of their functioning.
- The cold chain devices include temperature controlled storage, packaging and distribution facilities at ambient, refrigerated, frozen ultra-frozen, vapour-phase liquid nitrogen and liquid-phase liquid nitrogen conditions.
- The equipment/devices creating cold chain storage temperature conditions are:
  1. Ice-lined refrigerator (ILR)
  2. Walk-in cold rooms
  3. Walk-in freezer (WIF)
  4. Walk-in cooler (WIC)
  5. Deep freezer (DF)

Cold storage of Drugs and Vaccines

Indian Pharmacopeia describes conditions for storage of some official substances which are likely to deteriorate; if not stored properly. It is important to follow the manufacturer's recommended storage conditions for all products. The terms used under definite meaning of the pharmacopeia are:

1. **Store frozen:** Some products, such as certain vaccines, need to be transported within a cold chain and stored at –20°C. Frozen storage is normally for longer-term storage at higher-level facilities.
2. **Keep cold:** Storage at any temperature NOT exceeding 8°C and usually between 2°C and 8°C but must not be frozen. These are usually kept in the first and second part of the refrigerator (never

the freezer). This temperature is appropriate for storing vaccines for a short period of time. A refrigerator is a cold place in which the temperature is maintained thermostatically between 2°C and 8°C.

3. **Keep cool:** Store at 8°–25°C. An article for storage in a cool place is directed, may, alternatively, be stored in a refrigerator (at temperature between 2°C and 8°C), unless otherwise specified in the individual monograph. Store at room temperature or do not store over 30°C: store at 15°–30°C.
4. **Storage at ambient temperature:** Store at the surrounding temperature. This term is not widely used due to significant variation in ambient temperatures. It means "room temperature" or normal storage conditions, which means storage in a dry, clean, well-ventilated area at room temperatures 15° to 25°C or up to 30°C, depending on climatic conditions.
5. **Protect from moisture:** To be stored in normal humidity at room temperature (relative humidity less than 60%)
6. **Protect from light:** To be stored in a light-resistant container.
7. The potency of vaccines, sera test kits, and many other items depends on cold storage. Vaccine, in particular, must be kept at precisely controlled temperatures from the point of manufacture to the point of administration. Also daily temperature record should be maintained properly.

Storage of Vaccines

All vaccines and diluents must be stored in the refrigerator for short term between 2°C and 8°C in a pharmacy that issues to the end-user or clinics. For long terms storage –20°C is preferred only for BCG, OPV and measles/MMR. Do not freeze other vaccines. Domestic refrigerator, ice lined refrigerator are used for short-term storage and deep freezer for long-term storage.

National and regional vaccine stores should be equipped with standby generators; ideally, district vaccine stores should have them as well. Having backups ensures that vaccines and other products are protected in the event of a power failure.

Q22. Describe various equipments/devices used for cold chain.

The equipments/devices used for creating cold chain storage temperature conditions are:

1. Ice-lined refrigerators (ILR)
2. Walk-in cold rooms.

3. Walk-in freezer (WIF)
4. Walk-in cooler (WIC)
5. Deep freezer (DF)
6. Refrigerator

1. Ice-lined Refrigerators (ILF)

- This device has a lining of ice packs, hence the name given is ice-lined refrigerator.
- This device has internal lining of ice, icepacks or cold water-filled compartments.
- If the electricity supply fails, then ice lining keeps the inside temperature of the refrigerator at a safe level for vaccines.
- They can maintain an ideal temperature between 2°C and 8°C with just 8 hours of power supply in 24 hours.
- Additionally, an ILR has a top-opening lid which prevents loss of cold air during door opening. Therefore, the temperature is kept up within ILR for much longer span than in deep freezers.
- ILRs are available in two sizes:
  i. Large ILR (for districts)
  ii. Small ILR (for PHCs)
- The bottom of ILR is its coldest part. Vaccines are stored in baskets hanging into the ILR cabinet.
- The vaccines are arranged according to their freeze sensitivity The least freeze-sensitive vaccines are placed at the bottoms of the basket and the most freeze-sensitive vaccines are placed at the top.
- Use of ILR (ice-lined refrigerators): They are mostly used in vaccine cold chain.

2. Walk-in Cold Rooms

- A walk-in cold room is a type of refrigerator chamber or insulated space designed to maintain an artificially generated temperature or range of temperatures.
- Cold rooms are used for storing temperature-sensitive, perishable items, such as food items, and pharmaceutical products like vaccines.
- Walk-in cold room and cold storage are designed for exact observing of temperature conditions required for cold storage.
- Walk-in cold room will work in temperatures between 0°C and 25°C. It maintains precise temperature for long-term cold storage.
- Cold rooms can vary in size from very small walk-in rooms to very large warehouse storage.

- Walk-in cold rooms and walk-in freezer rooms are refrigerated enclosures accessible via at least one door and large enough for a person to walk into, housed within existing building.

3. Refrigerator

- Refrigerator is the equipment used to assure specific medicines are safely kept within a narrow temperature range and their efficiency is maintained.
- It consists of a thermally protected compartments.
- The temperature of refrigerator is usually between 2°C and 8°C.
- The medicines stored in refrigerator include vaccines, insulin, chemotherapy drugs, topical preparations, eye drops, glucagon, etc.
- The top compartment (the freezer) is used for freezing ice-packs. If the refrigerator is working properly, this compartment will provide temperature range between –15°C and –20°C.
- The recommended temperature ranges are:
  Cold → 2°–8°C
  Cool/Refrigerator → 8°–25°C
  Room temperature → 25°–30°C

Q23. What do you mean by 'FEFO' and 'FIFO'? Give their advantages, disadvantages and importance.

A. FEFO

It stands for first expired, first out.

- FEFO is a term used in the field of inventory management to describe the process of dealing with logistics of products that have limited self-life.
- FEFO is an inventory management technique that permits for products with the earliest expiry date to be distributed first.
- FEFO is a simply highly effective inventory management technique that focuses on the handling and moving of date sensitive inventory.

Advantages of FEFO

1. It helps to sell the products with shortest expiry date at the first.
2. It reduces inventory, waste and addition work
3. It helps to reach the ultimate product before expiry date to the end user
4. It avoids unnecessary dumping/stock of certain items in the warehouse.
5. It provides guarantee of the product towards customer satisfaction.
6. It avoids of dead stocking.

Disadvantages of FEFO

1. An accurate product tracking system is required.
2. Proper space should be planned for the storage
3. Higher taxes.

B. FIFO

It stands for first-in first-out.

- It is based on the principle that the materials which are purchased first are sold first.
- It is simple and logistic method because it takes into consideration the normal procedure of utilizing first those materials which are received first.

Advantages of FIFO

1. It reduces impact of inflation.
2. The change in cost price, lot wise will not affect the sale.
3. Easy to apply
4. Produces higher income during inflation period.
5. This method is used for the products with stable prices and less frequency of purchase and sale.

Disadvantages of FIFO

1. In FIFO inconsistent prices may be given to the customers.
2. It may produce clerical errors.

Q24. Write about "expiry drugs removal"/expired drugs.

Expiry Drug Removal/Expired Drugs

Expired or unwanted medicines that should never be used and should always be considered as pharmaceutical waste.

Expired medicines include:

i. All expired medicines
ii. All bulk or loose tablets and capsules
iii. All cold chain damaged, unexpired medicines
iv. All unsealed tubes and creams, ointments, etc.
v. All unsealed syrups or eye drops (expired or unexpired)

- Pharmacist is required to check the total stock physically for damage or expiry or unsalable drugs
- A separate box is arranged for the storage of expired medicines or the medicines are segregated so that the suppliers can collect the

expired medicines accordingly. The suppliers may give replacement of the same medicines or others.

- The date on which the product shelf-life expires is its expiry date.
- Periodic physical checking activity in the hospital pharmacy department may avoid the deposition of expired medicines.
- The pharmacists have assigned the duty to check the expired medicines physically as per the SOPs.
- Expired drugs result in financial losses because they should no longer be distributed and must be discarded.
- The FEFO and FIFO methods should be practiced for the drugs stocked.
- The following SOPs should be followed regarding expired medicines.

1. SOPs for checking expiry of medicines

- Identity and assign the responsibility to a pharmacist.
- Check every product on shelf for every expiry date.
- Remove the products nearing expiry and store them in a designated area.
- Remove the expired products and store them in a separate cupboard labelled as "expired goods—not for sale".
- Maintain record of each activity, i.e. register for near expiry drugs and register for expired drugs.
- In case of near expiry drugs follow the procedure such as "interdepartmental distribution of such drugs or return to suppliers/manufacturers for replacement".
- Record of the action taken to be maintained.
- In case of expired drugs the "SOP for disposal of expired drugs" be followed.

2. SOP for disposal of Expired Drugs

- Prepare advocacy plan for the SOP.
- Chief pharmacist in the central pharmacy stores will receive the expired drugs along with the records, i.e. register.
- Determine the cost of expired drugs.
- Notify the concerned higher authority about the expired drugs.
- Request for appropriate action to be taken and get approval for it.
- Send the expired drugs in appropriate packages to either return back to suppliers/manufacturers; or to "incharge of biomedical waste" for disposal.
- Maintain the record of action taken.

Q25. Describe various methods of disposal of expired medicines/drugs or pharmaceutical waste.

Methods of Disposal for Expired Medicines/Drugs

The disposal of pharmaceutical waste should be carried out under the supervision of regional and national authorities, as per the criteria.

1. **Return to manufacturer:** Wherever possible returning unusable, expired drugs for safe disposal by the manufacturer should be explored especially the drugs for which disposal is critical and problematic, e.g. antineoplastics.
2. **Land-fill:** It means placing waste disposal directly into a land disposal site without prior treatment. It is the oldest and most widely practiced method. To avoid entry of chemicals into aquifer the waste is immobilized and then disposed into a land disposal site, and is known as engineered landfill.

   There are properly constructed designated landfill sites used for municipal solid wastes. These sites may be called highly engineered sanitary landfill and consists of evacuated pits isolated from water courses and above the water table.
3. **Waste immobilization:** In two different ways the waste is immobilized. One is by encapsulation in which the waste pharmaceuticals are packed in solid block within a plastic or steel drum. They are filled to 75% capacity with solid waste of pharmaceuticals and remaining 25% space is filled with cement/lime mixture. The drum is sealed by spot welding, placed at the base of landfill and covered with fresh municipal solid waste.

   Another way is by inertization, in which packaging materials, paper cardboard and plastic are removed from pharmaceutical waste. The pharmaceuticals are then ground and then mixture of water, cement and lime are added to it to form a homogenous paste. The paste is then landfill and decanted into normal urban waste.
4. **Sewer:** The liquid pharmaceuticals such as syrups, IV fluids can be diluted with water and flushed into the sewer in small quantities.
5. **Burning in open container:** Generally burning pharmaceuticals at low temperature should be avoided. Because it may release toxic pollutants into the air. Only very small quantities of pharmaceuticals may be disposed of in this way.
6. **Medium temperature incineration:** Using two-chamber incinerator operating minimum at 850°C (with a combustion retention time of at least two seconds in the second chamber can be used. Before incineration the pharmaceutical waste is diluted with large quantities of municipal waste.

7. **Novel high temperature incineration:** Furnaces used in industries use high temperature technology, i.e. well above 850°C have long combustion retention times and disperse exhaust gases to high altitudes through tall chimneys. At temperatures up to 2000°C all organic waste components are effectively disintegrated.
8. **Chemical decomposition:** If appropriate incinerator is not available, the chemical decomposition of pharmaceutical waste can be done, followed by landfill. However, this can be done upon recommendation of chemical expert.

Q26. How the narcotic drugs are disposed of?

OR

Explain the method of disposal of narcotic drugs.

Disposal of narcotic drugs

- The expired narcotic drugs must be disposed of to prevent its use by anyone without prescription.
- It will also prevent a child or animal from finding or using the narcotics by accident.
- The best way of disposal of narcotics is to return these to the manufacturer for proper disposal.
- Controlled drugs should be immobilized under supervision of authorized officer, the police or a judicial representative depending on the relevant regulations.
- After immobilization, controlled substances should be destroyed under the supervision of authorized officers by any one of the following methods.
  1. Landfill
  2. Incineration
  3. Waste encapsulation
  4. Waste inertisation

1. **Landfill:** Upon sorting, the narcotics should either be rendered unstable by encapsulation or inertization and then dispersed among the municipal solid waste in a landfill.
2. **Incineration:** There are two types of incineration methods based on incineration temperature and incinerator used.
   a. **Medium temperature incineration:** With two-chamber incinerator with minimum temperature of 850°C, cement kiln incineration.
   b. **High temperature incineration:** With industrial furnaces that operate at temperature above 1200°C.

3. **Waste encapsulation:** Encapsulation means coating the waste with inert materials. The coating materials are chemically stable, adhere to the waste and resist bio-degradation.
4. **Waste inertization:** The inertisation process minimizes the risk of toxic materials spreading into surface water or groundwater by mixing the waste with cement or other substances.

Q27. Write a note on 'disposal of cytotoxic drugs'.

Disposal of cytotoxic drugs

- Cytotoxic drugs are also known as antineoplastic drugs or anticancer drugs.
- Cytotoxic drugs have the ability to kill or stop development of living cells.
- If such cytotoxic drugs are released into the environment, they can have a serious effect, such as interfering with the reproductive process in different life farms. Hence disposal of cytotoxic is of prime importance and must be handled with care.
- Antineoplastic/cytotoxic drugs should be isolated from other drugs and kept separately in clearly marked containers with rigid walls.
- Cytotoxic drugs must avoid crushing cartons or withdraw the product from packages, only be discarded of, in landfill after encapsulation/ incineration and released in a sewage system after chemical decomposition.

The following methods are used for cytotoxic drug disposal:

1. Return to supplier
2. High temperature incineration.
3. Waste encapsulation

Q28. What types of documentation is maintained for purchase and inventory of pharmaceuticals?

OR

Write a note on "documentation for purchase and inventory of pharmaceuticals".

Documentation for Purchase and Inventory of Pharmaceuticals

The two important activities involved in hospital pharmacy department are:

a. Purchase
b. Inventory control

The documentation required during purchase and inventory of pharmaceuticals is as follows:

1. List/Index of suppliers.
2. Departmental purchase requisition.
3. Quotation request
4. Preparation of detailed specifications of required drugs, biologicals, etc.
5. Receiving memo
6. Return goods memo
7. Purchase order
8. Call for quotations
9. Vender audit forms
10. Purchase record form
11. Stock issue confirmation
12. Stock return
13. Inventory adjustment
14. Physical inventory purchase input
15. Stock transfer issue.

Objective Questions with Answers in Bold Letters

1. EOQ stands for **Economic Order Quantity**.
2. VED stands for **Vital, Essential, and Desirable**.
3. ABC stands for **Always, Better, Control**.
4. RFQ stands for **Request-for-Quotation**.
5. ILR stands for **Ice-Lined Refrigerators**.
6. FEFO stands for **First-expired, first-out**.
7. FIFO stands for **First-in, first-out**.
8. The purpose of supply chain management is **Integrating supply and demand management**.
9. The total number of copies of purchase order prepared are **07**.
10. **Supply chain** is the activity required by the organization to deliver goods or services to the consumer.
11. **Cold chain** is the system used for storage and distribution of temperature controlled medications that require specific temperature until it reaches to the user.
12. In ABC analysis 'A' items are **10% quantity of drug with low cost, 70% consumption**.
13. Cold storage temperature is **2° to 8°C**.

14. ABC-VED matrix analysis is based on the **cost and importance of drugs**.
15. Vitamins are stored in **cold temperature**.
16. **High temperature incineration** is a method of disposal used for cytotoxic drugs.
17. **Lead time** is a time taken between placing order and receipt of drugs to the department.
18. Buffer stock is known as **Safety stock**.
19. EOQ is the quantity at which ordering cost and carrying cost will be **minimum**.
20. ABC analysis is based on the **cost, quantity and consumption of drug**.
21. **e-tender** is the process for sending and getting tenders by electronic means, instead of old-paper-based technique.
22. **Purchase order (PO)** is in written form evidence of agreement between the **buyer and supplier**.
23. **Tender** is the process whereby hospital invites bids for drugs that must be submitted within a given time limit.
24. **Quotation** is a written offer to supply material at a given fixed price within a prescribed period and under specific conditions.
25. **NDPS drugs** require stringent provisions for the control and regulation of operations.
26. A high-alert medication is a drug that has a **high-risk** of causing harm to patients when misused.
27. Expired or unwanted medicines that should never be used and should always be considered as **pharmaceutical waste**.
28. **Schedule H_1 drugs** are the medicines required to sell on prescription only.
29. Reserved antibiotics are designated as **restricted antibiotics/high end antibiotics**.
30. Reserve group of antibiotics should be used as **"last resort options"**.
31. **Reorder quantity level** is the level of stock of any item at which next purchase procedure is started.
32. Cool means any temperature between **8°C and 25°C**.

Chapter 4

Drug Distribution

Q1. Define outpatient. Explain/give types/classification of outpatients. Give the method of dispensing to outpatients.

Outpatient

"The patient which is not admitted in hospital but receiving general or specific treatment is called outpatient."

Classification of Outpatient

i. **General outpatient:** The outpatients which are not receiving emergency or specific treatment are called general outpatients, e.g. diabetic patient, hypertension patient.
ii. **Emergency outpatient:** The outpatients if receiving emergency treatment or an accident care are called emergency outpatients.
iii. **Referred outpatients:** If outpatients are receiving specific treatment, then those are called referred outpatients, e.g. patients suffering from eye, ear, nose, teeth disorders.
iv. **Ambulatory patient:** "An ambulatory patient is 'able to walk' and since outpatients receive primary healthcare and walk off, they are wrongly called ambulatory patients". Majority of outpatients are ambulatory patients, e.g. cancer patient

Drug Distribution/Dispensing to Outpatient Department (OPD)

1. Whenever the outpatient visit for the first time, he should register his name at the registration counter.
2. Then he will be directed to particular specialist physician for the consulting and take the prescription from them.
3. The prescription would bear, the name, age, registration number and diagnosis of the patient.
4. Patient should produce this prescription to dispensing counter where pharmacist checks the prescription and assembles the materials for compounding.

5. The specific medications given in the prescription are dispensed properly in the packets/containers, etc. and labelled.
6. Patient counselling can be done during the dispensing regarding dose, route and use of the drugs.
7. The prescription along with the bills are issued to the outpatient.

Q2. Give the location and layout of outpatient dispensing.

Location of OPD

- There should be separate independent outpatient pharmacy.
- If inpatient and outpatient services are combined, separate windows should be provided for dispensing.
- The outpatients dispensing is done from the same pharmacy where stock preparations are made.
- There should be two prescription windows, one for men and other for women.
- The pharmacy receives its supplies from medical stores for at least a week and emergency supplies at any time.
- In some hospitals, outpatient department and pharmacy are separated geographically.
- In such a situation, it is necessary to have an autonomous outpatient pharmacy.
- Combined services of inpatients–outpatients are better to control for chief pharmacist.
- The outpatient department should be located in such a way that, it should not cause disturbance to the inpatients.

Layout of OPD

- Layout of OPD creates an image of the hospital.
- It shows the quality of service provided by hospital.
- In the layout there should be adequate number of windows for receiving and filling up prescriptions.
- Layout should be such that patient traffic can be easily controlled.
- Waiting time of outpatients should be reduced.
- Waiting rooms should be pleasantly furnished with sufficient reading material and educative posters hanged on the walls form an integral part of the OPD.
- To avoid overcrowding, more windows and manpower should be provided.

Typical Layout of Outpatient Dispensing Department

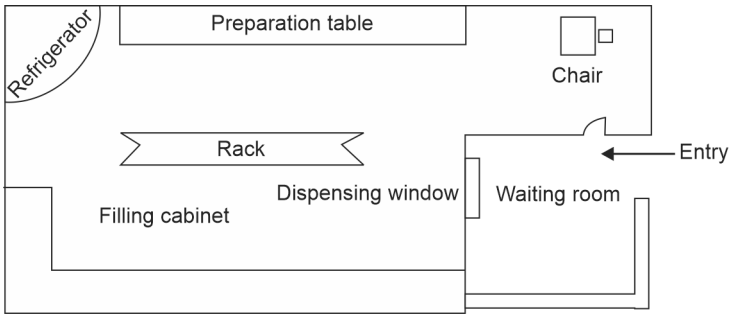


Fig. 4.1: Layout of OPD

Q3. Enlist different methods of drug distribution system/dispensing to inpatients in hospitals.

1. Individual prescription order system.
2. Floor stock/ward stock system
   i. Charge floor stock system.
   ii. Non-charge floor stock system (drug basket method and mobile dispensing unit.)
3. Combined individual prescription order system and floor stock system.
4. Unit dose dispensing system (UDDS)
   i. Centralized unit dose dispensing system (CUDDS)
   ii. Decentralized unit dose dispensing system (DCUDDS)
5. Satellite pharmacy
6. Bedside pharmacy.

Q4. Describe individual prescription order system/individual prescription medication for patient as distribution system in hospitals.

Individual Prescription Order System

- Small and private hospitals adapt this system.
- According to this system prescription is received by pharmacist and medicines are dispensed for inpatients.
- The collection of prescription is also done by pharmacist.
- Here the drugs are dispensed and labeled for each individual patient.
- Here medications are kept in nursing unit medication cabinet under the custody of nurse in-charge.

- Nurse is responsible for administering correct medications to each patient in ward.
- The nurses are advised by the pharmacist about proper storage, labeling and accounting of drugs and unwanted effect produced by drug, etc.
- For faster dispensing, commonly used drugs can be prepackaged.

Advantages

i. Review of prescription is possible by the pharmacist.
ii. Pharmacist can counsel the patient.
iii. Control over inventory is easy.
iv. Purchasing cost, maintenance cost, space required are less in comparison with other systems.
v. Maintenance of record is easy and paperwork is minimized.
vi. Adjustment of cost of prescription is possible by considering economical condition of the patient.

Disadvantages

i. Emergency medicines are not quickly supplied.
ii. Delay in receiving medicines.

Q5. Write a note on floor stock/ward stock system.

Floor Stock System

"It is the system where drugs are stored at each floor or near to the ward at nursing stations."

- The importance of a floor stock system is to avoid the time required to get a necessary medication from the pharmacy to nurses for administration to the patients.
- It is the responsibility of hospital pharmacist to work in co-operation with nursing service to provide an adequate supply of medicines and supervise over the proper charges made to the patient's account or not.
- Under this system the nursing station carries both charge and non-charge patient medications.

Types of Floor Stock System

PTC decides types of floor stock medicines as:

a. **Charge floor stock:** If charge floor stock medicines are given to the patient, cost of those medicines is directly added to the patient's

account, e.g. includes cost medicines such as penicillin, streptomycin, quinidine, diuretics, tranquillizers, etc.

- PTC decides charge floor stock drugs and its requirement.
- The selected list of charge floor stock is constantly being reviewed by the PTC for necessary revision.

b. Non-charge floor stock: These medications are stocked on nursing stations at all times, but they are not directly charged to an account of patient. The cost of such medicines is adjusted in the room rent, e.g. saline solutions, dextrose solutions are non-charge drugs.

Non-charge floor stock is also known as free floor stock drugs. There are two methods used for dispensing of non-charge or free floor stock drugs.

i. Drug basket method.
ii. Mobile dispensing unit

i. Drug basket method:

- In this method nurse of night duty checks the drug inventory in the medicine cabinet, utility room and refrigerator.
- This check is done against the master check list given by the pharmacy.
- Nurse ticks the quantity required for each drug on the requisition for supply.
- Empty containers along with requisition are placed in basket and it is sent to the pharmacy. In the morning just after opening the pharmacy, pharmacist fills up empty containers and keeps in the basket.
- These are then sent to the nursing station.
- Nurse administers drug to the inpatient and keeps the record of administered drug.

ii. Mobile dispensing unit:

- In this method, a trolley with castor wheels is used to carry the drugs to the wards.
- Here, nurse of night duty is relieved of checking the inventory and transporting the empty containers.
- Pharmacist or his assistant checks the nursing station for drug inventory.
- Pharmacist restocks the ward with necessary drugs and leaves requisitions carbon copy at the ward as a proof of delivery.
- Original requisition is sent back to the pharmacy for replenishment of mobile dispensing unit.

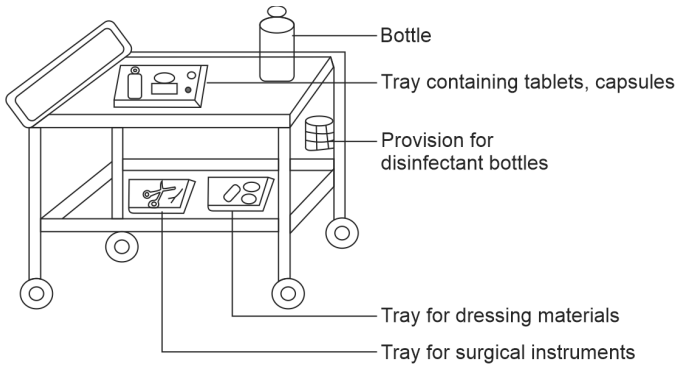


Fig. 4.2: Mobile dispensing unit

Selection of Non-charge, Floor Stock System

Criteria

i. Cost of the product.
ii. Frequency of use.
iii. Quantity of use.
iv. Effect on hospital budget.
v. Type of product.

Advantages of Floor Stock System

i. Waiting period is less. Medicines can be received immediately.
ii. Emergency medicines are easily available for quick distribution.
iii. Number of pharmacists required for dispensing are reduced.
iv. It avoids exercise of patient's relatives to bring the medications.

Disadvantages of Floor Stock System

i. Review of prescription by pharmacist is not possible.
ii. Inventory is increased, therefore, budget of hospital is increased.
iii. Counselling of patient by pharmacist is not possible.
iv. Paperwork is increased.
v. More space is required at nursing station for stocking medicines.
vi. Maintenance cost and wastage of medicines is increased.
vii. Medication errors are not minimized.
viii. It increases workload of nurses.

Applications

i. Useful in large hospitals.
ii. Helps to check the efficacy of nursing unit.
iii. It provides emergency supply of medicines to the patient.

Q6. Write a note on 'unit dose dispensing system' (UDDS).

Definition

It is the system which consists of dispensing unit doses to the patients containing a predetermined amount of drug.

- These unit doses are either stored or distributed from main pharmacy department only.
- The solid ingredients are repacked and liquids are remeasured.
- Unit doses are prepared as per the requirement.
- It is useful to inpatients and also to outpatients.

Types of Unit Dose Dispensing System

a. **Centralized unit dose dispensing system (CUDDS):** If the unit doses are dispensed from pharmacy department, it is called centralized unit dose dispensing system.
b. **Decentralized unit dose dispensing system (DCUDDS):** If the unit doses are dispensed from nursing stations, it is called decentralized unit dose dispensing system.

Advantages of Unit Dose Dispensing System

i. Avoids misuse of medication.
ii. Review of prescription is possible, therefore, medication errors are reduced.
iii. Time required for dispensing is reduced.
iv. Patient should pay the cost of medicines which are consumed by him.
v. Purchasing cost and budget of hospital is decreased.
vi. Accounting becomes easier.
vii. Paperwork is less at nursing unit as well as at the pharmacy.
viii. Better financial control.

Disadvantages of Unit Dose Dispensing System

i. Separate manpower is required for prepackaging.
ii. Separate containers, closures, machinery and also space is required.
iii. Unit dispensing should be handled by skilled person and supervised by pharmacist only.

Benefits of UDDS

i. The patients are charged only for those medications which are consumed by them.

ii. It reduces the medication error since the pharmacist checks a copy of physician's original order.
iii. It avoids wastage of drug.
iv. Less space is required as compared to bulky floor stock.
v. It allows the nurses more time for direct patient care.
vi. Patient receives the nursing service 24 hours a day.
vii. It avoids the duplication of orders and extra paperwork.
viii. It increases more efficient utilization of personnel.

Q7. What is satellite pharmacy?

OR

Write a note on satellite pharmacy.

Definition

The main pharmacy centre is called satellite pharmacy and subpharmacy centers are located at each floor and working as substations for satellite.

Satellite pharmacy service is developed with an advanced view of clinical pharmacy programs. These subpharmacies are located on wards. They receive their supply from main pharmacy and distribute them to the patients on current basis.

These pharmacies are managed by clinical pharmacist who is available in his professional capacity for patient counselling.

Advantages

i. Review of prescription is possible by pharmacist.
ii. Waiting period is decreased.
iii. Emergency medicines are quickly available for administration.
iv. Drug therapy can be monitored by pharmacist.
v. Pharmacist may counsel the patient.

Disadvantages

i. Inventory is increased, therefore, budget is increased.
ii. Paperwork, maintenance cost are increased.
iii. Separate space is required for keeping the stock.
iv. Number of pharmacists required for dispensing are more.

Q8. Explain in detail bedside pharmacy.

Definition

It is the drug distribution system in hospital in which drugs are kept near the bed of the patient so the patient can utilize the drug himself.

- It provides more patient-oriented service.
- An active participation of pharmacist in day-to-day management of patients at ward level is expected in this system.
- A bedside pharmacist offers advice regarding the action and uses of frequently used drugs to the medical or nursing staff.
- He also gives his own expert evaluation of the prescribed drugs.
- During his ward visit, he can take the feedback from the patient.
- He takes upon the additional responsibility of drug usage and drug information for which he is trained.
- He directs his efforts to safe and efficient use of drugs.
- He corrects the deficiencies in the use of drugs both by patient and prescribers.
- He monitors the drug use by conducting the pharmacokinetic studies.
- A bedside pharmacy is essentially a drug therapy advisor.

Advantages of Bedside Pharmacy

i. Professional skill of pharmacist is utilized.
ii. Review of prescription, counselling to patient is possible.
iii. Control over drug inventory and utilization is easy and done by pharmacist only.
iv. Professional skill about the pharmacokinetic studies about the drug interactions, ADR, etc. is used by pharrnacist to avoid the medication errors in prescription and simultaneous safe and better use of drug is possible.
v. Bedside pharmacy system helps to check patient compliance or to improve patient compliance.

Disadvantages

i. Number of pharmacists required are more in comparison with other systems.
ii. Chances of over utilization/misuse of drug by patient.

Q9. Discuss the method of distribution of drugs to ICCU/ICU/NICU/ emergency wards.

Distribution of Drug to ICCU/ICU/NICU/Emergency Ward

In hospitals, specialized units are dedicated for the patients who have life-threatening illness or injuries and need intensive care constant supervision.

The following are the specialized units:

1. ICU (Intensive Care Unit)
2. ICCU (Intensive Coronary Care Unit)
3. NICU (Neonatal/Newborn Intensive Care Unit)
4. Emergency ward

1. ICU:

- It is a special department for critical patients who needs intensive treatment and continuous observation.
- It is also known as critical care unit.

2. ICCU:

- It is also known an intensive cardiac care unit.
- It is a unit which is focused on intensive treatment for heart issues such as coronary heart disease, cardiac arrhythmia, heart attack, heart failure and other cardiac conditions.

3. NICU:

- It is also known as intensive care nursery (ICN):
- It is an intensive care unit specializing in the care of ill or premature newborn infants.

4. Emergency wards

- These are also known as accident and emergency department, casualty department.
- It provides a medical treatment facility specializing in emergency medicine, the acute care of patients who present without prior appointment, either by their own means or by that of an ambulance.

Distribution of Drugs

1. Patient receives prescriptions in the ward while receiving treatment in the specialized ward.
2. Specialized drug dispensing system is developed to emergency patients in which uses a special cabinet having medication bins that store selected and limited quantities of medications package in single unit containers.
3. Intravenous solution, irrigation solution, eye tray medications, drugs for cardiopulmonary resuscitation and refrigerated drugs are kept in areas of ready access.
4. The system provides for punched cards containing information on the drug.
5. These cards are stored with medication and are used for billing and reordering purposes.
6. A 24 hours supply of medications is required for these specialized units.

Common drugs used in the specialized units are

1. **In ICCU:** For example, aspirin, promethazine, heparin, hydrocortisone, streptokinase, metoprolol, pentazocin, frusemide.
2. **In ICU:** For example, epinephrine, atropine, sotalol, lidocaine, adenosine, procainamide, vasopressin.
3. **In NICU:** For example, gentamicin, ampicillin, caffeine citrate, frusemide, dopamine, azithromycin, ibuprofen, fluconazole.
4. **In emergency ward:** For example, adrenaline, salbutamol, atropine, aspirin, frusemide, hydrocortisone, insulin, lidocaine and medical oxygen.

Q10. What do you mean by automated drug dispensing system?

Automated Drug Dispensing System

- It means a robotic, mechanical or computerized device that is designed to distribute the medications in a licensed healthcare facility or packages medications for final distribution by a pharmacist.
- The automated drug dispensing system allows hospitals to store and dispense the drugs near to the point of use.
- Automated dispensing manages dosing and inventory to make dispensing efficient, safe and cost-effective to help patients to manage treatment plans.
- The system saves time of nurses and pharmacists and eliminates the possibility of incorrectly reading doctor's handwritten orders.

Types of Pharmacy Automated Systems

1. Automated dispensing cabinet
2. Robotic drug dispensing
3. Digital displays
4. PMR systems
5. Prescription recording
6. Electronic CD registers.
7. Prescription collection point
8. Pharmacy management systems

1. Automated Dispensing Cabinet

- It is a computerized drug storage device or cabinet designed for hospitals.
- It provides proper storage, inventory control and security for pharmaceuticals at the point of care.

- It can be used by authorized users who are authenticated by password.
- It is placed in wards, ICU rather than in central pharmacy.

Advantages

a. The commonly needed pharmaceuticals are available at the point of care, that will reduce the workload of nurses.
b. Controlled substances remain in secure lock box until needed and access is secured by multifactor authentication.
c. It can improve patient safety by providing drug allergy alerts, drug–drug interaction and advice on high risk medication.

2. Robotic Drug Dispensing

- Robot can store up to 35000 medicines and dispense around 12 prescriptions in less than a minute.
- So, the patients waiting time is significantly reduced.
- The dispensing process will be paper free as the robot will store the prescription as soon as a doctor documents it electronically.
- This also allows the pharmacist to focus on giving the customers right instructions on taking the medication.

Q11. What is remote dispensing? Give its advantages and disadvantages of remote dispensing of drugs.

Remote Dispensing of Drugs

- It is an automated system of dispensing of prescription medications, without an onsite pharmacist.
- It is useful especially for long-term care facilities.
- Through video-interface pharmacist is connected to patient to provide patient counselling.
- The patient medication orders are submitted online to central pharmacy, the pharmacist reviews the order and upon his approval, the medications are dispensed from the unit at remote care facility.
- The medications come out of dispensing machine printed with patient's name, medication name and other relevant information.

Advantages

1. 24 hours access to dispensing services that too at remote locations.
2. Service provides focused, uninterrupted and personalized time with pharmacist.
3. Tailored to dispensing habits of prescribers in a locality, certain machines can carry over 2000 different medications.

4. The technology facilitates patient continuity of care between prescriber and pharmacist.

Disadvantages

1. Remote dispensing creates physical barrier between patient and pharmacist limiting pharmacists ability to detect patient's non-verbal cues during counselling.
2. In case of patients taking controlled substances the lack of physical contact with patient, the risk of dangerous interactions cannot be avoided.
3. In case of failure of telecommunication services, the system is ineffective.
4. Variety of drugs offered through remote dispensing is limited in comparison to traditional pharmacies.

Q12. Write a note on "storage and distribution of narcotic and psychotropic substances".

Storage and Distribution of Narcotics and Psychotropic Substances

- Narcotic and psychotropic substances are defined as, "substances, products or preparations including certain medicines, that are either known to be have the potential to be dangerous or harmful to human health, including being liable to misuse or cause social harm.
- These substances are listed under the following schedules.

  Schedule 1: The drugs under this schedule have high potential for abuse and have no accepted medical use in the treatment, e.g. marijuana, raw opium.

  Schedule 2: The drugs under this schedule have high potentials for abuse but accepted for medical uses, e.g. Cocaine, morphine.

  Schedule 3: The drugs under these schedules have less as compared to above potential for abuse, accepted for medical treatment and have less physical dependence and psychological dependence, e.g. benzodiazepines, painkillers, phenobarbitone.

Storage of NDPS

- These drugs should be kept under lock and key.
- A separate register should be maintained to register the names of narcotics.
- Narcotics and psychotropic substances must be stored in a separate cupboard with double lock and key.

- The key of the locks should be kept in hand of two different people.
- Narcotic drugs and psychotropic substances must be procured and stored in such a manner so as to prevent their falling into the hands of unauthorized persons.
- The storage area for the narcotics and psychotropic substances may be opened and accessed by specific pharmacist in-charge and specific nursing in-charge of respective department.
- Narcotic and psychotropic drugs should bear the sign NRx in red on them and same are purchased from vendor having either schedule X or NDPS license.
- The record of sale/purchase of these medicines are audited regularly and same are maintained for minimum three years.

Dispensing of NDPS

1. A separate register should be maintained to record dispensing and a controlled procedure is used to issue or receive NDPS drugs.
2. Following persons are involved in dispensing,
   Medical superintendent is overall responsible for the proper safe-guarding and handling of narcotics and psychotropic substances.
   Chief pharmacist responsible for the purchase, storage, accountability and appropriate dispensing of the narcotics and psychotropic substances within the hospital.
   Head nurse: Responsible for the record of proper storage.
3. Prescription order of the narcotics and psychotropic substances should be made by using ink or indelible pencil, typing and duly sign by the respective doctor.
4. Prescription for narcotic and psychotropic substances must include the following information, patient's full name, address, date, name and strength of the drug, quantity of drug, signature of prescriber, dose and route of administration.
5. If the required drug is not in stock in the ward, the complete controlled drug prescription must be written on a hospital prescription blank form by registered medical practitioner and then it is signed and sent to the hospital pharmacy.
6. The complete form along with the empty containers and nurses inventory sheet is sent to the pharmacy for dispensing. The prescription signed by registered medical practitioner will also permit the patient to purchase drug from outside pharmacy.
7. The delivery of narcotic drugs from the pharmacy to the wards and nursing stations must be carried out through some reliable persons.

8. Charges for narcotic and psychotropic substances depend upon the policy of hospital. It could be like the charges may be made for individual dose received or flat charges for all narcotics and hypnotics.
9. After the dispensing of narcotics by the pharmacy, nurse in-charge must prepare special form in duplicate entries to cover incidence of every dose of narcotics and psychotropic substances given/ administered to patient or drug is lost or wasted in ward. Such accountability of control substances needs to furnish to pharmacy department while request for new supply of drugs. Original is filled in pharmacy and duplicate copy is kept for record to nursing office.
10. While administering a dose, if patient refuses or doctor cancels any dose, it is the responsibility of the nurse to destroy the drug into sink and record "Refused by patient" or "order cancelled by doctor". Nurses should always preserve a proper record in case of destruction/wastage/contamination.
11. Pharmacist needs to preserve the records of the receipt and return of narcotics and psychotropic substances for disposal. Documentation of the return of narcotics and psychotropic substances for demolition by the pharmacist from the respective ward of hospital is considered as good practice of record.

Q13. Give the differences between

a. Charge floor stock system and non-charge floor stock system.

b. Automated dispensing system and floor stock system.

c. Small volume parenterals and large volume parenterals.

a.

Charge floor stock system	Non-charge floor stock system
1. The charges are made in the patients account after they have been administered from the stock drugs.	1. The charges are not made in the account directly even after the drug have been administered.
2. Every dose of the drug administered to the patient is charged.	2. In this system the charges of the drug administered are already included in the room rent.
3. Only those doses are charged which are expensive, can rarely used	3. The cost of the drugs used are not so high as they are mostly used such as tablets capsule, etc.
4. Floor stock list is prepared which is sent to make the drugs available to all the nursing stations.	4. A pre-determined list is prepared by nursing stations
5. Examples of drugs: Penicillins, streptomycin, diuretics, tranquillizers	5. Examples of drugs: Saline solution, dextrose solution

b.

Automated dispensing system	Floor stock system
1. Automated dispensing system allow medications to be stored and dispensed near the point of care, while controlling and tracking drug distribution.	1. It is a system where drugs are stored at each floor or near to the ward at nursing stations
2. Its types are: i. Automated dispensing cabinet ii. Robotic drug dispensing iii. PMR systems	2. Its types are: i. Charge floor stock ii. Non-charge floor stock
3. Nurses spend less time doing related activities.	3. Nurses spend much time in collecting, storing, inventorying, checking and travel between pharmacy and patient care unit.
4. Pharmacists spend more time.	4. Pharmacists spend much less time
5. Rational utilization of both nursing and pharmacy services.	5. Optimal utilization of both nursing and pharmacy services is not possible
6. Equipment cost is high also development of interface software is costly.	6. No such expenditure on equipment and software but cost of drug storage is high.
7. Cost of expired drugs is greatly reduced.	7. Cost of expired drugs is high.
8. Reduction in number of missing medicines.	8. Missing medications number is high.

c.

Small volume parenterals (SVPs)	Large volume parenterals (LVPs)
1. They are injectables	1. They are generally infusions
2. Capacity is less than 100 ml	2. Capacity vary from 100 ml to 500 ml
3. SVPs are typically used for delivering medication at a controlled infusion rate.	3. LVPs provide electrolyte, supply of nutrients such as vitamins and glucose.
4. SVPs contain necessarily the medicament which is potent	4. LVPs contain one or more electrolytes
5. Administration with syringes and needles	5. Administration with IV set, etc.
6. Vehicle used is WFI, oils or PEGs	6. Only WFI is used as a vehicle

Contd.

Contd.

Small volume parenterals (SVPs)	Large volume parenterals (LVPs)
7. Containers used for packaging, glass ampoules and vials	7. Containers used generally for plastic bottles
8. Preservative is needed	8. Preservative is not needed
9. These are sometimes manufactured as multidose containers	9. These are manufactured as a single dose containers
10. For example, adrenaline injection, IP, BP	10. For example, normal saline solutions, IP, BP

Objective Questions with Answers in Bold Letters

1. The outpatients who are able to walk and receive primary healthcare are called **ambulatory patients**.
2. **Bed side pharmacy** is the drug distribution system where the drugs are kept near the bed or the patients.
3. **NDPS drugs** should be kept under lock and key.
4. The patients who come to the hospital with general symptoms like fever, cough and cold are known as **general outpatient**.
5. The NRx in red should bear on the label of **NDPS drugs**.
6. The sale/purchase records of NDPS drugs shall be maintained for minimum **3 years**.
7. The patients who require hospitalization are called **inpatients**.
8. CUDD stands for **centralized unit dose dispensing**.
9. DCUDD stands for **decentralized unit dose dispensing**.
10. ICU stands for **intensive care unit**.
11. ICCU stands for **intensive coronary care unit**.
12. NICU stands for **neonatal intensive care unit**.
13. UDDS stands for **unit drug dispensing system**.
14. OPD stands for **outpatient department**.
15. IPD stands for **inpatient department**.
16. ADS stands for **automated dispensing system**.
17. Idiosyncrasy is a **Type B ADRS**.
18. Drug basket method is used in **non-charge floor stock system**.
19. The number of pharmacists required for 100 bed capacity hospital are **05**.
20. **Ambulatory patients** mean those patients who are not admitted in the hospital or who are not confined to bed.

Chapter 5

Compounding in Hospitals

Q1. What is bulk Compounding? Give its benefits/advantages.

Bulk Compounding

- Compounding is the creation of a pharmaceutical preparation of a drug by a licensed pharmacist to meet the unique needs of an individual patients when a commercially available drug does not meet those needs.
- Bulk compound means the bulk drug or active pharmaceutical ingredient of client product in bulk form.
- Pharmacy compounding allows for alternative medication dosage forms.
- In addition to adding flavor to the medication taste is more pleasant, compounding pharmacists also have the capability to create medicines in the form of patient's choice.
- The bulk compounding formulations in hospital pharmacy include:
  i. Mixtures
  ii. Syrups
  iii. Solutions
  iv. Suspensions
  v. IV preparations, eye drops, injections, TPN
  vi. Ointments, creams, pastes, paints, lotions
  vii. Gargles.

Reasons for bulk compounding in hospital pharmacy are:

1. Drug shortage in hospital
2. Adjustment of dose requires in premature infants
3. Changes need in dosage form to make medication easier to ingest in children and elder patients.
4. Patient has an allergy and needs a medication to be made without certain dye.

5. Individual doses of drugs that hospitals use on regular basis such as IV preparations, eye drops, injections, IV admixture services, TPN.

Benefits/Advantages of Bulk Compounding

1. **Allowing access to discontinued medications:** When large manufacturer discontinues production of certain drugs, it is very difficult to get medications in time to the patients. In this case compounding pharmacists play an important role in providing access to discontinued medications by recreating required medication by compounding.
2. **Making medication easier to use:** As per patients convenience and improve compliance, the compounding pharmacist can add the suitable colour and flavor to the medication while compounding.
3. **Allowing alternative dosage forms:** Sometimes patients may need their medication in different dosage forms, e.g. liquid oral than the tablet. Compounding pharmacist may alter the dosage form to fulfil the patients need.
4. **Making medication allergy-friendly:** Some patients may show allergic, sensitivity, unwanted reactions to dyes, lactose, gluten or alcohol while taking a certain medication. A compounding pharmacist make a formula excluding allergic excipients, to get right treatment to the patient.
5. **Offering unique services than the pharmacy chains:** A compounding pharmacist can take information of the patient regarding allergy, choice and dosage by asking questions and compound the dosage form as per the patients need and satisfaction. Pharmacy chains will not have a direct contact of patient, so it will not give satisfactory results of the treatment.

Q2. What are intravenous admixtures? Explain incompatibility in intravenous admixtures?

Intravenous Admixtures

- Intravenous admixtures are the preparations consist of one or more sterile drug products added to IV fluids—generally dextrose or sodium solution or Ringer solution alone or in combination.
- IV admixtures are used for drugs intended for continuous infusion and for drugs that may cause irritation or toxicity when given via IV injection.
- IV fluids commonly used for IV admixtures are
  1. Dextrose–2.5% to 50%

2. Dextrose and sodium chloride: Dextrose 5 to 20% with sodium chloride 0.11% to 0.9%.
3. Lactated Ringer solution
4. Sodium chloride solultion—0.45%, 0.9%, 2%, 5%

- **Uses of IV fluids**
  1. Correction of disturbances in electrolyte balance
  2. Correction of disturbances in body fluids.
  3. Providing basic nutrition.
  4. Providing total parenteral nutrition.
  5. As a vehicle for other drug substance.

Intravenous Admixtures Incompatibilities

- IV admixture incompatibility is the simultaneous administration of two or more drugs that interfere with therapeutic efficacy of the medications and patient safety.

Two types of incompatibilities related with intravenous administration are:

1. Physical incompatibility:

- It occurs when a drug mixture produces and observable modification in the appearance of a solution.
- It is observed easily by alteration in the appearance of admixture such as the evolution of gas, precipitate formation, or change in colour.

2. Chemical incompatibility

- It occurs when the chemical degradation of the admixed drugs, which show toxicity.
- Chemical degradation of drugs in chemical incompatibility appears as change in colour, precipitation and turbidity.

Effects/consequences of incompatibilities in IV admixtures

1. Damage from toxic products, e.g. multiorgan failure, thrombosis, local redness.
2. Particulate emboli from crystallization and separation.
3. Tissue irritation due to major pH modifications.
4. Therapeutic failure
5. May extend time span and total cost of patient's hospitalization in hospital.

Role of Pharmacist in Intravenous Admixture Service

- Permanent supervision and involvement of clinical pharmacist is essential in IV admixture services.

- Pharmacist prepares protocol for IV admixture service and establish reporting error system.
- It provides expert advice on compatibility and stability for the use of multiple drugs if required for IV administration.
- It updates staff on new clinical practice guidelines and help to interpret guidelines as they apply to patients with advanced disease.
- It can prevent dangerous incompatibility through the available literature, databases, services and information material.
- Colour coding is given for preventing incompatibility and it also helps in clear indication of drug separation.
- Prepares individual labelling for each drug preparation.
- It always checks the alternative methods of administration and use multi-lumen catheters.
- Appropriate use of inline filters can reduce the influx of particles that result from incompatibilities.

Q3. Write a note on "total parenteral nutrition" (TPN).

Total parenteral Nutrition (TPN)

Definition

- Total parenteral nutrition (TPN) is intravenous administration of nutrients in adequate quantities to achieve tissue synthesis and anabolism.
- TPN is also known as intravenous or IV nutrition feeding.
- TPN is a method of getting nutrition into the body through the veins.
- TPN is also known as hyperlimentation.
- TPN provides nutrients for patients who do not have a functioning of GI tract or who have disorders requiring complete bowel rest.
- When nutrition mix containing glucose, salt, amino acids, lipids and vitamins is administered to a person, it is called total parenteral administration (TPN)
- TPN is beneficial because it provides nutrients that are vital in maintaining high energy, hydration and strength levels.

Need/Importance of TPN

1. To provide all or most calories and nutrients through solutions that contain a mixture of protein, carbohydrate, glucose, fat, vitamins and minerals to the body.
2. TPN can be administered in the hospital or at home for the patients with Crohn's disease, cancer, short bowel syndrome or ischemic bowel disease.

3. In critically ill patients who cannot receive nutrition orally, TPN is useful.
4. TPN is used with severe pancreatitis, paralytic ileus, diarrhoea.
5. TPN products are generally administered to avoid multiple injections of nutritional requirements of the patients by the intravenous route.
6. TPN is given to fulfil the nutritional requirements in pre-operative and post-operative conditions.

Ingredients/Contents of TPN

TPN is a mixture of separate components which contain carbohydrates, lipids (fat), amino acids, electrolytes, trace elements, vitamins and fluids. TPN composition can be adjusted as per requirement of individual patient.

1. **Carbohydrates:** Carbohydrates is the main source of energy. Dextrose and monohydrates of glucose used as primary source of carbohydrate in TPN. Carbohydrate source such as galactose, fructose and sorbitol should not be used as energy sources in TPN.
2. **Lipids (fat):** Linoleic acid is used as primary source of essential fatty acid in TPN. Linoleic acid is useful as precursors of prostaglandins and in the synthesis of other fatty acids which are essential for cell membrane integrity.
3. **Electrolytes:** Sodium (Na): 100 to 200 mEq, Potassium (K): 80 to 120 mEq, Magnesium (Mg): 8 to 16 mEq, Calcium (Ca): 5 to 10 mEq, Chloride (Cl): 100 to 200 mEq.
4. **Vitamins:** Vitamins are required for the metabolism of carbohydrates, proteins, fats. Water soluble (B1, B2, B3, B5, B6, B7, B9, B12 and C) and fat-soluble vitamins (A, D, E and K) used in TPN formulation.

Indications of TPN

TPN is indicated in the conditions such as:

- Inability to absorb nutrients via the gastrointestinal tract
- Patient who is not expected to eat sufficiently
- Moderate to severe pancreatitis when adequate enteral intake is not expected for 5 to 7 days
- Chronic intestinal obstruction as in intestinal cancer
- Organ failures—liver, renal, respiratory
- Malnourished oncology patients.
- When the patient is unable to sustain nutritional status due to severe diarrhoea or vomiting

- Malnourished patient before major surgery.
- Inflammatory bowel diseases such as: Surgery-related short bowel syndrome, ulcerative colitis, Crohn's disease, severe diarrhoea

Objective Questions with Answers in Bold Letters

1. TPN stands for **total parenteral nutrition**.
2. Total parenteral nutrition is also known as **intravenous** or **IV nutrition feeding**.
3. **Intravenous admixture** is a preparation of a pharmaceutical mixture of two or more drugs added into IV fluids alone or in combination for medication purposes.
4. **Hartmann's Ringer** is used for IV admixtures.
5. FFDCA stands for Federal Food Drug and Cosmetic Act.

Chapter 6

Radiopharmaceuticals

Q1. Define radiopharmaceuticals. Give the ideal characteristics of radiopharmaceuticals.

Radiopharmaceuticals are medicinal formulations containing radio-isotopes which are used in major clinical areas for diagnosis and treatment.

Ideal Characteristics of Radio Pharmaceuticals

1. It should have relatively short half-life
2. It should emit gamma particles
3. It should be able to localize on target site before being metabolized
4. The energy of radiopharmaceuticals should range from 30 to 300 kiloelectron volts (keV)
5. It should excrete from the body.
6. It should be easily available and should be expensive.

Q2. Write in brief about "storage of radiopharmaceuticals".

Storage of Radiopharmaceuticals

- Radiopharmaceuticals should be kept in well-closed containers and stored in an area assigned for the purpose.
- Storage conditions must fulfil radiation protection requirements and protect the product from deterioration.
- Radiation protection guidelines will specify the maximum permissible dose rate and may give special requirements such as fire precautions and safety against theft.
- The storage area must be a dry, clean place.
- Storage at 2° to 5°C will often be required.
- All labellings of pharmaceuticals should clearly show the expiry date.
- The storage condition should be such that the maximum radiation dose rate to which person may be exposed is reduced to an acceptable level.

- Necessary care should be taken to comply with national regulation for protection against ionizing radiations.
- Radiopharmaceuticals preparation intended for parenteral use should be kept in a glass vial, ampoule or syringe that is sufficiently transparent to permit the visual inspection of the contents. Glass containers may get darkened under the effect of radiation.
- The period for use of each radiopharmaceuticals is normally fixed with regard to radiochemical purity, radionuclide purity or similar parameters.

Q3. How are radiopharmaceuticals dispensed?

OR

Explain process of dispensing radiopharmaceuticals.

Dispensing of Radiopharmaceuticals

- The dispensing area should be separate, dedicated and secure area.
- The dispensing room should be closed to the imaging and injection areas.
- The operational area should be in a good condition and hygiene must be ensured.
- All work surfaces should be smooth and impermeable and should permit easily cleaning and decontamination.
- Dispensing should be safe, straightforward and reliable.
- Radiopharmaceutical dispensing has been the production of ready to use kits or cold kits which provide individual or multiple doses and can be reconstituted by the addition of radionuclide at the time of intended use.
- Chemical reagents are prepared in a sterile environment using pyrogen free raw materials and dispensed into single or multiple unit dose containers. The preparation of individual doses can be carried out rapidly and safely when required with minimum manipulation.
- The cold kit preparation should be subjected to terminal sterilization preferably by autoclaving or if not by membrane filtration.
- Radiopharmaceuticals are never dispensed directly to patients, they are provided to trained healthcare professionals at the hospital or clinics and then administered to the patients.
- Recommended dosage level is calculated on the basis of patient history, age, weight, surface area and other factors.
- Dispensing of prescription is done as per applicable pharmacy law and appropriate records are maintained.

- Policies and procedures are developed in a way that the correct drug in correct dosage and dosage form is received by the correct patient at the correct time via the correct route of administration.
- Good radiation practices (GRP) should be strictly followed for operations with unrelated sources to reduce the unwanted and avoidable radiation exposure.

Q4. How the radiopharmaceuticals are disposed of?

OR

What are different methods of disposal of radiopharmaceuticals?

Disposal of Radiopharmaceuticals

- The radiopharmaceuticals which are of no more use must be disposed to avoid any hazard to environment.
- The disposal has to be taken local regulations for both contamination sources into account. It is useful to segregate short half-life waste from long half-life radionuclides.
- The practices that produce large volume of radioactive waste must be avoided.
- The radioactive waste generated in radiopharmacy laboratory includes syringes, elusion vials, pharmaceutical vials, needles and swabs. All such waste should be primarily stored into waste bin built into the contained workstation.
- Other items such as gloves, paper waste may be deposited in shielded waste bin in the pharmacy. The waste bins should be closed marked as radioactive, dated and removed to radioactive waste store. Once the waste radioactivity decayed to background level, it should be disposed of, for which the hospital waste disposal policy should be followed.

Methods of Disposal

1. Dilute and disperse
2. Delay and decay
3. Concentrate and buried
4. Dump to sanitary sewer
5. Incineration
6. Shift to disposal site
7. Dispose of as if not radioactive
8. Waste disposal tag

1. **Dilute and disperse:** The low activity solid articles may be disposed of as ordinary hospital waste provided the activity of the articles does not exceed 1.35 μCi. Such articles include vials, syringes, cotton swabs. Similarly, liquid radioactive waste with activity less than microcurie level can be disposed of into the sanitary sewerage system with adequate flushing with water following the disposal.
2. **Delay and decay:** The radioactive waste should be stored for a minimum period of about 10 half lives when after decay only 0.1% of the initial activity remains.

   The waste is then monitored for the residual activity and if the dose limit is low, it is disposed of as similar to solid or liquid waste. The radiation safety officer can hold waste with half-lives up to 100 days.
3. **Concentrate and buried:** Radioactive waste is collected in suitably designed and labelled containers and the buried in exclusive burial sites approved by the competent authority.
4. **Dump to sanitary sewer:** Water soluble radioactive materials should be checked by radiation safety officer and with his permission it is dumped into sanitary sewers.
5. **Incineration:** Insoluble liquid waste such as that from the liquid scintillation systems may be disposed of by incineration.
6. **Shift to disposal site:** Sealed gauges, detectors or counters, and check sources are sent to approved disposal site for disposal.
7. **Dispose of as if not radioactive:** Scintillation cocktail containing not more than 0.05 μCi per ml of H-3 or C-14 be discarded as if it is not radioactive.

Q5. What precautions are to be taken while handling and storage of radiopharmaceuticals/radioactive materials?

Handling of Radiopharmaceuticals

- Radioactive substances should never be touched with hand but handled with forceps.
- Activities like smoking, drinking, eating should be avoided in the area where radioactive substances are kept.
- Sufficient protective clothing should be used during handling of radioactive substances.
- Area where the radioactive materials are kept should be tested regularly for the presence of fluorescence.
- There should be proper disposal of radioactive materials.
- Radioactive materials may be kept in a suitable, labelled container.

- They should be kept in remote area.
- All surfaces of the containers should be smooth, nonporous, non-wetting, and heat resistant.
- Fluorescence should be removable.
- The wall finishes should be hard and smooth and should not easily get contaminated.
- The amount of wood material should be minimum.
- The benches, cupboards should be made up of plastics.
- There should be minimum movement of workers.
- Workers should wear protective clothes while entering the area where radioactive materials are stored.

Objective Questions with Answers in Bold Letters

1. **GM counter** is used for the measurement of radioactivity.
2. Radiopharmaceuticals should have a **short half-life**.
3. GRP stands for **good radiation practices**.
4. Sodium rose Bengal (I-131) is used in **liver scanning**.
5. Radiopharmaceuticals should emit **gamma particles/rays**.
6. Xenon-133 gas (Xe-133) is used for **pulmonary scanning**.
7. The compounds or substances which exhibit radioactivity and which are used in medicine for various purposes are called as **radiopharmaceuticals**.
8. The hospital radioactive waste is mostly composed of **low level waste**.
9. **Incineration** reduces the bulk of waste.
10. Radiopharmaceuticals should be stored at about **2°C to 5°C** temperature.

Chapter 7

Applications of Computers in Hospital Pharmacy Practice

Q1. Define computer. Give merits and demerits of computer. Explain its role in hospital pharmacy.

Computer

"It is the electric device performing the several complex and complicated functions and can store the information."

Advantages/Merits

1. High speed
2. Storage capacity—softwares, floppy disc, hard disc
3. Easy retrieval of data
4. Accurate results
5. Can perform complicated, several arithmetical and logical functions
6. Time saving
7. Space saving
8. Economic
9. Can work for 24 hours.

Disadvantages/Demerits

1. Cannot correct itself.
2. Lack of common sense.
3. Depends upon human instructions.
4. Electricity is required.
5. Skilled person is required for operation.

Role of Computers in Hospital Pharmacy

Computers are used more frequently for wide variety of work in hospital pharmacy.

1. In drugstore for billing, purchasing, stocking, ordering, etc.
2. In hospital pharmacy to record prescriptions.
3. In pathological laboratory.

4. In manufacturing section of hospital pharmacy.
5. In maintenance of patients' records.
6. In data storage and retrieval.
7. In inventory control.
8. In medication order entry.
9. In drug therapy monitoring.
10. In reporting ADRs.
11. In purchasing and accounting.
12. In billing of charge floor stock.

Q2. Describe in brief different parts/components of computer.

The basic components of computer are:
1. CPU (central processing unit)
2. Monitor
3. Keyboard.

i. CPU

It is the main component in which data is processed.

The capacity of hard disc depends upon total number of microprocessor units.

CPU consists of two types of memories:

1. RAM [Random assess memory]
2. ROM [Read only memory]

RAM is volatile, i.e. remains assist even if computer is off.

CPU has three drives and each drive has three connections.

a. To main switch.
b. To display unit.
c. To keyboard.

In CPU, the input is analyzed, evaluated and processed and the output can be displayed on monitor.

CPU has 2 drives for insertion of floppies called drive A and B. The separate drive for CD is available.

ii. Monitor

It is also called display unit or VDU. It has 3 buttons for brightness, contrast and on-off button.

It has two connections, i.e. to CPU and main switch. Display capacity is 25 rows and 50 columns.

Monitor may be coloured or black and white.

iii. Keyboard and Mouse

It is a commonly used input device. It is available in 2 types:

a. 84 keyboard
b. 101 keyboard.

It has alphabetical, functional, numerical and specific keys. 84 type keyboard has 10 functional keys while 101 type has 12 functional keys. Keyboard is connected to CPU only.

Mouse: Mouse is input device whenever required.

Q3. How are computers useful in record maintenance?

Records in hospital pharmacy can be conveniently grouped as:

1. Records related to patient.
2. Records related to drug.

1. **Records related to patient:** It includes:
   a. Personal information of the patient like:

Name:	Occupation:	Date of admission:
Age:	Address:	Date of transfer:
Sex:	Ward no:	Date of discharge:
	Bed no:	

   b. Drug allergies and habits and diseases, etc:

Allergies:	Non-prescribed drug:
Body disorders:	Addicted by:
Previous disorders:	

2. Records related to drugs prescribed to the patient on a daily basis

Date:	Route of administration:
Name of drug:	Frequency of drug administration:
Dose of drug:	Changes in dose of drug:

3. Records related to charges or bill to the patient for charge floor drugs.
4. Records related to ADRs if reported.
5. Inventory control record for drugs in hospital formulary.

Database is collection of information related with particular section in hospital. MEDLINE is loaded in computer, which is a medical literature database. It helps to mention medical records and also for taking the correct decisions about the diagnosis and treatment.

Data of physicians like name, qualification, address, phone no, are stored in computers so that emergency contact is possible. Prescriptions

can be recorded and stored in computers so that patient compliance, refilling frequency can be checked.

PAD, MEDIPHORS, MEDLARS packages related to drug information are available which are useful in hospital pharmacy department. For maintenance of records of employees computer is useful. The names, qualification, experience, payments, allowances and other information are also maintained.

Q4. Define drug inventory control. Explain the role of computers in inventory control.

Drug Inventory Control

"Drug inventory control is a balance between not ordering too much and avoiding out-of-stock situation."

There are two types of systems used in inventory control:

1. Periodic inventory control system
2. Perpetual system.

Role of Computers in Inventory Control and Purchasing

In inventory control, computer is useful to maintain the records of inventory, distribution or available stock. For preparing budget and for statistical analysis separate packages are available in market. By taking these packages inventory control can be performed.

Computers show minimum and maximum stock levels and also reorder levels so that requirements and purchase order can be prepared.

1. **Periodic inventory control system:** In this system one person is appointed to check the stock of items periodically so that no extra items are stocked and it avoids inventory.
2. **Perpetual system:** In this method day-to-day checking of stock and checking of store ledger is done which gives correct information regarding actual stock at hand. Thus, further purchasing procedure can be started.

The main use of computers in purchase and inventory control is:

i. To detect the items which have reached minimum order level. ·
ii. To prepare list of items to be purchased and their quantities.
iii. To prepare purchase order for vendors and avoids duplication of orders.
iv. To detect infrequently purchased items for possible return or elimination from pharmacy drug supply.

v. To produce periodic summary and purchasing and inventory control statistic.
vi. Inventory control of drugs manages current stocks, outgoing stocks, incoming stocks, order procedure, etc.

Q5. Explain the role of computers in medication monitoring or in monitoring of drugs in hospitalized patients.

Medication Monitoring

It means constant supervision by pharmacist on the administered drugs to the patients to observe the specific pharmacological action, drug interaction or adverse effects, if any.

For monitoring of drugs computers provide immediately statistical data of drugs and also show variations in pharmacological actions as the doses administered, e.g. in cardiac patients changes in pulses, heartbeats, etc.

i. Computers generate hourly 'fill lists' of drugs for patient and pharmacist prepares and dispenses unit dose for each patient along with proper label and sends this for administration of drugs to the patient.
ii. Prior to this, check is made for drug to drug interaction.
iii. Medication administered in ward to the patient is entered in computer as medicine administration record.
iv. Drug lab-test values are also recorded if required.

This cycle continues till the time patient is hospitalized. For monitoring drug therapy hand-held computer terminals can be used by clinical pharmacist on hospital floor or at the patient's bedside.

These terminals have sophisticated programs for predicting drug levels and required dosing parameter based on pharmacokinetic principles.

To maximize the therapeutic action of the drugs and avoiding any toxic effects, pharmacist starts taking help of some pharmacokinetic and non-pharmacokinetic parameters. This method of therapeutic drug monitoring is most important in geriatric and pediatric patients.

Thus in medication monitoring computer will have mainly two types of applications:

a. **Pharmacokinetic applications:** It includes statistical calculation and graphical interpretations. By using computer programs like NONLIN the pharmacokinetic parameters can be predicted very easily. Depending on these parameters dose of drug administration can be adjusted.

b. Non-pharmacokinetic applications: It includes drug–drug, drug–laboratory, drug–allergy, drug–disease interaction detection.

Q6. Explain how computers are useful in data storage and retrieval.

- Various softwares like MEDLAR, AMA, FOOD ID, MEDIPHOR, PAD, etc. are available in the market.
- These softwares contain the information about drugs, their description, uses, doses, side effects, dosage forms, etc.
- Packages like MEDIPHOR means monitoring and evaluation of drug interaction by pharmacy oriented reporting system which contains information about drug interaction.
- Other package like AMA means American Medical Association and contains description and diagnostic symptoms for more than 3500 diseases and information of special cases.
- These packages provide the information, therefore, whenever required this information can be retrieved and therefore, further useful for research work and record keeping.
- Whenever required the information about the physiological parameters, properties of drug, pharmacological actions is used to develop new drugs or its dosage form. For this QUAR package is useful.
- In computer the data of patients such as name, age, sex, address, patient history, case papers, report of analysis, diagnosis papers, drug therapy given can be stored. Therefore, record keeping is easier.
- Due to retrieval facility the information is used to study refilling frequency, patient compliance, to make drug history and to send reminder to the patient.

Q7. Explain the role of computers in pathology laboratory.

The packages like LNS, KINPAK, NONLIN, SUMEX are loaded on computers, therefore, analysis reports can be obtained quickly with probable diagnosis.

Simultaneously reports are stored in computers, therefore, documentation will be easier.

The paperwork is also minimized.

Whenever required, information can be stored and retrieved.

Q8. Explain the role of computers in drugstore.

Computers have several advantages like more speed, great accuracy, and more working power, negligible mistakes, storage of information, etc. Therefore, they are used in drugstore for:

1. Maintenance of records
2. Preparing purchase list
3. Preparing purchase order
4. For budget adjustment
5. Preparation of receipt
6. Storage of prescriptions
7. To prepare a list of expired drugs
8. To control overstocking and understocking of drugs
9. To get information of different manufacturers, their products, brand names and prices, etc.
10. It helps to prepare comparative statement of quotations from different suppliers/manufacturers.

Q9. Explain the applications of computers in hospitals.

In hospitals a number of departments are present. As per requirements the computers can be used for getting several types of applications. In hospitals computers have a wide scope in the following departments.

1. Drug information centre
2. Pharmacy department
3. Manufacturing section
4. Clinical pharmacy department
5. Consulting section
6. Registration counter
7. Billing and accounting section.

In all these departments computers help to store so much information and avoids paperwork.

It also helps in diagnosis of various disorders, medication, monitoring, etc.

It helps in charging of the prescription for charge floor stock.

For DIC it is very important to collect, edit the information for registration of the patient it helps and to take basic information of the patient and store it in a particular file.

Q10. What do you mean by electronic health records (EHRs). Give its benefits/advantages/importance and disadvantages.

Electronic Health Records (EHRs)

Definition

- Electronic health records are computer-based applications used to convert all the information found in paper-based medical records to a computer-based system.

- EHR systems are basically designed to collect, store, manage and display healthcare related records entered by healthcare provider.
- An electronic health records (EHR) are a real time, patient centered records that make information available instantly and securely to authorized users.
- EHR contains a patient's medical history, diagnosis, medications, treatment plans, immunization dates, allergies, radiology images and laboratory test results.
- The computerized records have been broadly used by clinicians, paramedical staff, patients and health insurance companies for the purpose of generating, managing and retrieving the health information of patients everywhere.

Benefits/Advantages/Importance of Electronic Health Records

1. EHR provides a summary of the various healthcare events in the life of a person.
2. It collects all information from patient records which helps to provide evidence-based treatment.
3. Patient information can be accessed from any place.
4. Data can be easily captured or transferred from one device to the other.
5. Errors can be reduced with EHR systems as all the information are immediately legible, which further reduces the potential risk of miscommunication between system users.
6. EHR systems can be connected directly to medical devices which triggers alert upon a significant change in a patient health.
7. The EHR systems maintain patients information in more secured manner compared to paper-based systems.
8. EHR increases accuracy and faster diagnosis that determines the most suitable medications for diseases, and monitoring the patient's health in the future.
9. It helps to avoid repeating unnecessary investigations.
10. EHRs useful for tracking and monitoring disease.
11. EHR helps in selecting the most efficient paths of treatments.
12. It provides effective, safe and efficient healthcare services, and decreases cost of healthcare.

Disadvantages of EHR

1. Lack of ability of exchange and use data when many systems are involved.
2. EHR systems are expensive to purchase, implementation and maintenance.

3. Healthcare providers may not have any direct benefit from their investment on EHR system.

Q11. Give the advantages/benefits of pharmacy operation softwares.

Advantages/Benefits of Pharmacy Operation Softwares

1. **Electronic health record (EHR) software:** EHR programming is one of the most popular types of software used by hospitals and clinics. EHR software collects data on patients. For example, ClinicalWorks, Allscripts, Nextgenclinic.
2. **Medical billing software:** This software supports hospital accounting departments in maintaining track of patient bills, payments and also in other financial functions. For example: Epic Care.
3. **Hospital management software:** Hospital management software helps hospital administration in day-to-day functions. These types of programs usually help with the automation of accounting, medical billing, claims, outpatient management, inventory, bed management, and others. Hospital management software often combines with EHR software to help at the same time and maintain track of patient records. For example, Availity.
4. **Medical equipment management software:** The purpose of this type of software is to relieve hospitals from manual stock taking and equipment maintenance. Medical equipment management software supports the smooth functioning of hospitals with features like automatic maintenance of inventory alerts and scheduling of medical equipment. For example, Sortly.
5. **Medical research software:** Medical research software is used for the purposes of education and sharing research with the healthcare community. This type of software is generally used to train medical personnel and to help diagnose if no similar clinical cases among the patients. For example, PubMed.gov
6. **E-prescribing software:** Most of the countries around the world are shifted to electronic prescriptions, which also suggests e-prescribing software is becoming essential for doctors. The software allows medical professionals to track, renew, and cancel prescriptions for their patients. It is also merged with national drug reference databases. For example, MediTab, ScriptSure.
7. **Telemedicine software:** Telemedicine software permits healthcare professionals to carry out appointments with patients online using web browser or a mobile application. In some software, the video conferencing feature is provided with e-prescriptions and a billing module.

8. **Therapeutic drug monitoring:** TDM programs are proposed to calculate drug dosage to suit individual patient's need. For example, WinNONLIN, USC*Pack.
9. **Personal health record software (medical diaries):** It helps for maintaining healthy lifestyle and monitoring diseases. It performs as medical diaries and can be either held on the patient's device or merged with the hospital's software. For example, Tulipa app software created for patients suffering from Parkinson's disease. In the app, the patients record any symptoms, medication, or treatment, and can generate a health report before their next doctor's visit. This type of software can assist the patient in the direction of recovery or aware medical staff on the worsening disease of a patient immediately the first symptoms occur.

Q12. Mention the applications of computer in hospital pharmacy practice.

Applications of computers in hospital pharmacy practice

1. Maintaining patient records
2. Maintaining drug records
3. Purchase and inventory control record:
   - To detect the things which have reached minimum order level.
   - To prepare the list of items to be purchased and their quantities.
   - To prepare purchase orders for supplier and avoid duplicate order.
   - To detect infrequently used purchased items for possible return or elimination from the pharmacy's drug supply.
   - To produce periodic summary of purchasing and inventory control statistics.
4. Therapeutic drug monitoring
5. Drug information retrieval
6. Drug dispensing
7. Avoiding medication error
8. Record relating to drugs in hospital formulary

Objective Questions with Answers in Bold Letters

1. EHR stands for **Electronic Health Record**.
2. DAWN stands for **Drug Abuse Warning Network**.
3. TDM stands for **Therapeutic Drug Monitoring**.
4. MAR stands for **Medication Administration Record**.
5. **Micromedex** provides information on drugs and their identification, poison, emergency drugs.

Chapter

8

Clinical Pharmacy

Q1. Define clinical pharmacy. Give its objectives.

Definition

1. Clinical pharmacy is a part of hospital pharmacy which deals with the preparation of patient drug profiles, recording patient drug history, advise about possible drug–drug interactions to trainees and drug effects on clinical laboratory test results.
2. Clinical pharmacy is a newborn discipline that carries a traditional hospital pharmacist from product-oriented approach to healthier patient-oriented approach, so as to ensure the patient's maximum well-being, while on drug therapy.

Objectives of Clinical Pharmacy

1. To assist the physicians in doing a better job of prescribing and monitoring drug therapy.
2. To assist nurses in administering medications (drugs).
3. To increase the patients' role in drug use process.
4. To maximize the effectiveness of drug therapy with minimum side effects or adverse effects.
5. To decrease the patients' non-compliance through the patient counselling.
6. To study drug therapy by monitoring it and it should maintain the records of drug therapies, any adverse effect or drug interaction should be reported to the PTC of hospital and also to physician of the hospitals.

Q2. Discuss the role/scope/functions of clinical pharmacy/clinical pharmacist.

1. Preparation of history of patient.
2. Preparation of drug history.
3. Participation in management of medical emergency.

4. Participation in drug investigation.
5. Participation in the management of chronic diseases like diabetes, hypertension, arthritis.
6. To control over drug utilization.
7. To monitor drug therapy.
8. To counsel with patient.
9. To help in selection of drug therapy to physician.
10. To communicate with physician and nurses through presentation and publication.
11. Detection and reporting of adverse drug reactions (ADRs).
12. To take part in educational programme related with medical pharmacy and nursing profession.
13. To provide the formal and informal consultation to the physician.
14. To explain the direction of use, route of administration and other related information to the patients.
15. Collection of knowledge of drug therapy and pharmacokinetics of drugs.
16. To take part in patients education, vaccination programme and other programmes related to social welfare arranged by the hospital.

Q3. What are the abilities required for clinical pharmacist?

Abilities of Clinical Pharmacist

1. He should have basic skill of the communication.
2. He should know about drug profile and pathophysiology of drug.
3. He should have advanced knowledge about pharmacology, pharmacokinetics and biopharmaceutics.
4. He should have adequate patience and better interest for development of clinical pharmacy.
5. He should have an interest in patient care.
6. He should have an art of giving information to the physician.
7. He should have knowledge of drug–drug interactions and adverse drug reactions.

Q4. What are the barriers in the development of clinical pharmacy?

Barriers in the Development of Clinical Pharmacy

1. Lack of knowledge.
2. Lack of motivation.
3. Lack of vocational courses.
4. Lack of inter- and intraprofessional discussions.

5. Lack of self-confidence.
6. Lack of multidisciplinary approach.
7. Lack of team approach.
8. Confusion about the role of clinical pharmacist.
9. The clinical pharmacy practice is supposed to be an encroachment by the physicians.

Q5. What steps should be taken in the development of clinical pharmacy?

1. Hospital pharmacist should increase the need of clinical pharmacist by performing counselling with patient and physician.
2. Hospital pharmacist should increase the knowledge and should be involved in interprofessional discussions.
3. Government should start different vocational courses related to clinical pharmacy.
4. Pharmacist should clarify the queries asked by physician and patient.
5. Pharmacist should increase the necessity of clinical pharmacist.
6. Pharmacist and physicians should have a team approach in taking care of the patients.
7. Pharmacist should understand exact role of clinical pharmacist.

Q6. Explain/comment on "ward round participation".

Ward Round Participation

Ward Round: A ward round is a visit made by a medical practitioner, alone or with a team of health professionals and medical students to hospital inpatients at their bedside to review and follow-up the progress of their health.

- Ward round is an important activity of the pharmacist in the total process of patient care in hospital.
- By taking ward round with the physician and nursing staff, clinical pharmacist can access the patient for drug related problems, monitor drug therapy or adverse effects, promote rational drug therapy and provide drug information to patient, physician and other health professionals.
- Ward round participation is the pharmacists fundamental responsibility to ensure that every patient in the hospital receives right drug treatment in most convenient and cost-effective form.

Goals and Objectives for Clinical Pharmacist on Ward Round

1. To improve understanding of patients clinical progress and status, current therapeutic goals, and planned investigations.
2. To provide relevant information on various aspects of the patient's drug therapy such as pharmacokinetics, pharmacology, drug avail ability, adverse reactions, drug interactions.
3. Optimize therapeutic management by influencing drug therapy selection, implementations, follow-up and monitoring.
4. Investigate unusual drug doses or orders.
5. To provide additional information about the patients such as co-morbidities, medication compliance or alternative medicine use that might be relevant to their management.
6. To detect drug interactions and adverse drug reactions.
7. To participate in patient discharge planning.

Procedure of Ward Round Participation

- Ward round participation provides many learning opportunities for pharmacists.
- It allows pharmacists to see firsthand how drugs are prescribed and used and to see the effects of these drugs on patients.
- With time, pharmacists develop an appreciation of how the patient's own wishes and their economic, social and cultural circumstances may influence therapeutic choices.
- Even for experienced clinical pharmacists in teaching hospitals, it is very rare to finish a ward round without gaining new perspectives on some aspect of patient care or therapeutics. For those involved in academia and research, ward rounds allow identification of cases for clinical publication and teaching.
- Ward round participation strengthens the inter-professional relationship among various health professionals, leading to better healthcare research and practice.

Q7. Write a note on treatment chart review/medication chart review.

Treatment Chart Review/Medication Chart Review

Definition: It is a fundamental responsibility of a pharmacist to ensure the appropriateness of medication orders.

It serves as starting point for clinical activities such as:

i. Adverse drug reactions (ADRs)
ii. Drug interactions (DI)
iii. Therapeutic drug monitoring (TDM)

Goals

1. To optimise the patients drug therapy.
2. To minimise or prevent drug related medication errors/problems.

Procedure

- The patient's medical record should be reviewed in relation with the medication administration record.
- Recent consultations, daily progress and treatment plans should be taken into account while determining the appropriateness of current medication orders and planning each patient's care.
- All recent and current medication orders should be reviewed.

Components of Medication Order Review Include

1. Checking that medication order is written in accordance with local and legal requirements.
2. Ensuring that the medication order is unambiguous and comprehensible, that appropriate terminology is used and that drug name are not abbreviated. Annotate the chart to provide clarification as required.
3. Detecting orders for medication to which the patient may be intolerant/hypersensitive.
4. Ensuring that medication order is appropriate with respect to:
   - The patient's previous medication order.
   - Patient's specific considerations, e.g. pregnancy, disease state.
   - Drug dosage schedule and dose, especially with respect to age, liver function, renal function.
   - Route, method of administration and dosage form.
5. Checking complete drug profile for medication duplication, incompatibilities or interactions.
6. Ensuring that administration times are appropriate, e.g. with respect to other drugs, food and procedures.
7. Checking the medication administration records to ensure that all orders, have been administered.
8. Ensuring that the drug administration order clearly indicates the time at which drug administration is to start.
9. Special considerations should be given especially in short course therapy as in analgesics and antibiotics.
10. Ensuring that the order is cancelled in all sections of medication administration record when the drug therapy is intended to stop.
11. Ensuring implementation of appropriate therapy monitoring.

12. Ensuring that all necessary medication is ordered, e.g. prophylaxis, premedication.
13. Reviewing medication for cost effectiveness.
14. Identification of drug related problems.

Q8. What are adverse drug reactions (ADRs)? Write a note on adverse drug reaction monitoring.

Adverse Drug Reactions (ADRs)

According to WHO definition of ADRs:
"Any response to a drug which is noxious and unintended, and which occurs at doses used in man for prophylaxis, diagnosis or therapy."

- ADRs may be predictable or non-predictable.
- Patient safety is an important issue for hospitals and pharmacies.

Causes/Reasons for Adverse Drug Reactions

i. ADR due to improper prescription and dispensing: Sometimes improper doses are prescribed without taking patient's history.
ii. Some drugs have very low margin of safety, i.e. therapeutic index.
iii. Many formulations of different companies are therapeutically not equivalent due to difference in bioavailability and thus cause ADRs.
iv. Some other factors such as presence of disease of liver or kidney may accumulate the drug in the body which can result in ADRs.
v. Use of potent drugs also causes adverse drug reactions.
vi. Genetic factor is also responsible for causing ADRs.

Goals of Adverse Drug Reaction Monitoring

l. To minimize the risk of adverse drug reaction
2. To reduce consequences after adverse drug reaction

Procedure

Pharmacist is involved in the following steps of monitoring of ADR:

l. Literature review
2. Patient history
3. Drug level studies
4. Therapeutic decision making

Pharmacist with better knowledge of the pharmacological action, adverse reaction and the pathophysiology of diseases can make the therapy to be safer.

Role of Pharmacist in the Management of ADR

1. Monitoring the patients who are at greater risk of developing ADRs
2. Monitoring the patients who are prescribed with drugs highly susceptible to cause ADRs
3. Assessing and documenting the patient's previous allergic status
4. Assessing the patient's drug therapy for its appropriateness
5. Assessing possible drug interactions in case of multiple therapies
6. Assessing healthcare professionals in detection and assessment of ADRs
7. Encouraging/stimulating healthcare professionals in reporting on ADR
8. Documentation of suspected reported reactions for future reference.
9. Follow-up of patients to assess the outcome of the reaction and management
10. Obtaining feedback about the reported reaction
11. Educating healthcare professionals about the importance of an ADR
12. Educating patients

Q9. Write a note on "drug information and poison information".

Drug information and poison information

- Drug information and poison information is an independent body in hospital which provides information on drugs, poisons and their health aspects.
- Drug and poison information service is established keeping this view for collecting the information of drug and poison by abstracting information about them.
- Drug information means providing clinically relevant information on any aspect of drug use relating to individual patients or general information about the drugs.

Goals

1. To uplift the profession of pharmacy by bringing better interaction between the pharmacist and the community.
2. To improve patient compliance with drugs dosage regimen and to improve therapeutic effect.
3. The drug and poison information is collected by using suitable techniques and methods such as verbal, written or audio-visual communication for educating and counselling the patient.

4. Drug and poison information can provide information regarding poisons, their toxicity and treatment round the clock.
5. The concept of drug and poison information is an attempt to collect the information of drugs by abstracting information about them.
6. Drug and poison information is the knowledge gathered either in written form (books, journals, periodicals, etc.) or transmitted by oral communication or by electronic device of the physical, chemical, biological and healthcare sciences.

Procedure

- Pharmacists have fundamental responsibility and a function that is unique to their profession as providers of drug information.
- The information may be either patient specific, as an integral part of pharmaceutical care, or relative to a group of patients such as in the development of a therapeutic guideline, publishing an electronic newsletter, or updating a website.
- The pharmacist can serve as a resource for issues regarding selection and use of cost-effective medication, medication policy decisions (drug benefits), medication information resources or practice-related issues.
- Pharmacists involved in patient care areas (e.g. hospitals, clinics, long-term care, and home healthcare) now frequently answer drug information questions; participate in evaluating a patient's drug therapy, and conduct medication usage evaluation activities.
- Drug information is the provision of verbal and/or written information or advice about drug therapy and drug in response to a request from other healthcare providers, organizations, patients, committees or members of the public.
- Drug information service describes activities to optimize drug use undertaken by pharmacists in providing information.
- Drug information service provides well referenced, critically evaluated, unbiased and up-to-date information on any aspect of drug use.
- Pharmacist's involvements directly impact patient care, improve medication compliance and decrease the likelihood of medication errors.

Q10. Write about 'medication history of the patient'.

Medication History

"It is the collective information of the patient about his body disorders, drug allergies and other information."

It is the job of the pharmacist to take the complete medication history of the patient.

Medication history provides vital information about the patient.

Objectives of Taking Medication HIstory

1. To develop a list of the patient's current and past medications.
2. To determine if the patient has allergies or adverse reactions with some drugs.
3. To know about patients self-prescribing habits or to study the tendency of OTC drugs.
4. To study the ability of the patient to show compliance.
5. To maintain essential information of the patient.
6. To study refilling frequency of patient.
7. To know about habits of the patient.
8. For adjustment of better drug therapy.
9. To avoid drug–drug interaction.
10. To reduce overutilization of drugs.

Medication history includes information about:

1. Name
2. Age
3. Sex
4. Date of birth
5. Address, phone, fax
6. Family background
7. Economical and social status
8. Tendency about the consumption of medicines
9. Views and way of thinking of patients
10. Habits
11. Body disorders
12. Drug allergies
13. Tendency of taking OTC drugs
14. Previous diseases
15. Previous medicines consumed, etc.

Method of Taking Medication History

1. The medication history should be collected and maintained by clinical pharmacist.
2. It is collected by asking some direct and indirect questions.

3. It should be completed within 24 to 40 hours after his hospitalisation.
4. Clinical pharmacist should provide minimum privacy and confidence to the patient.
5. He should ask some time efficient questions.

General Format to Medication History

Name of Patient	Age:	Sex:	Birth date:
Address:			Phone No:
Family backgound:			Previous diseases:
Drug allergies:			Drugs used:
Body disorder:			Prescriber's name:
Adverse effects suffered:			Non-prescribed drugs:
Consumption of:			
i. Caffeine			
ii. Alcohol			
iii. Tobacco			
iv. Morphine, heroin			

Importance and Significance of Medication History

1. It gives vital information about patient compliance.
2. To avoid probable allergic hypersensitivity reactions.
3. To counsel the patient.
4. To adjust better drug therapy to the patient.
5. To develop a list of the patient's current medication
6. To study refilling frequency of the patient.
7. To know about dietary habits of the patient
8. To avoid drug–drug interactions.

Q11. Define patient counselling. Give the objectives/goals of patient counselling. Explain counselling process and contents/items for counselling.

OR

Describe the "concept of patient counselling".

Patient Counselling

"Patient counselling is the part of clinical pharmacy practice to give maximum benefits to the patient and includes the instruction or advice given by the pharmacist to the patient about the use of the drugs prescribed."

Objectives/Goals of Patient Counselling

- To improve the patient compliance and thus can reduce consequences of non-compliance.
- Patient can understand the safe and appropriate use of medicines.
- Improves the coping strategies to deal with medication side effects and drug interactions.
- Motivates the patient to take medicine for improvement of his/her health status.
- The patient becomes an informed, efficient and active participant in disease treatment and self-care management.
- It encourages the patient to establish a working relationship with a pharmacist and foundation for continual interaction and consultation.
- Patient recognizes the importance of their well being.

Procedure of Patient Counselling

Introduction

- Review the patient record prior to counselling.
- Conduct an appropriate patient counselling introduction by self and patient.
- Explain the purpose of counselling session.
- Obtain specific initial drug related information, e.g. drug allergies, and other medications.
- Warn the patient about taking other medications including OTC drugs, herbals, or botanical drugs and alcohol which could inhibit or interact into the prescribed medication.
- Assess the patient understanding of reason for therapy.
- Assess any actual or problems of importance to the patient.

Role of Pharmacist in Patient Counselling/Contents for Counselling

1. **How to remove the drug from the package:** If it is found that patient is not familiar with packaging, the pharmacist should demonstrate how to remove the medicines from the package.
2. **Route of administration:** Pharmacist should tell the patient about route by which medicine should be taken, e.g. by mouth, to be instilled into eye, ear or to be rubbed on the skin.
3. **Time of drug administration:** The pharmacist should instruct the patient about the time of administration of drug, e.g. every 6 hours, at bedtime, etc.

4. **Duration of drug therapy:** The pharmacist must ensure that the patient understands clearly the length of time, the medication is to be used. Otherwise, resistance may develop.
5. **Storage of drugs:** The pharmacist should counsel the patient about the proper storage of the medicine to ensure safety and stability. Medicines should be kept beyond the reach of children at home.
6. **Side effects of drugs:** Possible side effects should be told tactfully to the patient.
7. **Drug interactions:** The patient should be warned about drug interaction which mainly occurs with food, e.g. tetracyclines with milk.
8. **Allergies:** Pharmacist should ask the patient about drug allergies to him to avoid further complications.
9. **Refilling frequency:** Pharmacist should indicate whether or not the prescription is refillable or should be refilled.
10. **About therapeutic effects of drugs:** Pharmacist should tell the patient about effectivity and use of drug.
11. Pharmacist should advise the patient about rest, diet and exercise.

Significance of Patient Counselling

1. It gives maximum benefits to the patient.
2. It avoids adverse effects of the drugs.
3. It avoids drug–food interactions.
4. It improves patient compliance.
5. Patient can understand safe and appropriate use of medicines.
6. It avoids overutilization and underutilization of drugs.

Q12. What is interprofessional collaboration? Give the objectives and benefits of interprofessional collaboration.

Interprofessional Collaboration

Definition

It is defined as the multiple health workers from different professional backgrounds work together with patient, families, caregivers and communities to deliver the highest quality of care.

Goals and Objectives of Interprofessional Collaboration

1. To improve the patient care, safety and compliance
2. To reduce medical errors
3. To start treatment faster

4. To reduce healthcare costs and inefficiencies
5. To improve job satisfaction and staff relationships
6. To reduce preventable adverse drug reactions, optimize medication dosages and decrease mortality rates.

Benefits/Importance of Interprofessional Collaboration

1. Improves efficiency
2. Helps to provide mere holistic services
3. Sharing and interchanging of new concepts and new ideas.
4. Provides an access to potential peoples to enter into the healthcare team.
5. It provides opportunities to learn and go beyond traditional ways of thinking.
6. Development of lifelong relationship that may be beneficial in future.
7. Association with others who are successful.
8. It provides a knowledge to solve the problems occurring during work.
9. It provides greater level of responsiveness.
10. Large scope for innovation and creativity.
11. Patient-centric practice can be exercised.
12. Helps to improve staff relationship and job satisfaction.

Q13. Explain different barriers to patient counselling.

Barriers to Patient Counselling

The barriers that come in the way of conducting patient counselling are:

1. A busy pharmacy
2. Lack of privacy
3. Noise
4. Physical barrier
5. Patient factors
6. Physical disabilities
7. Comprehensive difficulties
8. Illiteracy
9. The pharmacist
10. Time

1. **A busy pharmacy:** The pharmacist is supervising number of difficult activities at the same time and is unable to devote his/her full attention to an individual matter.
2. **Lack of privacy:** Both community and hospital outpatient departments have counselling rooms/areas but may not have privacy during counselling.

   For communication to be effective, it is often necessary that consultation should take place in a quite environment, free of interruptions.

   The abovementioned condition in which pharmacist frequently works require additional skills to overcome the lack of ideal facilities.
3. **Noise:** Noise levels within the working environment are an obvious barrier to good communication.
4. **Physical barriers:** Pharmacy counters and OP dispensing doorways are physical barriers. This in turn can create problems in developing effective communication.
5. **Patient factors:** They are not expecting time to be spent with them for checking, understanding of medicines or health related matters.
6. **Physical disabilities:** Dealing with patients who have sight or hearing impairments will require the pharmacist to use additional communication skills.
7. **Comprehensive difficulties:** Choosing appropriate language for counselling is very important as patients level of understanding is concerned. Pharmacist must choose the language of patient's choice for better understanding and counselling.
8. **Illiteracy:** High proportion of people in India is illiterate. Obviously for these patients any written materials will be meaningless. As well as, it is not always easy to identify illiterate patient because patient may feel ashamed and are unlikely to admit it.
9. **Pharmacist:** Not all pharmacists are natural good communicators but identifying their strength or weakness will assist in improving our communication skills.

   Some of the weakness which can be barrier to good communication are listed below:

   Lack of confidence, lack of interest, laziness, a pharmacist who is not prone to delicate responsibilities.
10. **Time:** In many instances, time or lack of it can be a major problem for good communication.

Q14. Define pharmaceutical care. Give the goals/objectives of pharmaceutical care.

Pharmaceutical Care

Definition

Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve patient's quality of life.

Goals/objectives of Pharmaceutical Care

The goal of pharmaceutical care is to optimize the patient's health-related quality of life and achieve positive clinical outcomes. To achieve these goals the following approach is required:

- It requires an established patient to pharmacist relationship.
- It requires records of medication to be kept and, with the patient's informed consent, additional patient specific information to be collected, organized, recorded, monitored and maintained.
- It requires patient-specific medical information to be evaluated and, in the case of prescribed medicines, a therapy plan to be developed involving the patient and the prescriber.
- It requires the pharmacist to ensure that the patient has all supplies, information, and knowledge, necessary to carry out the drug therapy plan.
- It requires the pharmacist to review, monitor, and modify the therapeutic plan in concern with the patient and healthcare team.
- Elements to provide quality pharmaceutical care are:
  i. Knowledge and skills of personnel.
  ii. Systems for data collection, documentation, and transfer of information.
  iii. Efficient workflow processes.
  iv. References, resources and equipment.
  v. Communication skills.
  vi. Commitment to quality improvement and assessment procedures.

Q15. What is need/purpose of pharmaceutical care? Mention the principles of practice for pharmaceutical care.

Need/Purpose of Pharmaceutical Care

The pharmaceutical care is a responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.

1. Pharmacy is the first point of contact to patient after leaving doctor, hence pharmacist can take care of patients.
2. Only pharmacist can help and inform the doctors about the drugs and their actions ultimately it is involved in due care of the patient.
3. After the doctor's consultation, patient visits the pharmacy frequently, so monitoring and correction of therapy, if any, can be counselled by pharmacist.
4. Most of the time doctors are not available for the patient care but pharmacists are always at any hour of time.
5. Multiple services and help under one roof can help the patient to motivate and adhere to the plan.
6. Visiting pharmacist is economical and easy as compared to doctor.

Principles/Elements of Practice of Pharmaceutical Care

1. **Responsibility of patient care:** The pharmacist should accept the responsibility of care of the patient.
2. **Provision of care:** The pharmacist should behave with the patient in such a way that patient should feel the caring attitude of the pharmacist.
3. **Caring nature of pharmacist:** It is a central piece of the pharmaceutical care.
4. **Positive outcomes:** The pharmacist should take care of medicines, and medication monitoring to produce positive outcomes to the patients.
5. **Improvement in patients quality of life:** Health status of a person is a major factor for deciding persons quality of life. The pharmacist is a main healthcare provider to the patients.
6. **Data collection:** The pharmacist must collect relevant data of the patient for further medical and pharmaceutical care.
7. **Additional services:** The pharmacist also measures the blood pressure, blood glucose level, weight, height, etc. as an additional facility.
8. **Evaluation of information:** The pharmacist must evaluate information collected from the patient for further medication management.
9. **A professional relationship with patient:** The pharmacist must keep good relationship with patient so that patient can access to pharmaceutical care at all times.
10. **Monitoring and modifying plan to get positive outcomes:** The pharmacist continuously monitors the progress in the patients and if required can change the drug therapy plan after discussion with the physician.

Q16. What is drug related problem? Classify various drug related problems.

Drug Related Problems/Medication Related Problems

Definition

The drug related problem is an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes.

Classification/Types of Drug Related Problems

The following are different drug related problems

1. **New drug therapy:** Patient has a medical condition that requires new drug therapy.
2. **Unnecessary drug therapy:** Patient is taking the drug therapy which is not suitable for his present condition.
3. **Use of wrong drug:** Patient has a medical condition as wrong drug is prescribed.
4. **Too low dose:** Patient has a medical condition for which too low dose of a correct drug is taken.
5. **Too high dose:** Patient has a medical condition for which too high dose of a correct drug is taken.
6. **Adverse drug reaction:** The patient has a medical condition that occurred due to adverse drug reaction.
7. **Non-compliance:** The patient has a medical condition for which the patient is not receiving the drug.
8. **Drug interactions:** The patient has a medical condition and there is a drug–drug drug–food or drug–lab test interactions.
9. Lack of monitoring of effect and toxicity of drugs.
10. Lack of the drug chart/prescription does not contain drug strength.

Q17. What is medication therapy management? Give its objectives and benefits.

Medication Therapy Management (MTM)

Definition

Medication therapy management is a distinct group of services provided by healthcare providers, including pharmacists to ensure the best therapeutic outcomes for patients.

Objectives/Goals of MTM

- To make sure that the medication is correct to the patient health conditions to get positive outcomes.

- To improve patient health outcomes through improved control of chronic disease and more careful attention to potential drug–drug interaction.
- To reduce medication related adverse effects.
- To increase participation of patient in their healthcare.

Medication Therapy Management Includes Five Core Elements

1. Medication therapy review
2. A personal medication records
3. A medication-related action plan
4. Intervention or referral.
5. Documentation and follow-up.

Role of Pharmacist in MTM

1. The pharmacist reviews patient medication for safety, efficacy and appropriateness.
2. The pharmacist reviews patient medication record and fill the record form to maintain the updates of health status and medication of the patient.
3. The pharmacist should ensure that prescribed drug therapy is effective, safe and economical.
4. The pharmacist should collect the patient data and continually access whether the drug therapy is producing expected therapeutic effects or adverse effects.
5. The pharmacist should try to reduce medication related problems by continuous monitoring.

Benefits of MTM

1. Improving the quality of patient care.
2. Reducing healthcare expenditures.
3. Reducing medication related adverse effects.
4. The patient who uses prescription medications, herbals, non-prescription medications or other dietary supplements may potentially benefit from MTM.
5. MTM is especially effective for patients with multiple chronic conditions, complex medication therapies, multiple prescribers and high prescription costs.
6. MTM encourages patient to be an active participant in their health-care, empowering them to be more responsible and knowledgeable for their health and medication use.

18. What is home medication review? Give the objectives, need, classification and role of pharmacists in HMR.

Home Medication Review (HMR)

Definition

Home medication review (HMR) is a patient-focused, careful and collaborative healthcare service provided in the community setting, to enhance quality use of medicines and patient understanding.

Objectives

- To identify, prevent and resolve potential medication-related problems
- To optimize pharmacotherapy and assist in achieving better health outcomes for patients at home.
- To increase patient's adherence to medication.
- To identity factors affecting non-compliance.
- To increase patient's knowledge on medication such as dosing, frequency, indication and administration (DFIA).
- To review patient's method of managing their medication at home.
- To identify drug related problems (DRPs).
- To reduce wastage (due to overstocking of medicines).
- To improve patient's quality of life.

Need of HMR

- The patients find it uneasy and difficult to get medical care in conventional settings like nursing homes, hospitals.
- They are not very much enthusiastic of meeting a doctor and getting evaluated.
- The patient would prefer to receive the healthcare in a personalized approach with confidentiality where the others do not come to know regarding his/her illness.
- This also avoided hospital ward charges as well as need for an attendant for patients.

Classification of HMR

Medication review can be classified as:

1. Prescription review
2. Adherence support review
3. Clinical review

1. **A prescription review** aims to address the technical issues of a patient's prescription such as changed items or anomalies.

2. **An adherence support review,** with the patient present, addresses a patient's medication-taking behavior focusing on improving a patient's knowledge of medicines and adherence to them.
3. **A clinical medication review,** with access to clinical notes and the patient present, is more comprehensive and addresses the patient's use of medication in the context of their clinical condition.

Role of Pharmacist in HMR

1. The HMR consists of visits by a pharmacist and analyzes the patients from the point of lifestyle, drug and disease.
2. The pharmacist prepares a customized care plan and implements it to the patient by explaining and educating about the drug, disease and lifestyle modifications.
3. He also prepares a medication therapy management plan as per the prescription.
4. The pharmacist with his skills tries to interpret the reasons for failed or mixed outcomes.
5. He can communicate with doctors and nurses regarding the diagnosis and treatment to discuss the patient care issues.

Q19. What is drug information service (DIS)? Give the need/objectives of DIS. What are the abilities/qualities required by a pharmacist to run DIS?

Drug Information Services (DIS)/Drug Information Centre (DIC)

Definition

Drug information centre is one of the departments of the hospital and gives the recent knowledge and information about the medical pharmacy field at any time to the physicians, staff of the hospital and to the citizens."

Need of DIC

1. To give first aid suggestions.
2. To get knowledge about recent developments in medical and supportive services.
3. To get idea about emergency treatments.
4. To clarify the queries about medical and supportive fields.
5. To store the information and retrieve it.
6. For adjustment of better drug therapy
7. To provide vital and necessary information to physicians and medical persons.

Abilities/Qualities Required by a Pharmacist to run DIS/DIC

DIS/DIC should run by pharmacist who should have following abilities:

1. He should be able to edit the information.
2. He can collect the data, quickly and accurately.
3. He should have good communication skills.
4. He should have a knowledge about research method and about the sources of information.
5. He should have knowledge about medical, pharmacy and nursing field.
6. He should attend the seminars, conferences and should collect essential information.
7. He should have an ability to study abstracts, literatures, journals and also should be able to deliver the knowledge to others.
8. He is the member of PTC and should have a knowledge about various aspects of drugs.

Q20. Give the location, requirements and facilities required for drug information centre (DIC)/DIS.

Location of DIC/DIS

- It should be away from inpatient department and should be possibly away from outpatient department also.
- This department should be near to pharmacy department and also near to the hospital library.
- It should provide essential environment for reading the books. Thus, it should be having negligible disturbances.

Requirements and Facilities of DIC/DIS

1. This department should provide good furniture, adequate books, audiovisual arrangements for conduction of seminars, photocopy, e-mail, fax, computers, telephones.
2. It should provide adequate electric and water facilities.
3. This centre should have rectangular, circular tables and adequate chairs.
4. The dimensions of this centre are dependant on size of hospital, type of hospital, number of staff utilizing library, number of publications to be kept in and overall utilization by citizens.
5. The reading area provided to the reader should be minimum 25 to 30 sq. feet. The minimum distance between two tables should be at least 5 feet and the distance in between wall and table should not be less than 3 feet.

6. It should have official books like several pharmacopoeias, Remington's pharmaceutical sciences, national formulary, various journals (American Journal of Hospital Pharmacy, Journal of Pharmacognosy, Indian Journal of Medical Research).
7. This department should be open for 24 hours.
8. It should have facility to conduct seminars for giving recent knowledge to the staff.

Q21. Write the functions of DIC/DIS.

Functions of DIC

1. **Collection and storage of information:** By reading the abstracts, journals, periodicals, the head of this centre obtains information and store it in the computers.
2. **Retrieval of information:** Whenever required the information is read by staff of hospital to get knowledge of recent development and to clarify queries.
3. **Evaluation of information:** The information is read by head of this centre and edited by him and published in drug information bulletin.
4. **As a community centre:** This centre communicates with other hospitals and arrange the seminars, lectures in that community to increase the educational standard of the public. It also clears the queries asked by citizens, therefore, increases the status of the hospital.
5. **As an information center:** It provides information about emergency treatment, first aid treatment and also about poisons and toxic substances.
6. **Information for research:** This department provides information to the staff involved in research work.
7. **Information regarding reported ADRs:** This department provides information regarding reported ADRs to other hospitals so that further ADRs do not occur.
8. This department has facilities like fax, e-mail, telephone, therefore, quick information can be collected by citizens.
9. It is opened for 24 hours for getting the information.

Q22. What is drug information bulletin (DIB)? Explain DIB.

Drug Information Bulltein (DIB)

It is the bulletin printed and published by DIC of the hospital which contains latest developments in medical sciences, new drugs introduced, update of drug interactions and adverse drug reactions.

Contents of DIB

1. It contains recent information about the drugs, developments and dosage forms.
2. It contains information about new methods of analysis, services offered by the hospitals, any ADRs reported in the hospital.
3. Question–answer type section.
4. Puzzles.
5. Latest information about developments in medical, paramedical services.
6. It should be published by hospital for internal circulation only.
7. The information in bulletin is collected and edited by the head of PTC.
8. This bulletin contains names of reference books, journals, proceedings of conferences.

Sources of Information

The sources of information for DIB are as follows:

a. Primary sources: It contains the information published by authority and it is generally called raw information. This information is nothing but articles in journals, abstracts, etc.

b. Secondary sources: It contains the comments or opinions or modified information. The information is collected from pharmacopoeias formulary, textbooks, etc. This information is evaluated by second party, i.e. original information is selected, modified, rearranged and condensed.

c. Tertiary sources: These are outputs of primary and secondary sources.

Importance/Need/Significance of DIB

1. It is the link between DIC and other health professionals.
2. It is the way of communication for giving the information to the physicians, pharmacists and also within very short time.
3. It is important for keeping the medical staff of hospital alert about the recent knowledge and developments.
4. A regular publication of the bulletin will update the knowledge of the patient care staff on the development in their area of specialization.

Q23. Give the meaning of following medical terminologies.

1. *Amoebiasis:* Amoebiasis is an infectious disease caused by protozoa, *Entamoeba histolytica*.

2. *Anaesthetic:* It means a substance which reduces pains by making the individual unconscious.
3. *Counterirritants:* It means the drugs that counteract irritation and thereby relieving pains.
4. *Laxatives:* The drugs which promote defaecation.
5. *Immunity:* It means the power of body to resist infection.
6. *Emetics:* The drugs which induce vomiting are called emetics.
7. *Analeptics*: The drugs which stimulate CNS are called analeptics.
8. *Cholagogue:* The drugs which increase secretion of bile.
9. *Sialogogue:* The drugs which increase secretion of saliva.
10. *Galactogogue:* The drugs which increase secretion of milk.
11. *Hydrogogue:* The drug which produces fluid motions.
12. *Tranquillizers:* The drugs which produce calming and quietening effect on the minds of patients are called tranquilizers.
13. *Astringents:* The drugs which cause precipitation of superficial proteins of the skin.
14. *Acidosis:* It means increased acid reserve in the body.
15. *Alkalosis:* It means increased alkali reserve in the body.
16. *Hyperuricaemia:* Increased level of uric acid in blood.
17. *Hypokalaemia:* Low level of potassium in blood.
18. *Oliguria:* Less urine formation.
19. *Anaemia:* Decrease in number of RBCs.
20. *Polycythaemia:* Increase in number of RBCs.
21. *Leukaemia:* Increase in number of WBCs.
22. *Leucopaenia:* Decrease in number of WBCs.
23. *Aplastic anaemia:* Defective formation of RBC.
24. *Blood dyscrasis:* An abnormality of blood cells.
25. *Agranulocytosis:* Marked reduction in granulocyte count.
26. *Haemolysis:* Destruction of RBCs.
27. *Thrombocytopaenia:* Marked decrease in platelet count.
28. *Actinomycosis:* It is a fungal disease caused by actinomyces.
29. *Arthritis:* Inflammation of joints.
30. *Carcinoma:* Cancer.
31. *Congenital:* Existing from birth.
32. *Diaphoresis:* Sweating, perspiration.
33. *Embolism:* Obstruction of blood flow due to clot, air or tumour cells.

34. *Enuresis:* Bed wetting.
35. *Iatrogenic:* Drug-induced diseases.
36. *Ischaemia:* Condition due to reduced blood supply.
37. *Etiology:* Cause of disease.
38. *Parturition:* Act of bearing a child.
39. *Postpartum:* After birth.
40. *Rhinitis:* Swelling of nasal mucous membrane.
41. *Spasm:* A sudden, violent involuntary contraction of muscle.
42. *Teratogen:* A substance which can cause foetal abnormality.
43. *Tumour:* A mass of abnormal tissue growth due to cancer.
44. *Virilism:* Presence of male characters in females.
45. *Amnesia:* Loss of memory.
46. *Analgesia:* Loss of pain sensation.
47. *Anxiety:* A feeling of uneasiness, tension.
48. *Delirium:* Abnormal mental condition.
49. *Dizziness:* A sensation of falling.
50. *Coma:* Deep sleep with complete loss of consciousness.
51. *Epilepsy:* A disease of brain due to abnormal electrical discharge.
52. *Euphoria:* A feeling of well being.
53. *Hallucination:* A sensation of false perception without sensory stimulus.
54. *Lethargy:* Sluggishness.
55. *Mania:* A mental depressive disease.
56. *Meningitis:* Inflammation of meninges due to infection.
57. *Motion sickness:* A feeling of nausea and vomiting during travelling.
58. *Migraine:* A severe sudden headache.
59. *Narcosis:* Drug-induced unconsciousness.
60. *Ototoxic:* Toxicity in ear.
61. *Parasthesia:* Abnormality of sensation.
62. *Parkinsonism:* A degenerative syndrome of CNS due to cholinergic dopaminergic imbalance.
63. *Peripheral neuritis:* Inflammation of peripheral nerves.
64. *Stupor:* Loss of consciousness.
65. *Tinitus:* A ringing sound in ear.
66. *Trauma:* Due to external force, a wound or injury is produced.
67. *Tremor:* Involuntary muscular movements.

68. *Vertigo:* A sensation of rotation of oneself.
69. *Insomnia:* It means lack of sleep.
70. *Miosis:* Constriction of pupil.
71. *Mydriatic:* Dilatation of pupil.
72. *Cycloplegia:* Paralysis of ciliary muscles of eye leading to loss of accommodation.
73. *Conjunctivitis:* Inflammation of conjunctiva.
74. *Diplopia:* Double vision.
75. *Iritis:* Inflammation of iris.
76. *Night blindness:* Absence of vision in dark due to deficiency of vitamin A
77. *Glaucoma:* Increased intra-ocular tension.
78. *Photophobia:* Difficulty to expose eyes to light
79. *Acnes:* A common skin disease
80. *Alopecia:* Loss of hair leading to baldness.
81. *Anaphylaxis:* A severe hypersensitivity.
82. *Cyanosis:* A bluish tinge observed under nails, lips and skin due to lack of oxygenated haemoglobin.
83. *Erythema:* Reddening of skin.
84. *Pruritis:* Itching.
85. *Inflammation:* A reaction of tissue to injury.
86. *Apnoea:* Temporary cessation of respiration.
87. *Dyspnoea:* Difficulty in breathing.
88. *Hypoxia:* Deficiency of oxygen in tissues.
89. *Anoxia:* Lack of oxygen in tissues.
90. *Demulscent:* An agent producing soothing and protective action.
91. *Arrhythmia:* Abnormal rhythm of heart.
92. *Bradycardia:* Decrease in heart rate.
93. *Tachycardia:* Increase in heart rate.
94. *Angina:* Pains in the chest due to less oxygen supply to myocardium.
95. *Myocardial infarction:* Damage to myocardium due to inadequate blood supply.
96. *Ionotrophy:* It means force of contraction of heart.
97. *Chronotrophy:* It means rate of heart.
98. *Anorexia:* Loss of appetite.
99. *Colitis:* Swelling of colon.

100. *Dyspepsia:* Indigestion.
101. *Dysphagia:* Difficulty in swallowing (deglutition).
102. *Glossitis:* Inflammatory tongue.
103. *Heart burn:* Due to hyperacidity, gastric contents come into mouth causing a burning sensation in chest.
104. *Paralytic ileus:* Paralysis of intestinal muscles.
105. *Achlorhydria:* Absence of hydrochloric acid secretion by gastric gland.
106. *Diarrhoea:* Excretion of watery stools.
107. *Libido:* Desire of sex.
108. *Menopause:* Menstrual cycle termination.
109. *Neonates:* Newborn up to 1 month.
110. *Infant:* Child less than 1 year old.
111. *Micturition:* Act of urination.
112. *Dysmenorrhoea:* Painful menstruation.
113. *Medicine:* It is the term explaining all the aspects of sciences of prevention, investigation and treatment of diseases.
114. *Disease:* It means some abnormality in structure or function of body.
115. *Acute:* It means rapid onset and rapid progress.
116. *Chronic:* It means slow onset and slow progress.
117. *Organic:* Associated with abnormality in structure or organ.
118. *Acquired:* Acquired after birth.
119. *Congenital:* Present at birth.
120. *Familial:* Occurring in families.
121. *Systemic:* Involving in body system.
122. *Local:* Involving only a part of body.
123. *Neoplastic:* Formation of tumour.
124. *Infective:* Due to infection.
125. *Allergy:* Due to hypersensitivity.
126. *Psychiatric:* Due to abnormality in mind.
127. *Semiparalysis:* Paralysis of one side of body.
128. *Paraplegia:* Paralysis of legs.
129. *Saluresis:* Excretion of sodium and chloride ions in urine.
130. *Pathogenesis:* It refers to development of diseases.

Q24. Give the meaning of the following terms.

S.No.	Terms	Meaning
1.	**Airlock**	Automatic lock by the more positive air pressure room than outside room. It prevents the entry of dust particles, microbes from outer room.
2.	**DIB**	Drug information bulletin
3.	**BAL**	Dimercaprol (British anti-Lewisite)
4.	**SVP**	Small Volume Parenteral
5.	**LVP**	Large Volume Parenteral
6.	**Positive pressure**	Positive pressure present in the aseptic room which prevents the entry of dust particles, microbes from outer room.
7.	**Brand name**	It is a trade name of the drug. This name is privately owned by the manufacturer or distributor.
8.	**Generic name**	The official, common or public name used to designate an active drug entity, whether in pure form or in dosage form.
9.	**Drug product**	It is finished dosage form which contains the active drug ingredient generally, but not necessarily, in association with inactive ingredients.
10.	**Polypharmacy**	It refers to the concurrent use of many drugs during the course of treatment for a particular illness or condition.
11.	**Contraindication**	Any condition which renders a particular line of treatment improper or undesirable.
12.	**Over-the-counter (OTC) drugs**	These are the drug products that can be purchased without prescription.
13.	**Secondary effects**	A by-product or complication of drug use which does not occur as part of the drugs primary pharmacological activity.
14.	**Superinfection**	A new infection complicated the course of antimicrobial therapy of an existing infection due to invasion by bacteria or fungi resistant to the drugs in use.
15.	**Drug clearance**	It is defined as the volume of plasma in the vascular compartment that is cleared of drug per unit time.

Q25. Give the English meaning of the following Latin terms.

S.No.	Latin term	Meaning in English
1.	**Semel in die**	Once a day
2.	**Omnihora**	Every hour
3.	**Ter in die**	Three times a day
4.	**q.i.d.**	Four times a day
5.	**Secundus horis**	Every two hours
6.	**Semis horis**	Every half four
7.	**Hora somni**	At bedtime
8.	**Ana**	Of each
9.	**Unus**	One
10.	**Semel**	Once
11.	**S O S**	When required or when necessary
12.	**Mane**	In the morning
13.	**Nocte**	At night
14.	**p.n.r. (pro re nata)**	Occasionally
15.	**Dandus**	To be given
16.	**Folium**	Leaf
17.	**Radix**	Root
18.	**Flos**	Flower
19.	**Succus**	A juice
20.	**Charta**	A powder
21.	**Pulvis**	Powder
22.	**Parvus**	Small
23.	**Magnus**	A tumbles
24.	**Fortis**	Strong
25.	**Minim**	Minimum
26.	**Pasta**	A paste
27.	**Tincturase**	Tincture
28.	**Ungentum**	An ointment
29.	**Trochiscus**	A lozenge
30.	**Haustous**	A draught
31.	**Collutorium**	A mouthwash

Contd.

Contd.

S.No.	Latin term	Meaning in English
32.	**Nebula**	A spray solution
33.	**Cataplasma**	A poultice
34.	**Collyrium**	An eye lotion
35.	**Dolore urgente**	When the pain is severe
36.	**Mistura**	Mixture
37.	**Guttae**	Drops
38.	**Tussis**	A cough
39.	**Naristillate**	Nasal drops
40.	**Auristille**	Ear drops
41.	**Dulicis**	Sweet
42.	**Granum**	Grain
43.	**Drachma**	Drachm
44.	**Octarius**	Pint
45.	**Coagius**	Gallon

Q26. Give the long form of the following abbreviations used in medical practice.

5-HT : 5-hydroxy tryptamine (serotonin)
ACE : Angiotensin converting enzyme
ACE-I : Angiotensin converting enzyme inhibitor
ACTH : Adrenocorticotropic hormone (corticotropin)
ADA : American Diabetes Association
ADH : Antidiuretic hormone
ADME : Absorption, Distribution, Metabolism, Excretion
ADP : Adenosine diphosphate
AFB : Acid-fast bacilli
AIDS : Acquired immunity deficiency syndrome
ALL : Acute lymphocytic leukemia
ALP : Alkaline phosphatase
ALT : Alanine aminotransferase
AMI : Acute myocardial infarction

ASA	:	Acetyl salicylic acid (Aspirin)
AST	:	Aspartate aminotransferase
AT	:	Antithrombin
ATP	:	Adenosine triphosphate
AUC	:	Area Under the Curve
AV	:	Atrioventricular
BAL	:	British anti-Lewisite (Dimercaprol)
BBT	:	Basal body temperature
BCG	:	Bacillus Calmette-Guérin
BMI	:	Body mass index
BMR	:	Basal metabolic rate
BP	:	Blood pressure
BSA	:	Body surface area
BSL	:	Blood sugar level
BT	:	Bleeding time
BUN	:	Blood urea nitrogen
CA	:	Carbonic anhydrase/cancer antigen
CAD	:	Coronary artery disease
CAT	:	Computerized axial tomography
CHD	:	Coronary heart disease
CHF	:	Congestive heart failure
CK	:	Creatine kinase
CLL	:	Chronic lymphocytic leukemia
COPD	:	Chronic obstructive pulmonary disease
CPK	:	Creatinine phosphokinase
CRH	:	Corticotropin releasing hormone
CT	:	Computed tomography
CYP450	:	Cytochrome P450 enzyme
DDT	:	Dichlorodiphenyl trichloroethane
DI	:	Diabetes insipidus
DKA	:	Diabetic ketoacidosis
DM	:	Diabetes mellitus
ECG	:	Electrocardiogram

ELISA	:	Enzyme-linked immunosorbent assay
ERV	:	Expiratory reserve volume
ESR	:	Erythrocyte sedimentation rate
FDA	:	Food and Drug Administration
FPG	:	Fasting plasma glucose
FSH	:	Follicle stimulating hormone
G6PD	:	Glucose-6-phosphate dehydrogenase
GC	:	Gas chromatography
GC-MS	:	Gas chromatography and mass spectrometry
GERD	:	Gastroesophageal reflux disease
GFR	:	Glomerular filtration rate
GLC	:	Gas liquid chromatography
GLUT	:	Glucose transporter
GOLD	:	Global initiative for chronic obstructive lung disease
HAP	:	Hospital acquired pneumonia
HAV	:	Hepatitis-A virus
HBV	:	Hepatitis-B virus
HCV	:	Hepatitis-C virus
HDL	:	High-density lipoprotein
HDV	:	Hepatitis-D virus
HEV	:	Hepatitis-E virus
HIV	:	Human immunodeficiency virus
HMG-CoA	:	Hydroxymethylglutaryl co-enzyme A
HPLC	:	High performance liquid chromatography
HSV	:	Herpes simplex virus
IA	:	Immunoassay
IC_{50}	:	Inhibitory concentration 50%
ICU	:	Intensive care unit
IHD	:	Ischemic heart disease
LBBB	:	Left bundle branch block.
LDH	:	Lactate dehydrogenase
LDL	:	Low-density lipoprotein

LFT	:	Liver function test
LH	:	Luteinizing hormone
LMP	:	Last-menstrual period
LSD	:	Lysergic acid diethylamide
MCH	:	Mean corpuscular hemoglobin
MCHC	:	Mean corpuscular hemoglobin concentration
MCV	:	Mean corpuscular volume
MDR	:	Multi-drug resistance
MI	:	Myocardial infarction
MIC	:	Minimum inhibitory concentration
MPV	:	Mean platelet volume
MRI	:	Magnetic resonance imaging
MS	:	Mass spectrometry
NCEP	:	National cholesterol education programme
NNRTI	:	Non-nucleoside reverse transcriptase inhibitor
NRTI	:	Nucleosicle reverse transcriptase inhibitor
NSAID	:	Non-steroidal anti-inflammatory drug
OA	:	Osteoarthritis
OGTT	:	Oral glucose tolerance test
PCR	:	Polymerase chain reaction
PFT	:	Pulmonary function test
PICU	:	Pediatric intensive care unit
PID	:	Pelvic inflammatory disease
PPD	:	Purified protein derivative
PPG	:	Postprandial glucose
PPT	:	Proton pump inhibitor
PT	:	Prothrombin time
QC	:	Quality control
RA	:	Rheumatoid arthritis
RAAS	:	Renin-angiotensin-aldosterone system
RBC	:	Red blood cell
RF	:	Rheumatoid factor
RI	:	Reticulocyte index

RIA	:	Radioimmunoassay
RIDT	:	Rapid influenza diagnostic test
RNA	:	Ribonucleic acid
RR	:	Respiratory rate
RT	:	Reverse transcriptase, Reverse transcription
RT-PCR	:	Reverse transcriptase polymerase chain reaction
RV	:	Residual volume
SA	:	Sinoatrial
SCr	:	Serum creatinine
SD	:	Standard deviation
SI	:	International system of units
SPEP	:	Serum protein electrophoresis
SSRI	:	Selective serotonin reuptake inhibitor
STD	:	Sexually transmitted disease
SV	:	Stroke volume
T_3	:	Triiodothyronine
T_4	:	Thyroxine
TB	:	Tuberculosis
TBW	:	Total body water, Total body weight
TC	:	Total cholesterol
TCA	:	Tricyclic antidepressant
TDM	:	Therapeutic drug monitoring
TF	:	Tissue factor
TG	:	Triglyceride
TID	:	Three times daily
TLC	:	Thin layer chromatography/Total lung capacity
TRH	:	Thyrotropin-releasing hormone
TSH	:	Thyroid stimulating hormone
TST	:	Tuberculin skin test
TT	:	Thrombin time
TV	:	Tidal volume
TXA_2	:	Thromboxane A_2
UA	:	Unstable angina

ULN	:	Upper limit of normal
UTI	:	Urinary tract infection
VC	:	Vital capacity
VDRL	:	Veneral disease research laboratory
VLDL	:	Very low density lipoprotein
VZV	:	Varicella zoster virus
WB	:	Western blot
WBC	:	White blood cell
WHO	:	World Health Organization
WNL	:	Within normal limits

Objective Questions with Answers in Bold Letters

1. ADRs stand for **Adverse Drug Reactions**
2. TDM stands for **Therapeutic Drug Monitoring**
3. MTM stands for **Medication Therapy Monitoring**
4. HMR stands for **Home Medication Review**
5. DIS stands for **Drug Information Service**
6. DIB stands for **Drug Information Bulletin**
7. The **Counselling content** is the heart of counselling sessions
8. PTC stands for **Pharmacy and Therapeutic Committee**
9. DRPs stand for **Drug Related Problems**
10. Congenital means **existing from birth**
11. Gutta means **drops**
12. **Alopecia** means loss of hairs
13. SOS means **when required/when necessary**
14. **Galactogogue** means increased secretion of milk.
15. Hora somni means **at bedtime**
16. **Dysphagia** means difficulty in swallowing
17. Long form of BAL is **British anti-Lewisite**
18. Tachycardia means **increase in heart rate**
19. Semel in die means **once a day**
20. Haustus means a **draught**

Chapter 9

Clinical Laboratory Tests

Q1. What are clinical laboratory tests? Give its importance.

Clinical Laboratory Tests

These are the laboratory tests used in diagnosis, monitoring, screening or investigation of various diseases or disorders.

- Many of the clinical tests are related to the impaired function of a particular organ, hence are also called organ function tests.
- The pathophysiological findings obtained by ordering 'clinical laboratory test' involved in the estimation of constituents in a body fluid samples.
- The commonly used body fluids for analysis are blood and urine.

The following are various organ function tests used commonly:

i. Liver function test
ii. Renal function test
iii. Thyroid function test
iv. Test associated with cardiac disorders
v. Pulmonary function tests

IMPORTANCE OF CLINICAL LABORATORY TESTS

Clinical laboratory test results are very important parameters in diagnosis, monitoring and screening of disease. The laboratory test data is useful to healthcare team for the following purposes.

1. **Understanding patient and his disease state:** For pharmacist to provide better services as drug information specialists and consultants. On drug therapy, he needs to understand the patient and his disease state. The pathophysiological findings of the patient, along with his demographic data and medication history shall comprehensively be useful for understanding patients disease state.
2. **Diagnosis of disease:** Presence of certain abnormal constituents and/or abnormal count/amount of certain physiological values is

indicative of the disease state of organ/system. Along with signs and symptoms and other related parameters; the laboratory test results shall be useful in diagnosis of a disorder.

3. **Therapeutic management decision:** Laboratory test results can be useful in setting therapeutic goals, thereby deciding appropriate therapy and thereafter therapeutic management decision.
4. **Drug therapy monitoring:** Once therapeutic goals are decided and therapy instituted; the next step is to monitor the therapy to see whether expected therapeutic goal are achieved or not. To support clinical assessment, the laboratory tests results shall be required in this monitoring process. This will assist in deciding whether therapy is appropriate, adequate, efficient or needs any modification.
5. **Communication with other members of healthcare team:** The knowledge and expertise of pharmacist in clinical laboratory test results and their interpretation shall make him competent to actively participate in patient care along with other members of healthcare team.

Q2. Write a note on haematological tests. Give the significance and interpretation of test results.

OR

Write a note on clinical laboratory tests of blood.

HEMATOLOGICAL TESTS

Hematological tests are most commonly used clinical laboratory tests for the purpose of diagnosis.

Hematological tests			
Sr. no.	**Physiological terms**	**Normal range**	**Significance**
1.	RBC/ Erythrocyte count	Men: 4.5 to 5.5 million/mm^3 Women: 3.5 to 5.5 million/ mm^3 Children: 5 to 5.5 million/ mm^3	RBC count increases in heart diseases, polycythemia, cholera. Decrease indicates anemia
2.	Hemoglobin value	Men: 15.5 ± 2.5 gm% Women: 14 ± 2.5 gm% Children up to 18 gm%	Hemoglobin value above normal indicates polycythemia Hemoglobin value below normal is seen in anemia

Contd.

<table>
<tr><th colspan="4">Hematological tests (Contd.)</th></tr>
<tr><th>Sr. no.</th><th>Physiological terms</th><th>Normal range</th><th>Significance</th></tr>
<tr><td>3.</td><td>WBC/ Leucocyte count</td><td>4000 to 11000 cells/mm^3</td><td>High count indicates leucocytosis, leukemia
Low count indicates leucopenia, typhoid, hepatitis</td></tr>
<tr><td>4.</td><td>Erythrocyte sedimentation rate (ESR)</td><td><table><tr><th>Methods</th><th colspan="2">Normal values (mm/hr)</th></tr><tr><th></th><th>Male</th><th>Female</th></tr><tr><td>Western green</td><td>0–15</td><td>0–20</td></tr><tr><td>Wintrobe</td><td>0–9</td><td>0–15</td></tr><tr><td>Culter</td><td>0–8</td><td>0–10</td></tr></table></td><td>High ESR in coronary thrombosis, cancer, anemia
Low ESR in allergy</td></tr>
<tr><td>5.</td><td>Clotting time of blood</td><td><table><tr><th colspan="2">Methods</th><th>Normal values in minutes</th></tr><tr><td rowspan="2">Capillary blood method</td><td>Slide method</td><td>2–6</td></tr><tr><td>Capillary tube method</td><td>2–6</td></tr><tr><td rowspan="2">Venous blood method</td><td>Howel method</td><td>10–30</td></tr><tr><td>Lee and White method</td><td>5–15</td></tr></table></td><td>It is used to diagnose hemorrhagic diseases where clotting time taken abnormal
For example, Hemophilia, Vit K deficiency, obstructive Jaundice, anemia</td></tr>
<tr><td>6.</td><td>Prothrombin time</td><td>10–14 seconds</td><td>PT is prolonged if there is deficiency of factors VII,X,V or II or fibrinogen.</td></tr>
<tr><td>7.</td><td>MCV (Mean Corpuscular Volume)</td><td>87 ± 5 um^3/cell</td><td>Increased count indicates macrocytic anemia
Decreased count indicates microcytic anemia</td></tr>
<tr><td>8.</td><td>Platelet count</td><td>150000 – 300000/mm^3</td><td>Increase is seen in rheumatoid arthritis, tuberculosis, liver cirrhosis, etc.</td></tr>
</table>

Contd.

Hematological tests (Contd.)			
Sr. no.	**Physiological terms**	**Normal range**	**Significance**
9.	Blood sugar	80–120 mg/l00 ml (normal range for fasting and post-absorptive blood sugar)	Blood sugar above normal causes diabetes mellitus, (hyperglycemia) Blood sugar below normal causes hypoglycemia
10.	Blood cholesterol	150–240 mg% in young adult	Cholesterol value above normal value indicates diabetes, obstructive jaundice Cholesterol value below normal indicates hyperthyroidism, hemolytic jaundice.

Q3. What are liver function tests (LFT)? Give its objectives. Mention various liver disorders. Enlist/classify various liver function tests.

Liver Function Tests

Liver function tests are the tests based on excretory function of liver and are related to bilirubin metabolism.

Objectives/Uses of Liver Function Tests

1. To detect the presence of liver disease.
2. To distinguish among different types of liver disorders
3. To know the extent of liver damage
4. To follow the response to the treatment.

Various Liver Dysfunctions/Disorders

- Cirrhosis of liver
- Fatty liver
- Cancer of liver
- Genetic disorders of liver
- Hepatocellular diseases (viral hepatitis, ALD)
- Jaundice
- Hemochromatosis (iron storage)
- Wilson's disease.

Classification of Liver Function Tests

Liver function tests are classified into five classes according to the function of the liver as:

1. **Tests based on excretory function**
   It includes measurement of:
   - Serum bilirubin
   - Urine bilirubin
   - Urine bile salts
   - Bromosulphophthalein (BSP) dye tests
2. **Tests based on detoxification function**
   It includes determination of:
   - Hippuric acid test.
   - Blood ammonia and bilirubin
3. **Tests based on synthetic function**
   It includes determination of:
   - Plasma proteins, albumins and globulins
   - Prothrombin time
4. **Tests based on metabolic function**
   It includes:
   - Test related to carbohydrate metabolism
     - Galactose tolerance test.
   - Test related to lipid metabolism
     - Determination of serum cholesterol and ratio of free to esterified cholesterol.
   - Test related to protein metabolism
     - Serum protein estimation
     - Serum ammonia estimation
5. **Determination of serum enzymes**

- Serum aspartate transaminase (AST)
- Serum alanine transaminase (ALT)

Q4. Explain various tests used to access the liver function (LFT).

1. Test for Bilirubin

Bilirubin is the excretory end product of heme degradation. It is conjugated in liver to form bilirubin diglucoronide and excreted in bile.

A. Serum Bilirubin

- The normal concentration of serum bilirubin is in the range of 0.2–1.00 mg/dl.

- Out of this, the conjugated bilirubin is about 0.2–0.4 mg/dl while the unconjugated bilirubin is 0.2–0.6 mg/dl

I. van den Bergh Reaction

This is a specific reaction to identify the increase in serum bilirubin (above the reference level)

- Normal serum gives a negative van den Bergh reaction.
- **Direct and indirect reactions:** Bilirubin as such is insoluble in water while the conjugated bilirubin is soluble.
- van den Bergh reagent reacts with conjugated bilirubin and gives a purple colour immediately within 30 seconds.
- This is known as a direct positive van den Bergh reaction.
- Addition of methanol dissolves the unconjugated bilirubin which then gives the van den Bergh reaction within 30 minutes. and this is referred to as indirect positive.
- If the serum contains both conjugated and unconjugated bilirubin in high concentration, the purple colours produced immediately (direct positive) which is further intensified by the addition of alcohol (indirect positive).
- This type of reaction is known as biphasic.

II. van den Bergh Reaction and Jaundice

This reaction is highly useful in understanding the nature of jaundice.

- This is due to the fact that the type of jaundice characterised by increased serum concentration of unconjugated bilirubin (haemolytic), conjugated bilirubin (obstructive) or both of them (hepatic).
- Therefore, the response of van den Bergh reaction differentiates the jaundice as follows:

Indirect positive: Haemolytic jaundice

Direct positive: Obstructive jaundice

Biphasic: Hepatic jaundice

B. Bilirubin in Urine

- The conjugated bilirubin, being water soluble is excreted in urine but unconjugated bilirubin is not excreted in urine.
- Bilirubin in urine can be detected by Fouchet's test or Gmelin's test

a. Fouchet's test:

- **Principle:** Bilirubin is precipitated by barium chloride. This bilirubin is oxidised to green biliverdin by Fouchet's reagent.

- **Test (Fouchet's test):**
  i. Acidify 10 ml of urine with a few drops of dilute acetic acid and add 5 ml of 10% solution.
  ii. If there is no much precipitate add 2 drops of saturated solution of magnesium sulphate, mix and allow to stand for a few minutes.
  iii. Filter and unfold the filter paper.
  iv. Add one drop of Fouchet's reagent to precipitate.
  v. The development of green colouration indicates the presence of bile pigments.

b. Modified Gmelin's test: To 10 ml of urine, add 2–3 drops of dil. HCl. Filter it through paper, allow to dry and put a drop of con. HNO_3 at the apex of paper. Different coloration can be seen in the order of green, blue, violet, red and yellowish red, showing the presence of bile pigments.

2. Test for serum Enzymes

- Liver cells contain several enzymes which may be released into the circulation in liver damage.
- The measurement of some enzymes in serum is used to access the liver function.

a. Transaminases of aminotransferases

The activities of the following two enzymes are widely used to access the liver function.

i. Serum glutamate pyruvate transaminase (SGPT), recently called alanine transaminase (ALT)
ii. Serum glutamate oxaloacetate transaminase (SGOT), recently called aspartate transaminase (AST)
  - Serum ALT and AST are increased in liver'damage.
  - The alanine transaminase is more sensitive and reliable for the assessment of LFT.

b. Alkaline phosphatase (ALP)

- Alkaline phosphatase (ALP) is mainly derived from bone and liver.
- The rise in serum ALP (normal 3–13 KA units/dl) usually associated with elevated serum bilirubin which indicates the condition of obstructive jaundice.
- ALP is also elevated in cirrhosis of liver and hepatic tumors.

c. γ-Glutamyl transpeptidase

- Measurement of γ-glutamyl transpeptidase (GGT) activity provides a sensitive index to assess liver abnormality.

- Serum GGT is highly elevated (Normal 10 to 15 U/L) in biliary obstruction and alcoholism.

d. Serum albumin

- Albumin is solely synthesized in liver.
- It has half life of about 20–25 days, therefore, it is a good marker to access chronic liver damage.
- Low serum albumin is commonly observed in patients with severe liver damage.
- Functional impairment in liver is frequently associated with increased synthesis of globulins.
- Cirrhosis of liver causes a reversal of albumin/globulin ratio (A/G ratio).

Q5. Mention various tests used to assess the kidney/renal function.

The kidney function test divided into four groups.

1. Glomerular function tests:
   a. Clearance test
   b. Creatinine clearance test
   c. Urea clearance test

2. Tubular function tests
   a. Urine concentration test (dilution test)
   b. Urine acidification test

3. Analysis of blood/serum:
   a. Estimation of blood urea
   b. Estimation of serum creatinine
   c. Estimation of protein and electrolytes

4. Urine examination:
   a. Urine examination for volume of urine
   b. pH
   c. Specific gravity
   d. Osmolality
   e. For presence of abnormal constituents such as proteins, blood, ketone bodies, glucose

Q6. Explain the following tests to assess the function of kidney/renal function along with their clinical significance.

a. Clearance test.
b. Creatinine clearance test
c. Urea clearance test.

a. Clearance Test

Clearance test is used to access the rate of glomerular filtration (GFR) and renal blood flow.

Definition

The renal clearance of a substance is defined as the volume of plasma from which the substance is completely cleared by the kidneys per minute.

This depends on:

i. Plasma concentration of the substance and its excretion rate.
ii. GFR (normal 120 ml/minute)
iii. Renal plasma flow

Clearance (C) is expressed as ml/minute

Clearance can be calculated by using formula,

$$C = \frac{U \times V}{P}$$

Where, U = Concentration of the substance in urine

V= volume of urine in ml excreted per minute

P = Concentration of the substance in plasma

- The clearance of a given substance is determined by its mode of excretion.
- The maximum rate at which the plasma can be cleared of any substance is equal to the GFR.
- Inulin is intravenously administered to measure GFR.
- The two compounds, namely urea and creatinine are commonly employed for this purpose.
- Creatinine clearance (~ 145 ml/min) is marginally higher than the GFR, as it is cleared by the tubules.
- On the other hand, urea clearance (~ 75 ml/min) is less than the GFR, since it is partially reabsorbed by the tubules.

b. Creatinine Clearance Test

- Creatinine is an excretary product derived from creatine phosphate (largely present in muscle).
- Creatinine is filtered by the glomeruli and only marginally secreted by the tubules.
- The value of creatinine clearance is close to GFR, hence its measurement is a sensitive and good approach to access the renal glomerular function.

Definition of the Creatinine Clearance

Creatinine clearance may be defined as the volume (ml) of plasma that would be completely cleared of creatinine per minute.

- In the traditional method, creatinine content of a 24-hour urine collection and the plasma concentration in this period are estimated.
- The creatinine clearance (C) can be calculated as follows:

$$C = \frac{U \times V}{P}$$

where, U = Urine concentration of creatinine
V = Urine output in ml/min
(24-hour urine volume divided by 24 × 60).
P = Plasma concentration of creatinine

- **Reference values:** The normal range of creatinine clearance is around 120–145 ml/min. These values are slightly lower in women.
- **Clinical significance/Diagnostic Importance**
  1. A decrease in creatinine clearance value (< 75% normal) serves as sensitive indicator of a decreased GFR, due to renal damage.
  2. This test is useful for an early detection of impairment in kidney function.

c. Urea Clearance Test

- Urea is the end product of protein metabolism.
- After filtration by glomeruli, urea is partially reabsorbed by the renal tubules. Hence, urea clearance is less than the GFR. Therefore, urea clearance is not as sensitive as creatinine clearance for assessing renal function.
- **Definition of urea clearance:** Urea clearance is defined as the volume (ml) of plasma that would be completely cleared of urea per minute.
- Urea clearance is calculated by the formula,

$$Cm = \frac{U \times V}{P}$$

where, Cm = maximum urea clearance
U = Urea concentration in urine (mg/ml)
V = Urine excreted per minute in ml
P = Urea concentration in plasma (mg/ml)

The normal value of urea clearance is around 75 ml/min

- **Standards of urea clearance:** It is observed that the clearance drastically changes when the volume of urine is less than 2 ml/min.

This is known as standard urea clearance (Cs) and the normal value is around 54 ml/min.

Q7. Explain various common tests performed for urine examination/ urine analysis.

Urine Analysis/Urine Examination:

The urine analysis includes the following various tests:

1. Physical examination
2. Chemical examination
3. Microscopic examination of urine.

1. Physical Examination

A Physical examination includes:

a. The 24 hours urinary output (volume)
b. Appearance (color)
c. Specific gravity and osmolality
d. pH
e. Odour

a. Volume

The daily output of urine in adult is 800 to 2,500 ml with an average of 1,500 ml/day.

The quantity normally depends on the water intake, the external temperature, the diet and the mental and physical state, cardiovascular and renal function.

Polyuria: Volume more than 2,500 ml/day occurs in

- Diabetes mellitus, up to 5–6 L/ day
- Diabetes insipidus, 10–20 L/ day
- Later stages of chronic glomerulonephritis, 2–3 L/day

Oliguria: Volume 500 ml/ day due to: Fever, diarrhoea, acute nephritis, early stages of glomerulonephritis, cardiac failure.

Anuria: Complete cessation of urine occurs in: Acute tubular necrosis, bilateral renal stones, surgical shock.

b. Appearance (colour)

- Normal urine is transparent pale yellow or amber colour.
- Variation in colour may be physiological or pathological.
- Darkening from the normal pale yellow colour indicating more concentrated urine or presence of another pigment.

  - Hemoglobin and myoglobin in urine produce brownish coloration.
  - Turbidity in a fresh sample may indicate infection but also may be due to fat particles in an individual with nephrotic syndrome.
- Reddish colouration in hematuria is due to renal stones, cancer, some injury or disease of kidneys or urinary tract.

c. Specific gravity and osmolality

- The specific gravity indicates the concentrating ability of the kidney. It normally varies from 1.016 to 1.025 with an average 1.020. It can vary widely depending on diet, fluid intake and renal function. If renal function is impaired, the quantity of eliminated urine will be very less. In this condition increased specific gravity may be seen.
- The urine osmolality of normal individuals varies widely depending on the state of hydration. After excessive intake of fluids, the osmotic concentration may fall as low as 50 mOsm/kg, whereas with restricted fluid intake it is up to 1,200 mOsm/kg have been observed. On an average, fluid intakes 300 to 900 mOsm/kg are found.

d. pH

The urine is normally acidic in reaction with a pH of about 6.0 (range 5.5 to 7.5).

Alkaline urine is found in urinary tract infection.

e. Odour

Fresh urine is normally aromatic. Foul smell indicates bacterial infection.

2. Chemical examination

Chemical examination includes detection of the following:

- Glucose
- Protein
- Blood
- Pus
- Ketone bodies
- Bile pigments and salts

Glucose

- Normal urine contains small amounts of glucose which cannot be detected by routine test.
- Excretion of detectable amounts of glucose in urine is called glycosuria. It indicates disease diabetes mellitus.

Protein

- Increased amount of protein in urine, i.e. proteinuria can be caused by:
  - Increased glomerular permeability
  - Reduced tubular reabsorption
- Most common type of proteinuria is due to albumin.

Blood

Presence of blood in urine is called hematuria and is commonly seen due to some injury or disease of kidneys or urinary tract. It may be found in renal stones, cancer, tuberculosis, trauma of kidney or acute glomerulonephritis.

Pus: The presence of pus in the urine is called pyuria. Pyuria is caused due to inflammation of urinary bladder, urethra and pelvis of the kidney.

Ketone bodies: The presence of ketone bodies in the urine condition is called as ketonuria.

Ketonuria occurs in the following pathological conditions:

i. Carbohydrate starvation
ii. Pregnancy
iii. In anaesthesia.

Bile pigments and bile salts

When bile appears in the urine the condition is called jaundice.
The bile pigments appear in all types of jaundice.

i. Haemolytic jaundice
ii. Obstructive jaundice
iii. Toxic jaundice.

3. Microscopic Examination

- Microscopic examination of the centrifuged urinary sediment is done to detect:
  i. **Cells**, e.g. RBC, WBC, pus cells
  ii. **Crystals**, e.g. calcium phosphate, calcium oxalate, amorphous phosphates, etc.
  iii. **Casts**, e.g. hyaline casts, granular, casts, red blood casts, etc.
  iv. Presence of crystals in the urine may be a clue to the diagnosis of a specific type of renal calculus. Various components are observed on microscopic examination of urine in renal disease.

Q8. Explain various thyroid function tests.

Thyroid Function Tests

Thyroid function tests are classified as:

1. *In vitro* thyroid function tests

i. Serum total T4 and T3 by immunoassay
ii. Free serum T3 and T4

iii. Thyroxin binding globulin (TBG)
iv. Resin uptake test (T3RU)
v. Serum thyroid stimulating hormone (TSH)

2. ***In vivo* thyroid function tests**
   i. Thyroid iodine uptake test
   ii. TRH stimulation test
   iii. TSH stimulation test

A. Thyroid gland:

- Thyroid gland secretes two main hormones
  i. Thyroxine (T4)
  ii. Tri-iodothyronine (T3)
- Thyroid gland influences the body growth, metabolism and storage of iodine.
- Thyroid gland utilizes the iodine from the blood plasma for synthesis of these two hormones.
- The overproduction of thyroid hormones is called hyperthyroidism and underproduction of hormones is called hypothyroidism.

B. Parathyroid glands:

- This gland secretes parathyroid hormone, i.e. parathormone which is responsible for regulating serum calcium and phosphate levels.
- The excess secretion (hyperparathyroidism) raises plasma calcium levels and causes extensive decalcification of bones leading to deformities and fracture.
- The low secretion of (hypoparathyroidism) leads to decrease in plasma calcium level may cause muscle spasm and twitching.

Thyroid function test, values and interpretation is as follows:

Sr. no	Name of test	Normal range	Interpretation
1.	"TSH" test—thyroid stimulating hormone/serum thyrotropin	0.5 to 5 milli units/L	Lesser value indicates hyperthyroidism Higher value indicates hypothyroidism
2.	Total T_4/serum thyroxine	5.5–12.5 µg/dL	Decreased value indicates hypothyroidism. Neoplastic disease, DM, burns, trauma, liver disease, renal failure, prolonged infections and CVD are illness that can lower total serum T_4 concentrations. Increased value indicates hyperthyroidism. Psychiatric disorders happens.

Contd.

Contd.

Sr. no	Name of test	Normal range	Interpretation
3.	Free T_4	0.9 to 2.3 ng/dl	Lesser value is considered indicative of hypothyroidism.
4.	Total T_3/serum tri-iodothyronine	80–200 ng/dl	Lesser value indicates hypothyroidism leading to malnutrition, cirrhosis and uremia.

Q9. Discuss various clinical tests associated with cardiac disorders.

Tests associated with cardiac disorders include:

1. Lipid profile tests (lipid panel)
2. Cardiac markers

1. Lipid Profile/Lipid Panel

Lipid profile and lipid panel is a panel of blood tests that acts as a initial screening tool for abnormalities in lipid, such as cholesterol and triglycerides.

A complete cholesterol tests are also known as lipid profile or lipid panel. A typical lipid profile includes the following tests:

l. High density lipoprotein cholesterol (HDL cholesterol), i.e. "good cholesterol''.
2. Low density lipoprotein cholesterol (LDL cholesterol), i.e. "bad cholesterol".
3. Total cholesterol
4. Triglycerides.
5. LDL/HDL ratio
6. Very low density lipoprotein cholesterol (VLDL cholesterol)

Lipid profile

Lipid profile tests are used to estimate increased risk of cardiovascular diseases.

Type	Normal range	Border line	High risk
Cholesterol	<200 mg/dl	200–239 mg/dl	240 mg/dl
Triglycerides	<150 mg/dl	150–199 mg/dl	200–499 mg/dl
HDL cholesterol	60 mg/dl	35–45 mg/dl	< 35 mg/dl
LDL cholesterol	60–130 mg/dl	I 30–139 mg /dl	160–189 mg/dl
Cholesterol/ HDL ratio	4.0	5.0	6.0

Clinical Significance of Lipid Profile

Lipid profile is useful for-

1. Screening of suspected heart diseases like coronary artery disease, stroke, etc.
2. To evaluate CVS disorders by analysing cholesterol level in the blood.
3. To prevent the damage of blood vessels and arteries.
4. To avoid the rise of disorders like heart attack, arteriosclerosis, hyperthyroidism, multiple myeloma, hypercholesterolaemia.
5. Low levels of triglycerides may produce hypobetalipoproteinemia and high levels may produce metabolic syndromes.
6. Increased level of HDL is observed in excercise and moderate consumption of alcohol while decreased level of HDL is observed in obesity, tension, haepatocellular diseases and cigarette smoking.

2. Cardiac Markers

- After myocardial infarction, a number of intracellular enzymes and proteins are released from the damaged cells.
- These enzymes are called cardiac markers and are used in diagnosis of cardiac disorders.
- Cardiac markers are used in the detection of acute myocardial infarction (AMI).
- The cardiac markers include enzymes such as:
  - i. Creatine kinase (CK)
  - ii. Lactate dehydrogenase (LD)
  - iii. Serum aspartate amino transferase (AST), or
    Serum glutamate oxaloacetate transaminase (SGOT)
  - iv. Troponins (Tn)

i. Creatine kinase (CK)

- Creatine kinase has three isoenzymes.
- CK-2 isoenzyme is specific for the heart
- Reference values

  Normal value for CK: 10 to 100 U/L

  The upper limit for CK: 6 U/L

Clinical interpretation/Significance

- There is a rise in total CK activity following a myocardial infarction.
- CK-2 is a more sensitive and specific test for AMI than total CK.

ii. Lactate dehydrogenase (LDH)

- LDH is distributed widely in liver, cardiac muscles, kidney, skeletal muscle, erythrocytes.
- LDH has five isoenzymes. LDH-1 is specific for the heart.

Reference values

Total LDH = 125 to 290 U/L

LDH-1 = 100 U/L

Clinical interpretation

The serum total LDH is increased in a wide variety of disease including heart disease.

iii. AST/SGOT:

- AST is found practically in every tissue of the body, including red blood cells.
- High concentration of AST occurs in cardiac muscle and liver, intermediate in skeletal muscle and kidney.

Reference value

Normal concentration of serum AST = 6 to 25 U/L

Clinical interpretation:

Prolonged myocardial ischemia, congestive heart failure are also associated with an increased AST level.

iv. Troponins (Tn)

- It is a complex of three proteins:

a. Troponin T

b. Troponin C

c. Troponin I

Troponin I is very sensitive and specific for myocardial tissue.

Reference value

The normal value of troponin I = 0.7 to 1.5 μg/L

Clinical interpretation:

Increased level of troponin I greater than 2.0 μg/L is indicative of acute myocardial injury.

Q10. Explain clinical laboratory tests of fluid and electrolyte balance.

Tests for Fluid and Electrolyte Balance

A. Test for total body water (TBW)

- Total body water includes water both inside and outside of cells and water normally present in the gastrointestinal and genitourinary systems.

Reference values

Men: 60% of body weight

Women: 55% of body weight

Clinical significance:

- Increase in body water content is associated with renal failure
- Decrease in body water content associated with dehydration and circulatory failure.

B. Tests for Electrolytes

- The electrolytes are well distributed in body fluids and play an important role in distribution and retention of body water by regulating osmotic equilibrium.
- The concentration of electrolytes is expressed as milliequivalent per litre (mEq/L)
- The changes in blood levels of some electrolytes and their significance is shown as follows.

Sr. no	Electrolyte	Normal range	Variation	Interpretation/Significance
1.	Sodium	135–145 mEq/L	Increase	Hypernatremia, typically causes thirst, may lead to brain dysfunction. It is due to water depletion, combined sodium and water depletion or sodium excess. Lithium, phenytoin are the drugs that induce hypernatraemia.
			Decrease	Hyponatraemia, function due to loss of sodium, water retention or combination of both. Drugs which augment the action of ADH and/or release of ADH, e.g. chlorpropamide, carbamazepine.
2.	Potassium	3.7-5.2 mEq/L	Increase	Hyperkalemia: Kidney disease Addison's disease, drug-induced hyperkalemia are due to drugs like antihypertensives (beta blockers, ACE inhibitors), NSAIDs antibiotics like amoxicillin.
			Decrease	Hypokalemia: Vomiting, use of drugs like phenytoin, phenobarbitone, frusemide. Pancreatitis, Vit. D deficiency.

Contd.

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Sr. no	Electrolyte	Normal range	Variation	Interpretation/Significance
3.	Calcium	9–11 mEq/L	Increase	Hypercalcemia, malignant disease, hyperthyroidism, thyrotoxicosis, etc. Drug-induced hypercalcemia is due to drugs like lithium, thiazide diuretics, tamoxifen, etc.
			Decrease	Hypocalcemia: Hypoalbuminaemia, pancreatitis, liver disease, renal disease. Phenytoin, phenobarbitone, calcitonin, frusemide, etc. may induce hypocalcemia.

Q11. Write a note on pulmonary function test/lung function test.

Pulmonary Function Tests

Pulmonary function test are a group of tests that measure functional capacity of lung and how efficiently they transfer the oxygen into the blood.

These tests are useful in accessing the functional status of the respiratory system.

The following tests are used to check pulmonary functions:

1. Spirometry
2. Diffusion capacity test
3. Body plethismography
4. Exercise challenge testing
5. Six-minute walk test (6 MWT)
6. Maximal inspiratory pressure and maximal expiratory pressure.

1. Spirometry

- Spirometry is a pulmonary function test (PFT)
- Spirometry is helpful in accessing breathing patterns that identify conditions such as asthma, pulmonary fibrosis, cystic fibrosis and COPD (chronic obstructive pulmonary disease).
- Spirometry measures the maximum amount of air that can be exhaled by the patient after complete inhalation.
- Spirometry measures how much air you breathe and out and how fast you blow it out. This is measured in two ways:
  i. Peak expiratory flow rate (PEFR)
  ii. Forced expiratory volume in 1 second (FEV_1)

- PEFR refers to the amount of air you can blow air out as quickly as possible.
- FER_1 refers to the amount of air you can blow in 1 second.

Procedure

- The test is done by taking a deep breath and then blowing out all of the air as fast as possible into a tube connected to spirometer.
- Test is repeated three times to get the best result.

Parameters Used

a. FEV_1: It is the forced expiratory volume in 1 second. FEV_1 is the indicator of airway function.

b. FVC: Forced vital capacity.
It is the total volume of air in litres forcefully and rapidly exhaled in one breath.

c. SVC: Slow vital capacity
When the full inhalation–exhalation procedure is repeated slowly (instead of forcefully and rapidly), it is called the slow vital capacity.

d. RV: Residual volume
It is the volume of air left in the lungs at the end of forced expiration.
Normal value: 1200 to 1500 ml
In diseases like COPD, the RV increases since the patient is unable to mobilise the air trapped in the lungs behind these obstructions.

e. TLC: Total lung capacity.
It is the total amount of air present in the lungs at maximum inhalation.
Normal value: 6 litres.

2. Diffusion capacity test

- This test measures the ability of gases to cross (diffuse) the alveolar-capillary membrane.
- This test measures the transfer of gas (CO) from alveoli to the blood.
- The test is called diffusion capacity of lungs to carbon monoxide (DLCO).
- The normal DLCO value ≥70% of the predicted value is considered as normal.

Clinical Interpretation/Significance

- An increase in DLCO indicates the pulmonary edema or asthma.
- Diffusion capacity is low in pulmonary fibrosis, sarcoidosis.

3. Body Plethismography

- Body plethismography is a pulmonary function test
- A plethismography is an instrument used for measuring changes in volume within an organ or whole body.
- Body plethismography is a pulmonary function test that determines how much air is in the lungs after you take in a deep breath.

Clinical Interpretation

It is used to obtain various lung volumes at different stages of inflation of the lungs.

4. Exercise Challenge Testing

- This test is used to confirm exercise-induced bronchospasm (EIB) and to evaluate the effectiveness of medications used to treat or prevent EIB.
- Exercise tests are usually done with a motor-driven treadmill or an electromagnetically braked cycle ergometer.
- The exercist test is started at low speed that is gradually increased over two to four minutes until the heart rate is 80–90% of the predicted maximum.
- After the test, the spirometry is done and decrease in FEV_1 by 10% or more is considered as an abnormal response.

5. Six-Minute Walk Test (6MWT)

- This test is used to measure the distance that a patient can walk on a flat, hard surface in six minutes
- While performing this test, patient is asked to walk as far as possible in six minutes, allowing stopping and resting during the test. Pulse oxymeter is usually used before the test.
- Normal values for healthy adult is 500–630 meters and for healthy children 470 meters.

Clinical Significance

- This test is used to assess the amount of oxygen needed with exertion.
- The oxygen saturation of 88% or lower indicates the need for supplemental oxygen.

6. Maximal Inspiratory Pressure and Maximal Expiratory Pressure

- Maximal inspiratory pressure is a measure of the strength of inspiratory muscles, primarily the diaphragm and allows for the

assessment of ventilatory failure, restrictive lung disease and respiratory muscle strength.

- The test is quick and non-invasive.

Objective Questions with Answers in Bold Letters

1. MCV stands for **mean corpuscular volume**.
2. ESR stands for **erythrocyte sedimentation rate**.
3. AST stands for **serum aspartate transaminase**.
4. ALT stands for **serum alanine transaminase**.
5. ALP stands for **serum alkaline phosphatase**.
6. GFR stands for **glomerular filtration rate**.
7. HDL cholesterol stands for **high density level cholesterol**.
8. LDL cholesterol stands for **low density level cholesterol**.
9. VLDL cholesterol stands for **very low density level cholesterol**.
10. SGOT stand for **serum glutamate oxaloacetate transferase**.
11. PFTs stands for **pulmonary function test**.
12. Conjugated hyperbilirubinemia with raised phosphatase levels are found in **obstructive jaundice**.
13. **HDL** has a protective effect against myocardial infarction.
14. **Alkaline phosphatase** is important in the diagnosis of obstructive jaundice.
15. **Troponin** is a cardiac markers.
16. The volume of plasma that would be completely cleared of creatinine per minute is known as **creatinine clearance**.
17. Inulin clearance is used to access **glomerular filtration rate**.
18. The total solute concentration expressed as milli osmols per litre is known as **osmolality**.
19. The normal leucocyte count is **4000–11000 per mm^3 of blood**
20. In haemolytic "jaundice **urinary urobilinogen excretion is increased**.
21. Positive direct van den Bergh's reaction indicates presence of **conjugated bilirubin**.
22. Increased plasma level of **HDL cholesterol** is a risk factor of CHD.
23. A **complete blood count (CBC)** measures the size, number and maturity of the different blood cells.
24. Normal value of blood cholesterol is **150–240 mg%** in young adult.

25. Failure of concentrating capacity of urine is accessed by measurement of **fluid deprivation test**.
26. **Fouchet's test** is used for detection of bile pigments.
27. Prothrombin time in obstructive jaundice normalizes after **parenteral injection of vitamin K**.
28. GGT means **gama glutamyl transpeptidase**.
29. Creatinine clearance test is a **renal function test**.
30. Absence of urobilinogen in urine, it occurs in **obstructive jaundice**.
31. **Modified Gmelin's test** is used for the detection of bile pigments.
32. When blood appears in the urine, it is called **haematuria.**
33. Overproduction of thyroid hormone is called **hyperthyroidism**.
34. Lipid profile tests also known as **lipid panel**.
35. **Cardiac markers** are used in acute myocardial infarction (AMI).
36. If pus cells appear in the urine, the condition is called **pyuria**.
37. The total body water in men is about **60%** of body weight.
38. Normal range of serum thyroxine is **5.5 to 12.5 μg/dl**.
39. When bile appears in the rine, the condition is known as **jaundice**.
40. The concentration of electrolytes is expressed as **milliequivalent per litre (mEq/L)**.
41. **Spirometry** is a pulmonary function test (PFT).
42. Normal value of total lung capacity is **6 litres**.
43. Body plethismography is **pulmonary function test**.
44. The normal range of blood calcium level is **9–11 mEq/L**.
45. Six-minute walk test (6MWT) is a **pulmonary function test**.
46. FEV_1 means **forced expiratory volume in one second**.
47. **Plethismograph** is an instrument used for measuring changes in volume within an organ or whole body.
48. In polyuria volume of urine excreted per day is more than **2500 ml.**

Chapter 10

Poisoning

Q1. Define and classify poisons with suitable examples.

Poison

It is defined as a substance which when administered, inhaled, swallowed, applied locally, causes toxic effects on the body.

Classification of Poisons

A. Irritant poisons, e.g.
   a. Organic, e.g. snake-venom
   b. Inorganic, e.g. lead, mercury
   c. Mechanical, e.g. glass powder

B. Corrosive poisons, e.g. conc. HCl, conc. H_2SO_4

C. Neurotic poisons, e.g. opium, strychnine

D. Cardiac poisons, e.g. digitalis

E. Pulmonary poisons, e.g. CO

F. Miscellaneous, e.g. hallucinogens, antibiotics

A. Irritant poisons: They produce symptoms of pain in the abdomen, vomiting, etc.

They are classified as:

a. Organic irritants:
   i. Vegetable, e.g. ergot
   ii. Animal, e.g. snake-venom.

b. Inorganic irritants:
   i. Metallic, e.g. lead, arsenic
   ii. Non-metallic, e.g. phosphorus.

c. Mechanical irritants, e.g. glass powder.

B. Corrosive poisons: A corrosive poison is simply a highly active irritant and not only produces inflammation but also acute ulceration of tissues.

They are classified as:

i. Strong acids, e.g. H_2SO_4, HNO_3, HCl

ii. Organic acids, e.g. oxalic acid, carbolic acid.

iii. Concentrated alkalies, e.g. conc. NaOH, KOH

C. Neurotic poisons: These poisons mainly act on CNS and may produce symptoms like headache, delirium, stupor, paralysis, coma, etc.

For example, opium alkaloids, nux vomica, conium and curare alkaloids.

D. Cardiac poisons: These are acting on heart, e.g. digitalis.

E. Pulmonary poisons: These are affecting function of lung and interfere normal respiration, e.g. carbon monoxide.

F. Miscellaneous poisons: These include hallucinogens, antibiotics, antihistaminics.

Q2. What are different types of poisonings?

Types of Poisoning

A. According to purpose of poisonings it is classified as:

a. Suicidal poisoning: Person consumes poison to kill himself.

b. Homicidal poisoning: Poison is used to kill another person.

e. Accidental poisoning: The poison is consumed by mistake.

B. On the basis of onset of action poisoning is classified into two groups:

a. Acute poisoning

- It is generally due to consumption of a large amount of poison.
- It may be accidental, intentional or non-intentional.
- The symptoms develop very rapidly in severity.
- The aggravation of symptom is fast, therefore, treatment should be given quickly otherwise death may occur.
- The malfunctioning of respiratory and cardiac function causes further death
- General symptoms of acute poisoning are vomiting, diarrhoea, convulsions, coma, respiratory or circulatory failure.
- It requires supportive, symptomatic and specific treatment.

b. Chronic poisoning

- The symptoms are observed very slowly.
- It is due to consumption of small amount of poison but with definite period of interval.

- The aggravation of symptom is very slow.
- The death due to chronic poisoning is rarely observed because more time is available for the treatment.
- General symptoms of acute poisoning are GIT irritation, confusion, insomnia.
- Usually symptomatic treatment is given if required.

Q3. Define and classify antidotes with examples.

Antidotes

The substances which stop the effects of poison are called antidotes.

Classification of Antidotes

1. **Physiological antidote:** It changes the physiology of body to prevent the effect of poison, e.g. sodium nitrite used in cyanide poisoning (dose 10 mg/kg).
2. **Chemical antidote:** It reacts with poison and converts it into non-poisonous compounds, e.g. sodium thiosulphate (dose 0.3–0.5 mg/kg).
3. **Mechanical antidote:** It prevents the absorption of poison, e.g. activated charcoal, kaolin.
4. **Universal antidote:** It is a combination of mechanical antidotes. It is useful when type of poison is not known or more than one poisons are consumed.

Composition of Universal Antidote

Magnesium oxide	1 part (neutralizes acid)
Tannic acid	1 part (precipitates alkaloids)
Activated charcoal	2 parts (adsorbs alkaloid)

Dose

One to two tablespoonful should be taken with glass of water. The dose can be repeated after generally ½ hr interval till 4 to 6 hours.

Generally it is ineffective when poison is absorbed and the victim is unconscious.

Q4. Differentiate between acute poisoning and chronic poisoning.

Acute poisoning	Chronic poisoning
1. It is observed due to consumption of large amount of poisoning.	1. It is observed due to consumption of small amount of poison.

Contd.

Contd.

Acute poisoning	Chronic poisoning
2. The symptoms observed are very fast.	2. The symptoms observed are very slow.
3. The aggravation of symptoms is fast.	3. The aggravation of symptoms is slow.
4. Death may occur.	4. Death rarely occurs.
5. Symptoms: Vomiting, diarrhoea, convulsion, coma, respiratory or cardiac failure.	5. Symptoms: GIT irritation, confusion, coma, insomnia.

Q5. What are the steps involved in general treatment of poison? OR What are the principles of general treatment of poisoning?

The following are the steps involved in general treatment of poisoning:

1. Maintenance of normal respiratory and cardiac functions.
2. Removal of unabsorbed poison.
3. Removal of absorbed poison.
4. Use of antidotes.
5. Management of victim by treating general symptoms.

1. Maintenance of Normal Respiratory and Cardiac Functions

- For maintenance of normal respiratory and circulatory failure victim is first exposed to fresh air, if required artificial respiration is provided. Artificial respiration is adjusted by oxygen cylinders.
- CNS stimulants are also used, if required.
- Respiratory stimulants like ammonium carbonate is given.
- Cardiac massage is given.
- To maintain the circulatory function cardiac stimulants may be used.

2. Removal of Unabsorbed Poison

- If poison is ingested orally, gastric lavage is performed to withdraw the gastric contents if the victim is conscious.
- By using emetics such as syrup of ipecac, mustard powder, etc. vomiting is induced to withdraw the contents in stomach.
- Mechanical antidotes like activated charcoal is used to adsorb poison on its surface mainly in case of alkaloidal poisoning.
- Gastric lavage is washing of stomach and it is useful only up to 4 to 6 hours after its consumption. In this method one tube is inserted into the stomach and by creating vacuum the contents are removed

from GIT. This method is very useful in acid and alkaloidal poisoning because vomiting is not applicable for such poisoning treatment.

- To remove the poison from intestine purgatives like sodium or magnesium sulphate are used.
- If poison is inhaled then fresh air is used and artificial respiration is immediately given.
- If the poison is administered through skin, eye or wound then washing of skin or eye by plane warm water and also with water containing specific antidote is advisable.

3. Removal of Absorbed Poison

- The absorbed poison is prevented from its action by converting it into its non-poisonous form or by preventing binding of poison with specific receptors.
- Diuretics like mannitol, frusemide are administered intravenously to increase excretion of poison.
- Hot packs are used to increase the sweating which helps to excrete the poisons through skin.
- Absorbed poison is removed by dialysis method. Dialysis may be peritoneal dialysis or haemodialysis.

4. Use of Antidotes

According to the type of poison and on the basis of route of administration of poison, antidote is selected.

Antidotes either react with poison or prevent binding of poison with receptor.

Common antidotes are sodium nitrite, EDTA, nalorphine, BAL.

5. Management of Victim by General Treatments

i. In case of unconscious victim there is a maximum danger of respiratory infections, therefore, prophylactic antibiotics are used.
ii. To avoid oedema diuretics are used.
iii. To maintain glucose and ionic balance of blood, IV fluids are administered.
iv. To treat weakness, food supplements, vitamins, iron are used.
v. Hypotension is treated.
vi. Analgesics are used as pain killers.
vii. For restoring normal functioning of heart, cardiac stimulants are used.

Q6. Describe different poisoning along with their symptoms, treatments.

1. Mercury Poisoning

Symptoms	Treatments	Dose/Reason
a. Acute poisoning Metallic taste in mouth, grayish white tongue and mouth, nausea, vomiting, cold skin, pale face anorexia, dilated pupil, vomit with white mucus and blood, paralysis, renal failure, loss of weight, liver damage and shock.	• Egg albumin • Charcoal pdr. • Stomach wash • Dimercaprol • Peritoneal dialysis	Mechanical antidote 3 to 4 tablespoonful with water With 5% solutions of sodium formaldehyde. Systemic antidote To prevent renal failure
b. Chronic poisoning Multiple neurological disorders, irritability, shyness, loss of sleep, loss of memory, anxiety, tremors, hallucination, excessive salivation with metallic taste, loosening of teeth with painful gums, colitis, hypertension, anaemia discolouration of lens of eye, renal failure, paralysis, coma	• Artificial respiration • Penicillamine • Dimercaprol • Dry extract of belladonna	Removal of patient from exposure and fresh air is provided to patient Due to stable - SH gr. It is chelating agent. Antidote. When dimercaprol is ineffective, then penicillamine, is a drug of choice. 30 mg 3 times a day promoting elimination of mercury by kidney and bowels.

2. Cocaine Poisoning

Symptoms	Treatments	Dose/Reason
Mydriasis, dryness of mouth, increase in heart rate, hallucinations, black tongue, cyanosis, increase in nasal secretions.	• $KMnO_4$ • Artificial respiration • Phenobarbitone • Tricyclic anti-depressants	Gastric lavage with $KMnO_4$ [1 : 100 diluted H_2O] 100 mg after every 4 hr orally As per requirements Wash skin with water

3. Insecticide Poisoning

Insecticides are developed to kill insects and pests but they are absorbed from skin and GIT and are also toxic to human beings. They all are CNS stimulants and cause convulsions.

Symptoms	Treatments	Dose/Reason
Seizures similar to epilepsy with tremors, nausea, vomiting, ataxia, sensitization of myocardium leading to ventricular fibrillation, pulmonary oedema, liver and kidney damage, agranulocytosis	• Gastric lavage	To remove ingested poison. Skin is washed with soap and water if skin contamination is there.
	• Barbiturates (phenobarbitone 100 mg orally every 4 hr)	To control convulsions
	• Atropine	2 mg every 15 to 30 min by IM, IV.
	• Calcium acetate (10 ml of 10% solution)	Every 6 hr orally or IV to decrease toxicity of insecticides

4. Endrine Poisoning

Symptoms	Treatments	Dose/Reason
Nausea, vomiting, abdominal pains, salivation, convulsions, tremors, oozing of white froth form mouth and nostrils, coma, respiratory failure, death	• Barbiturates (phenobarbitone)	To control convulsions.
	• Calcium by IV	10 ml of 10% solution of calcium by IV after every 6 hr and calcium lactate orally decrease toxicity of endrine

5. Cannabis Poisoning

Symptoms	Treatments	Dose/Reason
Acute edema, excitement, depression, confusion, dilated pupil, drowsiness, hallucinations, increase in muscular movements, deep sleep, loss of weight, loss of appetite, weakness, tremors	• Stomach wash	With water
	• Saline purgatives	For removal of poison
	• Artificial respiration	
	• Strychnine	Hypodermal administration
	• Use of IV fluids	

6. Belladona Poisoning/Atropine Poisoning

Symptoms	Treatments	Dose/Reason
Dryness of mouth, bitter taste, abdominal pains, mydriasis, vomiting, delirium, fever, tachycardia, photophobia	• Stomach wash	With 5% tannic acid
	• Neostigmine physostigmine	As antidote
	• Sponging	To decrease body temperature
	• Diazepam	10 mg by IV

7. DDT Poisoning

Symptoms	Treatments	Dose/Reason
By contact: Tremors, convulsions, irritations of eye, nose, throat pulmonary edema, muscle spasms, paralysis of limb muscles, collapse and death.	• Barbiturates/diazepam (phenobarbitone)	To control convulsions
	• Gastric lavage	Stomach wash with water and antidote solution.
	• Saline cathartics	To increase peristalsis movements and to excrete DDT without absorption.
By oral route: Salivation, nausea, vomiting, abdominal pain, tonic convulsions, tremors, hepatic cancer	• Antibiotic	To treat infection. Use of fat, oils should be avoided.

8. Opium Poisoning/Morphine/Narcotic Poisoning

Symptoms	Treatments	Dose/Reason
1. Excitement: Pleasurable mental excitement with increase in heart rate	• Stomach wash	With water and then with $KMnO_4$ at early stage
2. Stupor: Headache, itching, strong tendency to sleep, sense of weighing limbs, cyanosis of face and lips.	• Enema	Stomach wash is continued till returned water is of pink colour and then to clear intestine, enema is given
3. Nacrosis: Deep coma, relaxation of muscles, loss of reflexes, pin-point pupil, hypertension, low respiration, hypothermia, frothing from mouth	• Glucose saline, naloxone and nalorphine	5% Glucose with saline antidotes till dilation of pupils

9. Organophosphorous Poisoning

Symptoms	Treatments	Dose/Reason
1. Smooth muscles and glands are first affected and then brain centres are affected.	• Artificial respiration • Atropine	To block peripheral actions to counter, i.e. act muscarinic effects
2. Headache, constriction of chest with pin-point pupils	• Oxime compounds, e.g. pralidoxime	To control convulsions
3. Nausea, vomiting, diarrhoea, abdominal cramps, sweating, salivation, muscular switching.	• Antibiotics	To treat respiratory infections
4. Pulmonary edema, coma, convulsions, excessive bronchial secretions, bradycardia, respiratory failure.	• Mercurial diuretics	To avoid oedema.

10. Barbiturate Poisoning

Symptoms	Treatments	Dose/Reason
Nausea, mental confusion, depression, hypotension, skin rash, hypothermia, tremor, muscular weakness, in-coordination, stupor, edema, alternate contraction and relaxation of pupil, decreased urine output, drug automatism, respiratory failure, cold sweat breaks out	• Gastric lavage • Artificial respiration • Metarminol IV • Glucose saline • Haemodialysis • Forced diuresis • Enema	With $KMnO_4$ 2.5 mg, to increase BP 5% with saline for electrolyte balance and nutrition For separation of poison To increase urinary excretion For removal of poison from GIT

11. Barbiturate Poisoning

Symptoms	Treatments	Dose/Reason
Metallic taste, excessive salivation, abdominal pains, diarrhoea, green blue vomit, brown stools without blood, urine like ink and contains albumin.	• Stomach wash • Charcoal powder • BAL	With potassium salt 3 to 4 tablespoonful with water. With usual dose as antidote.

Contd.

Contd.

Symptoms	Treatments	Dose/Reason
Chronic symptoms: Hypertension, constipation, metallic taste, weakness, anorexia, headache		For chronic poisoning additionally belladona extract may be used.

12. Arsenic Poisoning

Symptoms	Treatments	Dose/Reason
a. Acute: Capillary damage, epigastric and abdominal pains, vomiting, diarrhoea, jaundice, muscle cramps, pale face, dilated pupil, rapid pulse, convulsion, coma, death	• Artificial respiration • Ferric oxide • Sodium thiosulphate • Dimercaprol (BAL) • Morphine	To ppt. arsenic to harmless ferric arsenic By IV after every 46 hr Till the symptoms of arsenic disappear To reduce the pain.
b. Chronic: Peripheral neuritis, diarrhoea, pigmentation of skin, liver damage, conjunctivitis oedema, carcinoma	• Fresh air • Sodium thiosulphate	Place the victim in fresh air By IV 1 gm in 10 ml water 2 to 3 times/ week for many weeks
1. Anorexia diarrhoea, occasional vomiting, fatigue	• Dimercaprol (BAL)	Till the control over arsenic symptoms
2. Conjunctivitis, eye and nose are affected, sense of fullness of head	• Anticonvulsants • Antidiarrhoeals	To control convulsion To control diarrhoea.
3. Skin rash, brittle nails, falling of hairs		

13. Lead Poisoning

Symptoms	Treatments	Dose/Reason
a. Acute: Metallic taste, vomiting, abdominal pains, constipation, suppressed urine, headache, black stools, loss of sleep, loss of vision, hallucination, delirium, convulsions	• Stomach wash • Penicillamine • Calcium EDTA	10% $MgSO_4$ solution and then warm water. Repeated washing with regular interval Antidotes

Contd.

Contd.

Symptoms	Treatments	Dose/Reason
b. Chronic: Facial, abnormalities, lead line on gums (blue line on gums) anaemia, constipation, paralysis of muscles, encephalopathy, hypertension, menstrual disorders, abortion, nephritis, metallic taste, anorexia, weakness, headache	• EDTA • BAL	Mixed with saline given by IV For excretion of lead (in combination with EDTA it is more effective)

Q7. Write a short note on BAL/Dimercaprol.

BAL means British Anti-Lewisite.

- It is also known as dimercaprol.
- Most of the enzymes in the body have -SH (mercapto) groups, which are essential for their activity. Many heavy metals like arsenic, mercury have a great affinity for these -SH groups.

  Thus after combining with these -SH groups these compounds reactivate them.
- BAL has many -SH groups, which combine with these heavy metals leaving the -SH groups of enzymes of body free.
- The compound formed by heavy metal and di-thiol, dimercaprol is relatively stable and is excreted without causing damage to excretory mechanism (kidney, liver, etc.)

Preparations and Doses

i. BAL is given intramuscularly as a 5% solution in arachis oil with benzyl benzoate.
ii. BAL in the dose of 2.5–3 mg/kg administered by parenteral route.

BAL has considerable toxicities such as nausea, vomiting, burning sensation, anorexia, nephrotoxicity and hence should be used cautiously.

Uses of BAL/Dimercaprol

It is used as an antidote in metal poisoning due to antimony, arsenic, bismuth, gold, mercury, etc.

Q8. Mention the antidotes for different poisonings.

Poison	Antidote
1. Acid	CaO, MgO
2. Carbonic acid	$MgSO_4$
3. Lead	BAL,EDTA
4. Oxalic acid	Lime [$Ca(OH)_2$]
5. Phosphorus	Copper sulphate
6. Alkaloids	Tannins
7. Organophosphorus compounds	Atropine
8. Pilocarpine	Atropine
9. Morphine	Nalorphine, naloxone
10. Arsenic	BAL,EDTA
11. Copper	BAL, Penicillamine
12. Gold	BAL
13. Strychnine	Diazepam, chloroform,
14. Mercury	Penicillamine, BAL
15. Iron	Desferrioxime
16. Barbiturate	Sodium bicarbonate.
17. Ethylene glycol	Ethanol
18. Charas poisoning	Chlorpromazine
19. Quinidine	Tannic acid
20. Unknown	Universal antidote

Q9. Give the brief account of the following antidotes with their doses.

a. EDTA b. Penicillamine c. Desferrioxime d. Universal antidote

a. EDTA (Ethylene Diamine Tetra Acetate): It is a chelating agent which has great affinity for the lead. The chelated lead is excreted in the urine. Short courses of treatment are advised to avoid the depletion of metallic ions essential for metabolism.

Dose: 75 mg/kg 24 hours IM or slow IV infusion given in 3 to 6 divided doses for 5 days may be repeated for a second course after a minimum interval of 2 days. Each course should not exceed a total of 500 mg/kg.

b. Penicillamine: It has a stable SH group which confers the chelating action. It is less toxic than EDTA and can be given orally. It is used in copper, lead and mercury poisoning. It is also used for treatment of hepatolenticular degeneration (Wilson's disease).

Dose: 100 mg/kg/day (max. 1g) in divided doses for up to 5 days. For long-term therapy it should not exceed 40 mg/kg/day.

c. **Desferrioxamine:** It is a chelating agent which chelates iron in the stomach and binds iron in the blood. Thus, it is useful both orally and intravenously for avoiding systemic absorption and removing the absorbed iron.
   Dose: Oral 8–12 g in 40 to 60 ml distilled water IV 2 g in 5% laevulose solution.
   [140 mg of Desferrioxamine can bind about 1g of ferrous sulphate (200 mg of iron)]
d. **Universal antidote:** When the nature of ingested poison is unknown, the universal antidote is used.
   i. To neutralise the acids
   ii. To absorb the alkaloidal poisons, and
   iii. To precipitate or chelate the metals, certain glycosides and alkaloids.

Composition of Universal Antidote

1. Magnesium : 1 part
2. Activated charcoal : 2 parts
3. Tannic acid : 1 part

The mixture should be given in a dose of 1 tablespoon in 200 ml of water once or twice.

Q10. Give the definition, requirements, information resources and functions of "Poison Information Centre" (PIC).

Poison Information Centre (PIC)

Definition

The Poison Information Centre (PIC) is a specialized unit providing information on prevention, early diagnosis and treatment of poisoning and hazard management.

Information Resources of PIC

- The basis of this service is the databases on poisoning, drug reactions and also the continuous systematic collection of data from the library.
- This information service is available around the clock.
- The PIC has the training responsibility extending to medical and other health professionals and community.
- The laboratory service is an essential component of a poison control program, providing analytical services on emergency basis to help in diagnosis and management.

Location and Requirement of PIC

- PIC should be located at a leading hospital with emergency and intensive care services along with facilities like laboratory and medical library.
- If it is possible, it should be linked directly to a hospital department where poisoned patients are treated.
- Full time staff will be required to provide round the clock services and independent facilities must be provided if enquiries are more.
- It should be located in such a way that it is easily accessible but unauthorized persons should be restricted.

Facilities at Poison Information Centre

- Poison information center should be accommodated in suitable rooms, equipped with basic furniture and other required facilities to carry out its functions.
- It should have immediate access to the relevant literature and other sources of information.
- Rooms should be large enough to carry out all essential functions such as storage of records, conduct meetings, etc.
- One room should be allocated to the "answering service" and should contain telephones, internet connectivity with computers, basic files, protocols, books, etc.
- Medical library just aside the answering service room should be available.
- Administrative area, staff room, canteen facility and parking area should be available.

Functions of PIC (Poison Information Centre)

1. To provide information and advice about the diagnosis, prognosis, treatment and prevention of poisoning, about the toxicity of chemicals and the risks they pose.
2. It should provide professional program to update healthcare professionals regarding poisoning treatments.
3. To organize public education programs to create awareness regarding poison prevention techniques and inform them about the poison information centers.
4. To collect data on poisoning and their sources.
5. To evaluate efficacy of poisoning treatments, develop risk assessment guidelines.

6. To identify toxicities associated with new drugs and household products.
7. To participate in toxicology research and report unique poisoning cases to the medical community.

Objective Questions with Answers in Bold Letter

1. DIB stands for **Drug Information Bulletin**.
2. PIC stands for **Poison Information Centre**.
3. Antidote in morphine poisoning is **Nalorphine**.
4. EDTA stands for **Ethylenediaminetetraacetic Acid**.
5. BAL stands for **British anti-Lewisite**.
6. DDT stands for **Dichlorodiphenyl trichloroethane**.
7. **Penicillamine** is an antidote used in mercury poisoning.
8. Antidote for iron poisoning is **Desferrioxime**.
9. When type of poison is not known, then **universal antidote** is used.
10. **BAL** is also known as **Dimercaprol**.

Chapter 11

Pharmacovigilance

Q1. Define pharmacovigilance. Give the aims and objectives of pharmacovigilance.

Pharmacovigilance

Definition: Pharmacovigilance is defined as the science and activities concerned with the detection, assessment, understanding and prevention of adverse reactions to medicines.

Aims of Pharmacovigilance

1. Improve patient safety and care with respect to the use of medication.
2. Early detection of unknown adverse reactions and interactions.
3. Detection of frequency of adverse reactions.
4. Improve public health and safety with respect to use of medication.
5. Provide information to healthcare professionals and patients to optimize safe and effective use of medicines.
6. Contribute to assessment of effectiveness, harm, benefit and risk of medication encouraging their rational, safe and effective use.

Scope and Objectives of Pharmacovigilance

1. To monitor adverse drug reactions (ADRs).
2. To monitor benefit–risk profile of medicines.
3. To create awareness among healthcare professionals about the importance of ADRs reported in India.
4. To generate independent evidence-based recommendations on the safety of medicines.
5. To communicate findings with all stockholders.
6. To create a national centre of excellence at par with global drug safety monitoring standards.
7. To build and maintain a vigorous pharmacovigilance system.

Q2. Give the importance of pharmacovigilance.

Importance of Pharmacovigilance

1. Helps to promote the systematic, rational use and assures the confidence for the safety of drugs.
2. It improves patient care and safety, public health and safety.
3. It helps in causalty assessment and analysis of ADRs.
4. It computes risk–benefit and suggests regulatory action.
5. It helps to communicate for safe use of drugs among stackholders.
6. It helps to avoid medication errors and irrational use of medicines.
7. It is essential for risk minimization by making an early detection and preventing the progression of the adverse effects.
8. It helps to promote education and clinical training amongst the healthcare professionals.
9. It helps in identification of risk factors and possible mechanisms of reported adverse reactions.
10. It helps in identification, quantification and documentation of drug-related problems which are responsible for drug-related injuries.

Q3. Write a note on an overview of pharmacovigilance.

An Overview of Pharmacovigilance

- Pharmacovigilance is the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems.
- Pharmacovigilance plays a vital role in drug discovery and development.
- Pharmacovigilance plays a crucial role in healthcare system.
- In 1962, International Centre for Monitoring of Adverse Drug Reaction by WHO which was later shifted to Uppsala in Sweden in 1971, was established in Geneva, and this is the beginning of pharmacovigilance.
- Uppsala Monitoring Centre manages the international database of ADR reports received from national centres.
- The Uppasala Monitoring Centre (UMC) has established standardized reporting by all national centres and has facilitated communication between countries to promote rapid detection of signals.
- An international advisory clinical expert panel determines the validity and clinical importance of the signals generated.
- The UMC team, in collaboration with the WHO, facilitates and encourages the international collaboration, which was identified in 1972 as being vital for the success of pharmacovigilance.

- India started participating in the WHO pharmacovigilance program many years ago. The hospitals like AIIMS, New Delhi; PGIMER, Chandigarh; CMC Vellore; JIPMER, Pondicherry; KEM hospital, Mumbai were involved in the ADR monitoring setup.
- The National Pharmacovigilance Program (NPP) was initiated in 2004 under the guidance of the Central Drugs Standard Control Organization (CDSCO) with the objective of developing a sustainable ADR monitoring program.

Pharmacovigilance Program in India

The NPP (National Pharmacovigilance Program) constitutes:

1. **Administrative body:** It consists of steering committee, technical support committee and strategic advisory committee. The functions of these committees are:
   - Coordination of comprehensive national program.
   - Operational supervision of CDSCO.
   - Recommend procedure and guidelines for regulators interventions
2. **National pharmacovigilance centres:** Initially twenty-six peripheral centres, five regional centres and two zonal centres were established. The peripheral centres record the adverse events (AE) and send to the regional centres. The regional centres scrutinize the data received from the peripheral centres and submit it to zonal centres. The zonal centres will analyse the data and submit it to national pharmacovigilance centre. The zonal centre will also provide training and general support to coordinate the functioning of the regional centre.
3. **ADR monitoring centres:** The various ADR monitoring centres include:
   - MCI approved medical colleges.
   - Private hospitals and health centres
   - Autonomous institutions

   The functions of these ADR monitoring centres are:
   - Monitoring spontaneous report
   - Monitoring benefit/risk of medicine
   - Post-marketing surveillance of medicine

Objective Questions with Answers in Bold Letters

1. NPP stands for **National Pharmacovigilance Program**.
2. The National Pharmacovigilance Program (NPP) was initiated in 2004 under the guidance of the **CDSCO**.

3. Pharmacovigilance continues throughout **pre- and post-marketing surveillance**.
4. Pharmacovigilance **improves public health**.
5. Website of WHO for pharmacovigilance is **Vigimel**.
6. The Uppasala Monitoring Centre is located in **Sweden**.
7. The pharmacovigilance program of India, coordinated by the Indian Pharmacopoeia Commission, is situated at **Ghaziabad**.
8. **Drug mining** is vigorous search of data with specific inputs of parameter to identify an important observation with probable relation of ADR and drug.
9. UMC stands for **Uppsala Monitoring Centre**.
10. The International Centre for Monitoring of Adverse Drug Reaction by WHO was established in **Geneva**.
11. **Uppsala Monitoring Centre** manages the international database of ADRs reports received from national centres.
12. Pharmacovigilance is a branch of **pharmacoepidemiology**.
13. **Pharmacovigilance** is defined as the science and activities concerned with the detection, assessment, understanding and prevention of adverse reactions to medicines.
14. MedDRA stands for **medical dictionary for drug regulatory activities**.
15. The National Pharmacovigilance Program (NPP) was initiated in **2004**.

Chapter 12

Medication Errors

Q1. Define medication error. Give the types/classification of medication errors.

Medication Error

Definition: Medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of healthcare professional, patient or consumer.

- Medication error is any error in the prescribing, dispensing or administration of a drug.
- Medication errors are a common and preventable cause of patient harm, which can occur at any stage during the medication ordering and delivery pathway particularly at the time of prescribing.
- Medication errors can be decreased by an accurate and timely medication history is compiling, therapy optimizing and improving patient safety.

Classification/Types of Medication Errors

American Society for Hospital Pharmacist (ASHP) categorise medication errors as follows:

1. **Prescribing error:** It means those errors which occur due to improper drug selection dose, dosage form or route of administration. Examples of this type of error include:
   i. Prescribing a dose of drug, i.e. too high or too low
   ii. Writing a prescription illegibly
   iii. Ordering duplicate therapies
   iv. Inappropriate dosage interval
   v. Ordering a drug which is allergic to patient
   vi. Failure of monitoring side effects and serum drug levels
   vii. Prescribing an inappropriate medication for a particular patient
   viii. Inappropriate duration of therapy

2. **Omission error:** It occurs when a patient does not receive a scheduled dose of medication.
3. **Wrong time error:** It occurs when a dose is not administered in accordance with a predetermined administration interval.
4. **Wrong dose error:** This type of error occurs when a prescriber orders an inappropriate dose of medication. It occurs due to wrong calculations or wrong units of measurement or not measured properly.
5. **Wrong dosage form error:** It occurs when a patient receives a dosage form different from that prescribed.
6. **Wrong route of administration:** This type of error occurs when an agent meant for intramuscular administration is given intravenously.
7. **Wrong drug preparation:** This type of error occurs when a medication requires some preparation before its administration such as reconstitution of solution by adding water for injection in the vial.
8. **Unauthorized drug error:** This type of error occurs when a patient receives the drug which is not prescribed to him.
9. **Deteriorated drug error:** This type of error occurs when a patient receives an expired drug or deteriorated prematurely due to improper storage conditions.
10. **Monitoring error:** This type of error occurs when the patient is not properly monitored before or during the therapy, e.g. (i) In warfarin therapy, not conducting the patients response by doing adequate blood tests, life-threatening haemorrhage may happen. (ii) In community pharmacy, not reviewing the medication history by the pharmacist may result into drug–drug interaction.
11. **Compliance error:** This type of error occurs when the patient use medication inappropriately due to improper education of patient by the pharmacist or physician or both.

Q2. What are the causes/reasons for medication errors?

OR

Enlist various risk factors causing medication errors.

Causes/Reasons for Medication Errors

Risk factors causing medication errors:

1. Underutilization of medications
2. Overutilization of medications

3. Improper technique of drug administration
4. Using a medicine for wrong purpose
5. Consuming expired medicines
6. Incomplete patient information, e.g. patient's allergies
7. Unavailability of drug information
8. Inexperienced or inadequately trained staff
9. Miscommunication of drugs orders, poor hand writing of the prescriber
10. Wrong labeling of the medications
11. Job stress
12. Lack of patient counselling
13. Staff storage/untrained staff/high workload to staff
14. Poor drug distribution practices
15. Handling of drugs by non-pharmacy personnel
16. Night shifts of the staff
17. Verbal orders only
18. Lack of effective policies and procedures
19. Higher number of medications per patient
20. Improper drug storage

Q3. What are consequences (effects) of medication errors?

Consequences of Medication Errors

A medication error can lead to number of complications, including long-term injuries or deaths.

1. An abnormal pharmacodynamics response to drug, e.g. sensitivity to an opioid drug resulting in respiratory depression.
2. Anaphylactic or allergic reactions.
3. Adverse drug reactions, drug–drug interactions.
4. Chronic dose-related and time-related effects due to prolonged exposure of a drug, e.g. renal failure secondary to methoxyflurane.
5. Delayed toxicities, e.g. teratogenicity seen with thalidomide.
6. Withdrawl symptoms, e.g. discontinuation of antiepilectic therapy may produce rebound epileptic attacks more severe than previous ones.
7. Unexpected failure of therapy, e.g. awareness under general anaesthesia.
8. Non-compliance with prescribed medicines frequently produces adverse effects.

9. Uncommon medication errors can result in severe patient injury or death.
10. Wrong medications provided by nurses or doctors causing life-threatening syndrome to the patients. So these nurses or doctors are considered as second victim. So these types of litigations can impose additional emotional stress and boredom on the healthcare professionals from medication error.

Q4. Explain various strategies/measures to minimize medication errors.

OR

How are the medication errors prevented?

Strategies to Minimise/Prevent Medication Errors

1. Take the patients profile and medication history before prescribing medications.
2. Healthcare person should know the pharmacology, adverse effects, drug–drug interactions, ADRs of the medications prescribed.
3. Double-check the frequency and dosing of all high-alert medications.
4. Accurate documentation of each dose administered is essential which helps to minimize medication error.
5. If not sure about the dose of the drug, consult the pharmacist.
6. If prescription contains illegible handwritten, making confusion in understanding drugs, consult the physician.
7. Take an active role in correcting issues you identify.
8. Inform the patient about the drug administered and its beneficial effects.
9. Do not use abbreviations, write full forms of the route and frequency of dosage.
10. Always specify the duration of therapy.
11. Always consider the fact that each medication has the potential for adverse reactions.
12. Always be aware of high-risk medications.
13. Before prescribing any medication, check for liver and renal function.
14. Education and training to the practitioners and healthcare providers to minimize medication errors.
15. Immediate reporting of medication error to the organization and others to avoid the mistakes of others.

16. Patient counselling by the pharmacist, nurse and physician plays an important role in minimizing medication errors.
17. Intraprofessional communication among all the healthcare professionals helps to minimize the medication errors.
18. Health system need to improve quality of life care and minimize medication errors by investing maximum in information technology to develop health-related softwares.

Q5. What are LASA drugs as per ISMP? How medication errors due to LASA drugs are minimized/prevented?

LASA Drugs (Look Alike Sound Alike)

LASA drugs are the drugs that are visually similar in physical appearance or packaging and names of medications that have spelling similarities or similar phonetics.

- LASA drugs are the biggest source of medication error.
- LASA drugs create confusion in natural manner.
- LASA look or sound similar to each other, either by their generic name, or brand name.
- LASA drugs might have similar packaging, similar sounding names or similar spellings, e.g. ephedrine sounds a lot like epinephrine when said out loud.
- LASA medication names may be mistaken for each other, e.g. mercaptamine and mercaptopurine.
- Confusing medication names and similar product packaging may lead to potentially harmful medical errors.
- ISMP (Institute for Safe Medication Practices) list of confused drug names contains Look Alike and Sound Alike (LASA) name pairs of medication that have published in ISMP medication safety alert.
- Examples of LASA drugs:
  1. Cisplatin—Carboplatin
  2. Lantus—Lente
  3. Humalog—Novolog
  4. Chlorpropamide—Chlorpromazine
  5. Diabeta—Zebeta
  6. Folic acid—Folinic acid
  7. Retrovir—Ritonavir
  8. Zantac—Zyrtec

9. Prilosec—Prozac
10. Leukeran—Leucovorin

- LASA errors can occur at any point on the treatment pathway during dispensing, prescribing or administration of medicines. They may result in under-dosing, overdosing or inappropriate dosing, causing a significant threat to patient safety.

Prevention/Minimizing Medication Errors by LASA Drugs

1. Cares taken by pharmacist

- Pharmacist should separate LASA drugs from one another.
- Pharmacist should install warning system to staff by computer alerts, etc.
- Double checking of the drugs by pharmacists.
- Contacting the physician in case of any clarification regarding the prescription.

2. Cares taken by consumers

- Consumers can also reduce the chances of medication errors.
- Consumer must be aware about the appropriate usage of medication.
- Consumer should confirm that the physician has clearly written the name of drug which is easily readable.
- After buying the drug, the consumer should ensure to see whether the drug in hand is the same as written in prescription.

3. Tall man lettering

- Tall man lettering is an error-prevention strategy used to reduce the risk of look-alike medicine names errors.
- Tall man lettering uses a combination of lower and upper case letters to highlight the difference between look-alike medicine names, helping to making them more easily distinguishable.

Q6. What is tall man lettering? Give its importance.

Tall Man Lettering

- Tall man lettering is the practice of writing part of a drug's name in upper case letters to help distinguish sound-alike, look-alike drugs from one another in order to avoid medication errors.
- Tall man lettering, a term coined by the Institute for Safe Medication Practices (ISMP), describes a method for differentiating the unique letter characters of similar drug names known to have been confused with one another.

- Starting with a drug name printed in lower case letters, tall man lettering highlights the difference between similar drug names by capitalizing dissimilar letters, e.g.
  i. oxyCODONE and oxyCONTIN.
  ii. CeFAZolin and Ceftriaxone.
- Tall man lettering is an error-preventing strategy used to reduce the risk of look-alike medicine names errors.
- Tall man lettering is a typographic technique that uses selective capitalization in words to differentiate similar looking medicines.
- Its purpose is to help in selecting or supplying the right medicines to the patients.
- Tall man lettering can be used along with colour or bolding of letters to draw the attention to the dissimilarities between look-alike drug names to avoid confusion with another drug name.
- ISMP (Institute for Safe Medication Practices) has maintained a list of drugs names with recommended, bold tall man letters. It helps to improve the accuracy of drug name perception and reduce errors due to drug name similarity.
- Examples
  i. AcetaZOLAMIDE vs. AcetoHEXAMIDE
  ii. ChlorproMAZINE vs. ChlorproPAMIDE
  iii. CycloSERINE vs. CycloSPORINE
  iv. DAUNOrubicin vs. Doxorubicin
  v. NIFEdipine vs. niCARdipine
  vi. VinBLAStine vs. VinCRIStine
  vii. DiazePAM vs. DilTIAZem
  viii. ePHEDrine vs. EPINEPHrine
  ix. OXcarbazepine vs. CarBAMazepine
  x. PENTObarbital vs. PHENObarbital

Objective Questions with Answers in Bold Letters

1. ASHP stands for **American Society for Hospital Pharmacists**.
2. LASA stands for **like-alike sound-alike**.
3. ISMP stands for **Institute for Safe Medication Practices**.
4. The most common type of medication error is **administering improper dose**.
5. **Transcription error** is a medication error which causes misunderstanding of intended order.

6. **Dispensing error** is a medication error caused due to incorrect formulation or dosage form.
7. **Tall man lettering** is an error-preventing strategy used to reduce the risk of look-alike medicine name errors.
8. TML stands for **Tall Man Lettering**.
9. The medication error caused due to failure to adhere to prescribed medications is known as **compliance error**.
10. A **medication error** is a failure in the treatment process that leads to potential harm to the patient.

Chapter 13

Drug Interactions

Q1. Define and classify/types of drug interactions.

Drug Interaction

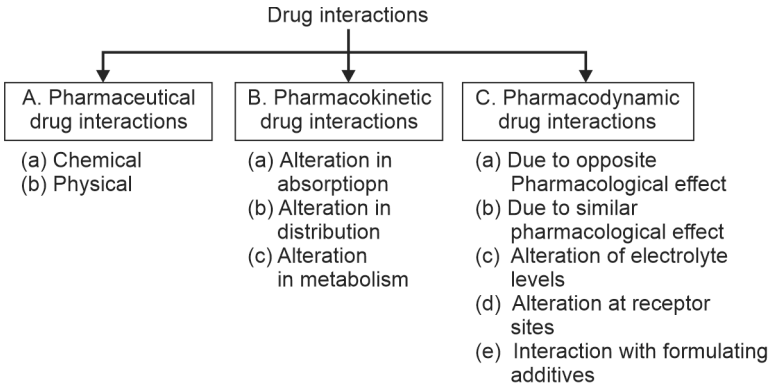
Definition: "The drug interaction is a reaction in which the effects of one drug are altered by prior or concurrent administration of another".

OR

"Drug or drug interaction is an alteration of effects of one drug by prior concurrent administration of another drug."

Classification of Drug Interactions

According to mechanism, drug interactions are classified as follows:



Q2. What are the reasons/causes of drug interactions?

1. **Administration of two or more drug simultaneously:** In common practice, more drugs are prescribed at a time which may be one of the main causes of drug interaction.
2. **Patient may refer many doctors/multi-prescription practice:** Sometimes patient is not satisfied by one doctor and may refer other doctors without informing about the previous consultation with

the first doctor. This may result in taking the drugs which may interact with each other.

3. **Concurrent use of prescribed and non-prescribed drugs:** Patient may take the drugs like aspirin, paracetamol, which are available without prescription. If such patients take other drugs prescribed by physician, drug interaction may occur and may be detrimental to the patient.
4. **Patient's non-compliance:** Sometimes, patient does not comply with instructions given by physicians, e.g. patient may take food which is being prohibited.
5. **Availability of potent drugs:** Potent drugs may interact with other drugs and thus may produce dangerous complications.
6. **Hepatic or renal disease:** The blood concentration of drug is increased in hepatic and renal dysfunction.
7. **Drug abuse:** The drug abuse or misuse of drug can cause drug interaction.
8. **Prescription errors:** Due to lack of knowledge or by mistake of prescriber, the drug–drug interaction may occur.
9. **Genetic factor:** Genes synthesize enzymes that metabolize drugs. Some races have genotypic variations that could decrease or increase the activity of these enzymes that will result into alteration of drug effect. This is seen in genotype variations in the isoenzymes of cytochrome P450.
10. **Old age:** Age is a factor that modify the drug action. Kidney function, metabolism, nerve transmission and bone marrow functioning is decreasing with age. This may result in accumulation of one drug resulting in interaction with other drug.

Q3. Give the significance/importance of drug interactions.

Significance/Importance of Drug Interactions

1. To produce synergistic effect.
2. To get an important therapeutic effect.
3. To provide greater margin of safety.
4. To get a more appropriate onset of duration of action.
5. To lower toxicity of drugs.
6. To enhance or increase the potency of drug.
7. Highly improved therapy is possible by use of drug interactions.
8. To modify effects of drug by prior administration, e.g. preanaesthetic medication.

Q4. Describe various pharmacokinetic drug interactions.

Pharmacokinetic Drug Interactions

In this type, absorption, distribution, metabolism and excretion of drug can be modified by other agents.

1. Alteration in Absorption

Alteration in absorption may be due to the following factors:

i. Alteration in pH
ii. Inhibition of GIT enzymes
iii. Change in osmotic pressure
iv. Absorption
v. Complexion
vi. Food

For example

i. Antacids decrease absorption of acidic drugs and increase absorption of basic drugs.
ii. Kaolin absorbs tetracycline and digoxin-like drugs, therefore, their absorption is decreased.
iii. Purgatives increase gastric motility, therefore, absorption of digoxin-like drug is decreased.
iv. Atropine decreases motility of GIT, therefore, absorption of some drugs is late but sustained action is obtained.
v. Antimicrobials change microbial flora of GIT, therefore, absorption of vitamins is decreased and also anticoagulant effect of anticoagulants.
vi. Phenytoin inhibits intestinal enzymes, therefore, absorption of folic acid is increased.

2. Alteration in Distribution of Drugs

Alteration in distribution of drug may be due to change in drug transport or due to protein binding of drugs, e.g.

i. Salicylates break binding of tolbutamide from their binding site, thus cause severe hypoglycemia.
ii. Phenylbutazone replaces warfarin from protein binding, therefore, warfarin serum level is increased, thus prolongs anticoagulant effect.

3. Alteration in Metabolism of Drugs

Alterations in metabolism are due to enzyme inhibition or increase in metabolism,

For example,

i. Barbiturates stimulate metabolic degradation of alcohol and phenytoin due to stimulation of liver enzyme, therefore, their effects are reduced.
ii. Phenylbutazone inhibits metabolism of tolbutamide, therefore, prolongs hypoglycemic effect.

4. Alterations in Excretion of Drugs

Alterations in excretion of drugs may be due to:

i. Inhibition of excretion
ii. Change in urinary pH
iii. Increase in renal excretion
iv. Change in tubular transport system,
    For example,
    i. Quinidine decreases excretion of digoxin. This toxicity of digoxin occur.
    ii. Sodium bicarbonate increases excretion of salicylates and barbiturates. Thus, it is useful in treatment of salicylate and barbiturate poisoning.
    iii. Acidic drugs are rapidly excreted in basic urine.
    iv. Antacids make urine alkaline, therefore, ionization of salicylates and barbiturate occurs which further causes rapid excretion of these drugs.
    v. Probencid decreases excretion of penicillin.

Q5. Describe pharmacodynamics drug interactions.

Pharmacodynamic Drug Interactions

Pharmacodynamic interactions are beneficial or harmful:

1. **Due to opposite pharmacological effect:** If two drugs are administered which are having opposite effect, i.e. one drug blocks the action of another drug and leads to drug interaction, e.g.
    a. Atropine blocks the actions of pilocarpine.
    b. Alcohol and amphetamine show opposite effects on CNS.
2. **Due to similar pharmacological effect:** If two drugs are administered having similar effect, it may produce synergistic effects, e.g.
    i. Sulphamethoxazole and trimethoprim both are bacteriostatic but their combination shows bacteriocidal effect.
    ii. Toxicity of digitalis can be increased by thiazides.
    iii. Aspirin and codeine produce good analgesic action.

3. Due to interaction with formulating additives, e.g. tetracycline with calcium.
4. **Alteration of electrolyte levels:** Some drugs cause alteration in fluid and electrolyte level balance, e.g. diuretics cause loss of potassium, may produce hypokalaemia in turn making heart more sensitive to digitalis.
5. **Drug interaction at receptor sites:** Effect of drugs occurs as a result of binding to specialized areas known as receptor sites.

Q6. Write a note on "drug–food interaction".

Drug–Food Interaction

It is an interaction due to concurrent administration of drug along with food materials.

Explanation

- Commonest route of administration of drug is oral or enteral. The presence of food in GIT affects bioavailability of drugs by changing absorption, distribution, metabolism and excretion of drug or by changing pharmacological action of drug.
- Drug–food interactions are either beneficial or harmful.
- Many times, presence of food in GIT may change pharmacokinetic or dynamics of the drug.
- The drugs may be diluted due to presence of food and its absorption is delayed. This reduces risk of GIT irritation.

Examples

1. Metronidazole taken along with food causes nausea, vomiting, headache, can be avoided.
2. MAO inhibitors are contraindicated with tyramine containing foods (cheese, banana, chocolate, milk products) because MAO inhibitors inhibit MAO enzymes which is essential for metabolism of tyramine. Thus, level of tyramine increases and causes hypertensive crises, heart failure.
3. Tetracyclines form complexes with ions like calcium, magnesium, aluminium. Hence, milk or antacids should not be given along with tetracyclines.
4. Iron compounds are less absorbed in presence of food and in absence of food if iron is consumed causes nausea, vomiting. Therefore, iron preparation should be taken at least ½ an hour after consumption of food.

5. Acidic fruits cause decomposition of erythromycin and reduce its effect.
6. Egg, green vegetables decrease anticoagulant effect of warfarin because of increase in synthesis of vitamin K.

Drug–Food Interactions

Name of drug	Type of food	Effect
1. MAOIs	Food rich in tyramine, e.g. cheese, banana	Hypertensive crisis
2. Erythromycin	Acidic fruits	Decomposition of drug reducing the effect
3. Quinidine	Basic foods, e.g. milk, most vegetables	Decreased renal clearance due to alkalinity of urine
4. Digoxin, tetracycline	Milk	Reduced GI absorption
5. Antihypertensive diuretics	Liquorice	Sodium retention, hypo-kalemia and increased BP
6. Griseofulvin	Fatty food	Increased absorption rate
7. Anticoagulant	Food rich in vitamin K, e.g. egg, yolk, green, leafy vegetables	Vitamin K enhances the synthesis of clotting factors in liver decreasing anticoagulant effect of drug

Q7. Explain the role of pharmacist in evaluation and prevention of drug interactions.

OR

What is the role of pharmacist to avoid drug interactions?

1. Pharmacist should do patient counselling to make the patients aware about drug interactions.
2. Pharmacist should provide vital information about the drugs to patients regarding drug selection and administration.
3. Pharmacist working in hospitals should maintain drug history and medical record of the patient.
4. Pharmacist can educate the public for safe and effective use of medications through verbal communication as well as by written materials and use of computers.
5. Pharmacist should warn the patients not to use OTC drugs without consultation of physician.
6. Pharmacist should tell the patients to strictly follow the instructions given by the physician regarding administration timing and dosage.

7. Pharmacist should guide the patient, not to take the treatment from multiple physicians.
8. Pharmacist should tell the patient not to consume excess drug than prescribed dose.
9. Pharmacist should tell the patient not to take different drugs at once.
10. Pharmacist should inform the patient about drug–food interactions and specific food during use of certain medications.

Q8 Explain/elaborate different drug–drug interactions giving suitable examples.

Drug–Drug Interactions

A. Analgesic Drug Interactions

1. Salicylic acid	Ammoniated mercury	Skin irritation
2. Salicylates	Tolbutamide	Breaking of protein binding of tolbutamide causing hypoglycaemia
3. Salicylates	Antacid (sodium carbonate)	Rapid excretion of salicylate
4. Salicylate	Indomethacin	Increased serum salicylate level
5. Aspirin	Heparin, warfarin	Anticoagulant activity increased
6. Phenylbutazone	Warfarin, tolbutamide	Enhanced hypoglycaemic activity

B. Diuretic Drug Interactions

1. Thiazide	Quinidine	Quinidine serum level increased
2. Thiazide	Tolbutamide, insulin	Thiazides antagonize effect of tolbutamide and insulin, therefore, dose of these drugs should be increased
3. Thiazide	Alcohol	Alcohol increases hypotensive effect of thiazide, thus causes severe hypertension
4. Spironolactone	Potassiun chloride	Hyperkalaemia
5. Thiazides	Digitalis glycosides	Hypokalaemia
6. Thiazide	Methyldopa, guanethidine	Excessive hypotension
7. Frusemide	Digitalis	Digitalis toxicity, renal toxicity

C. Antidiabetic Drug Interactions (Hypoglycaemic)

1. Tolbutamide	Thiazide	Thiazide antagonizes effect of tolbutamide and, therefore, dose of hypoglycaemic agent should be increased
2. Tolbutamide	Phenylbutazone	Increases hypoglycaemic activity
3. Tolbutamide	Salicylates	Increases hypoglycaemic activity
4. Tolbutamide	Sulphonamides	Sulpha drugs enhance hypoglycemic effect, therefore, dose should be adjusted
5. Tolbutamide	Warfarin, heparin	Increases hypoglycaemic activity
6. Tolbutamide	Oral contraceptives	Oral contraceptives develop glucose tolerance, i.e. oral contraceptives should not be used by diabetes patients
7. Phenformin, metformin	Alcohol	Severe hypoglycaemia

D. GIT Agents Drug Interactions

1. Sodium bicarbonate	Salicylates	Decrease GIT irritation
2. Potassium chloride	Spironolactone	Hyperkalaemia
3. Liquid paraffin	Anticoagulant	Due to decrease in absorption of vitamin K, effect of anticoagulant drug is increased
4. Kaolin	Digoxin	Absorbs digoxin. Thus decreases absorption of digoxin
5. Sodium bicarbonate	Barbiturate	Increases excretion of barbiturate
6. Aluminium hydroxide gel	Isoniazid	Increases absorption of isoniazid

E. Antihypertensive Drug Interactions

1. Guanethidine	MAO inhibitors	MAO inhibitors antagonize effect of guanethidine
2. Methyldopa	Ephedrine	Methyldopa reduces local mydriatic effect
3. Methyldopa	Amphetamine	Amphetamine reduces hypotensive effect of methyldopa
4. Reserpine	Atropine sulphate	Nasal decongestion due to reserpine blocked by atropine
5. Reserpine	Ephedrine	Nasal decongestion due to reserpine, blocked by ephedrine
6. Propranolol	MAO inhibitors	Severe hypertension occurs, hence contraindicated

7. Propranolol	Insulin	Propranolol binds blood sugar and also blocks clinical signs of hypoglycaemia. Therefore, combination should be used with caution.

F. Anticoagulant Drug Interactions

1. Warfarin, heparin	Tolbutamide	Increases hypoglycaemic activity
2. Warfarin, heparin	Aspirin	Increases anticoagulant activity
3. Anticoagulant	Liquid paraffin	Due to decrease in absorption of vitamin K, effect of anticoagulant is increased
4. Warfarin	Phenylbutazone	Increased hypoglycaemic activity
5. Oral anticoagulant	Vitamin E	Anticoagulant effect is increased
6. Heparin	Penicillin	Penicillin antagonizes anticoagulant effect
7. Warfarin, heparin	Streptomycin, sulphonamide, tetracycline, neomycin	These drugs increase anticoagulant effect

G. Vitamin–Drug Interactions

1. Vitamin D	Phenytoin	Serum level of vitamin D is decreased
2. Vitamin A	Mineral oil	Absorption of vitamin A is decreased
3. Folic acid	Phenytoin	Decreased absorption of folic acid
4. Vitamin B_6	Levodopa	Increased metabolism of levodopa thus serum level is decreased
5. Vitamin E	Oral anticoagulant	Anticoagulant effect is increased
6. Pyridoxine	Barbiturate	Increases metabolism of barbiturate
7. Pyridoxine	Oral contraceptive	Decreases level of pyridoxine
8. Vitamin C	Iron anticoagulant	Increases absorption of iron, decreases effect of anticoagulant

H. Cardiovascular Drug Interactions

a. Antiarrhythmic Drug Interactions

1. Procainamide	Sulphonamide	Antibacterial action is blocked
2. Procainamide	Antihypertensives	More hypotensive effect
3. Procainamide	Cholinergic agents	Procainamide antagonizes the effect of cholinergic drugs on skeletal muscle. Hence should be avoided in myasthenic patients

b. Cardiac Glycoside Drug Interactions (Cardiotonic)

1. Digitalis	Thiazide	Hypokalaemia
2. Digoxin	Kaolin	Absorbs digoxin. Thus decreases absorption of digoxin
3. Digitalis glycosides	Phenylbutazone, barbiturates, phenytoin	These drugs enhance rate of metabolism of cardiac glycosides, therefore, efficacy of cardiac glycosides decreases

Q9. What are the guidelines for pharmacists which are useful in preventing drug interactions?

Guidelines for Preventing Drug Interactions

1. **Identify the patient risk factor:** Factors such as age, the nature of patients medical problems, e.g. impaired renal function, dietary habits, smoking and problems like alcoholism will influence the effect of certain drugs and should be considered during the patient interview.
2. **Take a thorough drug history:** An accurate and complete record of both prescription and non-prescription medications, a patient is taking, must be obtained. The number of interactions have resulted from lack of awareness of prescription medications prescribed by another physician or non-prescription medications, the patient did not consider important enough to mention.
3. **Be knowledgeable about the pharmacological actions of drugs being used:** The knowledge of the properties and primary and secondary pharmacological actions of each of the agents used is essential if drug interaction potential is to be checked accurately.
4. **Consider therapeutic alternatives:** Two drugs that are known to interact can be administered monitoring of therapy or dosage adjustments to compensate for the altered response but in such situations also consider another therapeutic agent with similar therapeutic properties and less risk of drug interaction.
5. **Avoid complex therapeutic regimens wherever possible:** The number of medications used should be kept at minimum. The use of medications that permits less frequent administrations may avoid drug interactions which results from alteration of absorption example when drug is administered in close proximity to meals.
6. **Patient education:** Patients often know a little about their illness as well as benefits and problems that could result from the drug therapy. Patients should be encouraged to ask questions about their therapy and to report any excessive or unexpected responses by the drug therapy. Patients should know fully about how to use medications in the most effective and safest way.
7. **Monitoring therapy:** The risk of drug-related problems require close monitoring because it helps in checking the drug interactions, adverse drug reactions as well as non-compliance by the patient. Any change in patient behavior should be suspected as being drug-related until that possibility is excluded.

8. **Individual therapy:** The priority should be given to the needs and clinical response of the individual patient rather than to the usual dosage recommendations and standard treatment.

Objective Questions with Answers in Bold Letters

1. **Interactions at receptor** site causes pharmacodynamics drug interaction.
2. **MAO inhibitors** should not be administered along with cheese, chocolate, banana, etc.
3. Alteration in ADME of drug produces **pharmacokinetic** drug interaction.
4. The comparison of bioavailability between two dosage forms is referred to as **bioequivalence**.
5. An alteration of effects of one drug by prior or concurrent administration of another drug is called **drug interactions**.
6. Tetracyclines should not be given with **milk or antacid**.
7. Digitalis and thiazide drug interactions may cause **hypokalemia**.

Miscellaneous

Sample Question Paper 1

(As per PCI format)

Time: 03 hours **Marks: 80**

Q1. Attempt any six of the following. **6 × 5 marks each = 30 Marks**

a. Define hospital pharmacy. Give objectives and functions of hospital pharmacy.

b. What is Infection Control Committee? Give its composition, objectives, importance of Infection Control Committee.

c. Define procurement. Describe the procedure of procurement of materials for hospital pharmacy.

d. What is cold chain? Discuss the cold chain management of pharmaceuticals.

e. Describe in detail floor/word stock system of drug distribution system in hospitals.

f. Discuss the concept of patient counselling.

g. Explain pulmonary function tests in details.

Q2. Attempt any ten of the following. **10 × 3 marks each = 30 Marks**

a. Explain following tests to access renal function: 1. Creatinine clearance test, 2. Urea clearance test.

b. Define poisoning. Classify poisons giving suitable examples.

c. What is pharmacovigilance? Give the objectives and importance of pharmacovigilance.

d. What do you mean by LASA drugs? How medication errors due to LASA drugs are minimized?

e. Define pharmacokinetics. Describe pharmacokinetic drug interactions.

f. What are 'electronic health records"? Give benefits of EHR. Mention disadvantages of EHR.

g. What are different methods of disposal of radiopharmaceuticals?

h. Write a note on total parenteral nutrition (TPN).

i. Differentiate between automated dispensing system and floor stock system.

j. What is PTC? Give the scope and functions of PTC.

k. Define hospital. Mention the functions of hospital.

Q3. Answer all questions. **20 × 1 mark each = 20 Marks**

a. What is lead time?
b. Give one example of chemical antidote.
c. Define drug interaction.
d. ASHP stands for _____
e. Give the long form of ICCU.
f. What do you mean by ambulatory patient?
g. Define bedside pharmacy.
h. FEFO means _____
i. Galactogogue means _____
j. Give the English meaning of "semel in die".
k. Define clinical pharmacy.
l. Cool means temperature range between _____
m. Name the antidote used in morphine poisoning.
n. Give the normal count of leucocytes.
o. MCV stands for _____
p. The medication error caused due to incorrect formulation or dosage form is called _____
q. Name the country in which Uppasala Monitoring Centre is located.
r. Who is the secretary of PTC?
s. What is the use of tall man lettering?
t. How many number of pharmacists are required for 100 bed capacity hospital?

Sample Question Paper 2

(As per PCI format)

Time: 03 hours **Marks: 80**

Q1. Attempt any six of the following. **6 × 5 marks each = 30 Marks**

a. Define EOQ. Explain methods of EOQ. Mention advantages of EOQ.
b. What is ward round participation? Give the objectives and procedure of ward round participation.
c. What do you mean by hospital formulary? Give its need. Explain the contents and format of hospital formulary.
d. Give the detailed account of unit dose dispensing system in hospitals.
e. What is bulk compounding? Give reasons and advantages of bulk compounding.
f. Define and classify drug interactions. What is the role of pharmacist in prevention of drug interactions.
g. Define hospital. Give the classification of hospitals on different basis.

Q2. Attempt any ten of the following. **10 × 3 marks each = 30 Marks**

a. Define medication error. Explain types of medication errors.
b. Explain the principles of general treatment of poisoning.
c. Write a note on 'lipid profile test'/'lipid panel'.
d. Give the advantages of 'pharmacy operation softwares'.
e. What are radiopharmaceuticals? Explain dispensing of radio-pharmaceuticals.
f. Define outpatient. Explain types of outpatients.
g. Explain the role of pharmacist in prevention of antimicrobial resistance.
h. Define ADRs. Give the causes of ADRs. Discuss the role of pharmacist in the management of ADRs.
i. What are drug related problems? Classify various drug-related problems.
j. Define high-risk drugs. Give examples. What are the strategies used to reduce error using high-risk drugs?
k. Write in brief about: 1. Tall man lettering, 2. Drug information bulletin.

Q3. Attempt all questions. **20 × 1 mark each = 20 Marks**

a. VED stands for _____
b. Who is an administrator of the hospital?

c. What do you mean by medication history?
d. What are demulscents?
e. FIP stands for _____
f. What is medication management therapy?
g. Enlist two examples of narcotic drugs.
h. Give the English meaning of: (i) Pulvis, (ii) Nocte.
i. Give the long form of BAL.
j. What is PTC?
k. NICU stands for _____
l. What is remote dispensing?
m. Give any two softwares used in data storage and retrieval.
n. What is the normal range of blood sugar?
o. Name the antidote used in iron poisoning.
p. Define purchase order (PO).
q. What is the area requirement for hospital pharmacy?
r. A prescription for schedule II and schedule III controlled drug is valid for:
   i. 10 days ii. 12 days iii. 14 days iv. 20 days
s. ILR means:
   i. Integrated light refrigerator ii. Intensive lined refrigerator
   iii. Ice-light refrigerator iv. Ice-lined refrigerator
t. Positive direct van den Bergh's reaction indicates presence of:
   i. Conjugated bilirubin ii. Unconjugated bilirubin
   iii. Urobilinogen iv. Bile salts

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