(A) DRUG STORE MANAGEMENT AND INVENTORY CONTROL

Syllabus:- Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure

Drug Store

A drug Store/Pharmacy/Community Pharmacy/chemist's is a retail shop which provides prescription drugs, among other products. At the drug store, a pharmacist oversees the fulfillment of medical prescriptions and is available to give advice on their offerings of over-the-counter drugs. A typical pharmacy would be in the commercial area of a community. Every hospital should have a medical store for the purpose of procuring, stocking and distributing the drugs and medicines to various departments.

Organisation of Drug Store

Stores are defined as a sub-organisation in any hospitals where materials obtained are held in abeyance till inspected, approved and stocked. A store should have a standard specification of materials and since the store procured the drugs on behalf of the department for regular flow of material, the condition of storage should be proper.

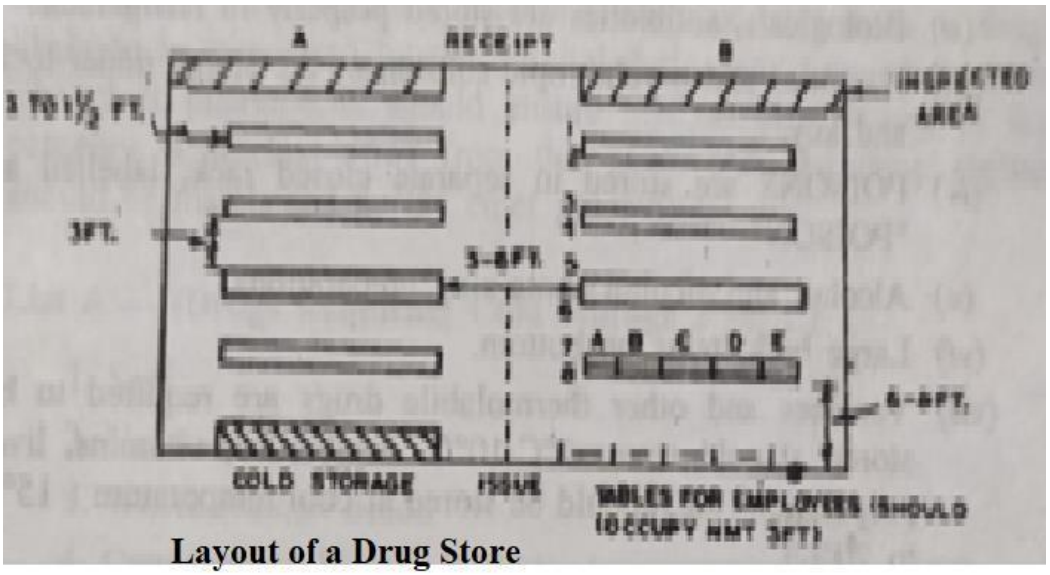
Objectives of Drug Stores

1. To stock all drugs and accessories required in the hospital.
2. To procure drugs from different sources.
3. To supply drugs to the consuming departments.
4. To store drugs required in research work.
5. To preserve records of receipt and issue of drugs.
6. To maintain records of receipt and issue of drugs.
7. To carry out all operations regarding drugs economically to save revenue.

Layout of Drug Store

The drug store should be preferably located on the ground floor close to the pharmacy. An area of at least 600-1000 sq ft should be allotted to medical stores. Adequate storage facilities should be there so that the drugs, chemicals, biological etc .Do not get deteriorated by moisture or heat.

An ideal store should have two entrances, one for receiving the articles and other for issue of materials. Generally racks are used for storage of material made of angled iron, having partitions. Costly items are stored in closed bins. The height of racks depend up on the height of ceiling and should be above 2/3 rd the height.



Layout of a Drug Store

Since large number of products are two be stored in the store, A definite location code is to be followed in order to identify the product or material placed in store. For this purpose analysis is carried out after studying there inventory like:

(i) F S N- Fast moving, slow moving, non moving
(ii)H M L- Heavy, medium, light materials

According to above mentioned categorisation, fast moving materials are placed near the issue exit while non moving articles are placed far from the exit. Similarly heavy items are placed at the bottom and light items on the top.

Now a day's records are maintained using Bin Card system.

A ledger or bin card has 4 codes like-

1 2 3 4

A 5 B 3
(1-Panel, 2-Row, 3-Rack, 4-Bin)

This means panel A, 5th row, Rack B and Bin 3 materials can be entered either in ledger or bin cards in Alphabetical order but this may cause problems as number of drugs are known buy different name. They may be categorised and stored depending up on their therapeutic effect.

TYPES OF MATERIALS STOCKED

Sufficient number of racks should be provided for storage of drugs and supplies. Carbon dioxide fire extinguishers should be provided at strategic points along with fire buckets to fight sudden fires due to stored drugs and chemical. Materials which are stocked are listed as under:

(i) Capsules, tablets, liquid dosage form and injections etc.
(ii) Biological antibiotics are stored properly in refrigerator.

(iii) Narcotic and psychotropic substances are stored under lock & key.
(iv) POISOINS are stored in separate closed rack, labelled as"POISION".
(v) Alcohol and alcohol containing preparations.
(vi) Large bulk items on bottom.
(vii) Vaccines and other thermolabile drugs are required to be stored at cold store 2-10^0 C. Antibiotics, vitamins liver preparations etc should be stored at cool temp (15-20^0 C).
(viii) To avoid pilferage costly drugs and prescribed schedule X drugs should be stored separately under lock and key.

Storage conditions

Cold storage: 2-8°C
Cool temp: 8-25 ^{0}C
Room temp RT-temp. Temperature prevailing in working area**.**
Warm: 30-40°C
Excessive Heat: Above 40°c

Cold storage (2^0-8^0C)

For proper storage of drugs, it is advisable to have a separate room or a portion maintained at this temp range. A recording thermometer should be provided and temp should be noted at least twice daily.

It should remain under the supervisor and in case a separate room is not available, adequate number of refrigerator should be provided for the purpose. The maintenance of these refrigerators in working order is the responsibility of the supervisor. Drugs such as insulin, sera, whole human blood, frozen plasma, thromboplastin, oxytocin injection, and certain vaccines etc. are not allowed to freeze. The chief pharmacist should personally check that such drugs are stored at respective places as per their prescribed storage conditions.

Storage at Cool Temperature (8^0C- 25^0C)

Drug such as antibiotics, vitamins, liver preparations are required to be stored at a cool temp. The space of this room should be adequate considering the maximum stock of drugs likely to be purchased by the hospital during any time of the year. The chief pharmacist should ensure that no drug falling in this category is stocked away from this room .An inspection register should be maintained by the Chief pharmacist.

List A –(Drugs requiring cold storage 2-8°c)

1. Sera

2. Vaccines

3. Whole human blood

4. Concentrated human red blood corpuscles(4-6°C)

5. Normal human plasma

6. Frozenn plasma –at a temp not above -18^{o}C

7. Thrombin

8. Tromboplastin

9. Cobra venom in solution

10. Viper venom in solution

11. Posterior pituitary injection

12. Oxytocin injection

13. Vasopressin injection

14. Corticotropin gelatin injection

15. Corticotrophin zinc oxide injection

16. Cholistin sulphamethate injection

17. Suxamethonium chloride injection

18. Insulin preparation

19. Human gamma globulin injection

20- Normal liquid human serum albumin

21- Schick test toxin

List – B (Drugs requiring storage at cool temp. 8-25^{o}C)

Antibiotics

1. Crystalline penicillin preparation

2. Potassium phenoxy methyl penicillin preparation

3. Benzethine penicillin preparation

4. Cloxacillin preparation

5. Methicillin preparation

6. Ampicillin preparation

7. Streptomycin sulphate and chloride preparation

9. Tetracycline,oxytetracycline,chlortetracycline preparation

10. Bacitracin and zinc bacitracin preparation

Arsenicals

11. Neoarsphenamine injection

12. Sulpharsphenamine injection

13. Tryprsanide injection

BLOOD PREPARATIONS

14. Dried plasma -below $20^{O}C$

15. Human fibrin foam -below $20^{O}C$

16. Human fibrinogen -below $20^{O}C$

17. Human serum dried -below $20^{O}C$

18. Human thrombin -below $20^{O}C$

Hormone preparations

19. Corticotropin

20. Betamethasone sodium phosphate injection

21. Chorionic gonadotropin

22. Prednisolone sodium phosphate injection

23. Oxytocin tablets

Vitamin preparations

24. Preparation containing vit. A,vit. B_1,vit.B_2,vit.B_6,vit.C,vit.D

25. Vit. B complex elixir and injection

26. Vit. K injection

27. Vit. K preparations

Others

28. Dextran injection

29. Dextran sulphate injection

30. Dextrose injection

31. Dextrose and sodium injection

32. Heparin injection

33. Hyaluronidase injection

34. Chlorambucin preparations

35. Chorhexidine

36. Choline theophyline preparation

37. Liver injection crude

38. Ergot liquid extract.

Purchase and Inventory Control

The basic purpose of purchases is to ensure continuous flow of raw materials of right quality, right quantity, right price and from right sources. Another objective of purchasing is the avoidance of duplication and wastage with respect to various items purchased. Centralized purchase by medical stores procures the drugs on behalf of all the departments and helps in getting quality drugs at cheaper rates. Some important terms explained below.

1.Right Quality-Right quality means the quality which is available according to the particulars mentioned in terms of grades, brands or trade name, physico-chemical characteristics, etc. The quality must describe even the national standards to the extent it is possible.

2. Right Quantity-Right quantity is an important parameter of purchasing for continuous supply of raw materials. "Economic order Quantity" or any other technique may be followed in order to avoid shortage.

3. Right Price-The term right price means consistant matching with the quality of drug. Generally tender system is followed in hospitals and the lowest bidder is chosen for supplying the order.

4. Right Source-The supplier should be dependable and capable of supplying as per requirements from time to time. The selection of supplier requires consideration of various factors.

5. Right Time-Purchased department should have lead time information for all products. Lead time is the total time period between the placing of order and receipt of material while doing purchases. The purchase committee should consider emergency situations like floods, strikes, accidents, etc.

PURCHASE PROCEDURE

Purchase procedure involves different steps for procurement of goods. They are as under:

I. Determination of Requirement- The materials to be purchased for particular period are well planned for the purpose of their regular and continuous use. Purchase requisition is generally prepared by departmental heads and provides information mentioned below.

(a) Type of material to be purchased,

(b) Time of requirement,

(c)Quantity to be purchased,

II. Source of Supply- The pharmacy and therapeutic committee sets adequate standards for the purchase of quality drugs. Procurement of stores is generally done by following sources:

(i) Medical store depot

(ii) Directorate general supplies and disposals

(iii) Direct from wholesellers and manufacturers

(iv) By inviting tenders

(v) Emergency purchases from local market

(i) Medical store depot (MSD).

This organisation has six medical store deport at Mumbai, Chennai, Calcutta, karnal, Hyderabad, Guwahati. The items purchased by these organisations are subjected to various in house tests at the testing units in Chennai and Mumbai. It runs on no-profit and no-loss basis.

(ii) Directorate General Supplies and Disposals (DGS &D)

DGS&D calls for tender and places the order. The payment is made only after the verification of inspection report by the indentor on the prescribed performa.

(iii) Direct Purchase from Wholesellers or Manufacturer

Direct purchases from wholesellers, manufacturers are done following a proper purchase procedure. Materials are then received and stocked at their relevant places under proper storage conditions.

(iv) By Inviting tenders.

Tenders are invited from various supplier and generally the lowest bidder is choosen for supplying the order. However price and quality both are considered as well.

(v) Emergency drugs from local market

Items not available at MSD, DGS &D and any emergency drug which is out of stock can be immediately purchased from local market. For this purchase from is prepared in duplicate, one copy is sent to the department and other copy is retained in the pharmacy. This avoids the department concerned to re order the same item.

III. Purchase Order-

After selecting the supplier, the chief pharmacist or any other suitable authority prepares a purchase order giving detailed description, specification, packaging, price and quantity needed etc. of the items. This purchase order is in written form and it is the evidence of contract between the buyer and the supplier.

Number of purchase order copies varies from hospitals to hospital.

(a) The original copy is sent to the supplier.

(b) One copy for accounts section.

(c) One copy for purchase department.

(d) One copy for the department.

(e) Fifth and Sixth copy for concerned receiving department.

(f) Seventh copy as history copy.

The purchase order should clearly indicate the terms and conditions, i.e., price, quality, and time of delivery. There should be a regular follow-up of purchase order so that drugs and supplies can be received timely.

PURCHASE REQUEST FORM

All India Institute of Medical Sciences(AIIMS), Bhubaneswar

Ref.---------- **Date.----------**

Code no.--------- **Charge no.--------**

Purchase order no.--------

Date of supply----------

Suggested Venders:

1.

2.

3.

No	Description of items required, Specification/ Prepacking	Price per unit	Units Required	Total Price	Quantity in Hand Required

Requested by ---------- **Approved By----------**

All India Institute of Medical Sciences (AIIMS), Bhubaneswar

To M/s----------Purchase Order No ---------- (Quote this No. on all package)

Date---------- **Our Ref. No.----------**

Account Code no.----------

Name of Account---------- Date ----------

Item no.	Specifications/Packing	Price per Unit	Quantity	Net amount(paid)

General terms and conditions*

-Deliveries must be made inside the hospital premises.

-Prepare all transport charges.

-The hospital will not be responsible for goods supplied which are not on this order form, not duly signed by the purchase officer.

-All consignments are subject to inspection.

-Installation and Demonstration, if required, is essential.

-No packing, forwarding or any other charges will be paid extra.

IV. Receipt of Acknowledgment- After placing the order to supplier by sending a copy of purchase order, the supplier in turn sends acknowledgement of the order saying that he will be able to supply the goods with the terms and conditions which are mentioned in the purchase order.

V. Receipt of Drugs- On receipt of drugs , there should be a system in the stores whereby the

supply of drugs received in the medical stores from the manufacturer are properly checked by

person specially assigned for this purpose. Preferably the same person is responsible for reviewing the stocks, date of expiry, description, quantity, batch number, as mentioned in the order form.

Random sampling can be done to make sure that products confirm to the tendered specifications like date of expiry and visible sign of deterioration , such as change of colour , caking etc.

If any such deterioration is observed the matter should be reported to medical superintendent and local drug inspector. These stocks should never be used until the drug inspector's permission is granted and even the information should be sent to the manufacturer.

After the thorough examination of drugs the above officer should give "No objection to accept the supply" in writing on the hospital copies of delivery challans, Invoices by putting signature and date. The invoice received from the supplier is sent to accounts section for accuracy along with price and quantity .After verification ,the accounts section certifies and passes, the invoice for payment and on this basis, cashier makes the payment either by cheque/draft.

VI. Distribution of Drugs to Wards---Drugs should be supplied in the original packing of manufacturers. However if it is not possible to do so, then that should be supplied in clean containers so that the integrity and original properties can be preserved. Name and quantity of the drug should be properly labelled. It is always advisable that suitable precautions should be taken to dispose off "Original empty containers" in order to avoid their misuse. The containers should be destroyed in the presence of a responsible person with a written statement signed by him.

Chief pharmacist should visit wards to check whether the drugs are properly stored under special storage conditions like cold storage, cool temperature and at room temperature.

INVENTORY CONTROL

Drug store management is based on principles of inventory control. mismanagement of stores and non-applicability of Scientific and Modern techniques has been identified as the root cause of material storage in majority of hospitals.

Objective of Inventory Control

(i) To supply drug in time.

(ii) To reduce investment in inventories and made effective use of capital investment.

(iii) Efforts are made to procure goods at minimum price without bargaining the quality.

(iv) To avoid stock out and shortage.

(v) Wastage are avoided

Techniques of Inventory control / Methods Used for Analysis of Drug Expenditure

(i) ABC analysis

(ii) VED analysis

(iii) EOQ

(iv) Lead time

(v) Buffer stock

(i) ABC analysis

ABC analysis is an inventory categorization technique. It is a basic tool with a selective approach for concentration upon the items. As ABC analysis the items are divided into three categories—

"**A items**" with very tight control and accurate records,

"**B items**" with less tightly controlled and good records, and

"**C items**" with the simplest controls possible and minimal records.

The ABC analysis provides a mechanism for identifying items that will have a significant impact on overall inventory cost, while also providing a mechanism for identifying different categories of stock that will require different management and controls.

The ABC analysis suggests that inventories of an organization are not of equal value. Thus, the inventory is grouped into three categories (A, B, and C) in order of their estimated importance.

'A' items are very important for an organization. Because of the high value of these 'A' items, frequent value analysis is required. In addition to that, an organization needs to choose an appropriate order pattern (e.g. 'just-in-time') to avoid excess capacity. 'B' items are important, but of course less important than 'A' items and more important than 'C' items. Therefore, 'B' items are intergroup items. 'C' items are marginally important.

There are no fixed thresholds for each class, and different proportions can be applied based on objectives and criteria. ABC Analysis is similar to the Pareto principle in that the 'A' items will typically account for a large proportion of the overall value, but a small percentage of the number of items.

Examples of ABC class are

'A' items – 20% of the items accounts for 70% of the annual consumption value of the items

'B' items – 30% of the items accounts for 25% of the annual consumption value of the items

'C' items – 50% of the items accounts for 5% of the annual consumption value of the items

Another recommended breakdown of ABC classes:

"A" approximately 10% of items or 66.6% of value

"B" approximately 20% of items or 23.3% of value

"C" approximately 70% of items or 10.1% of value

(ii) VED analysis is an inventory management technique that classifies inventory based on its functional importance. It categorizes stock under three heads based on its importance and necessity for an organization for production or any of its other activities. VED analysis stands for Vital, Essential, and Desirable.

V- Vital Category

As the name suggests, the category "Vital" includes inventory, which is necessary for production or any other process in an organization. The shortage of items under this category can severely hamper or disrupt the proper functioning of operations. Hence, continuous checking, evaluation, and replenishment happen for such stocks. If any of such inventories are unavailable, the entire production chain may stop. Also, a missing essential component may be of need at the time of a breakdown. Therefore, order for such inventory should be before-hand. Proper checks should be put in place by the management to ensure the continuous availability of items under the "vital" category.

E- Essential category

The essential category includes inventory, which is next to being vital. These, too, are very important for any organization because they may lead to a stoppage of production or hamper some other process. But the loss due to their unavailability may be temporary, or it might be possible to repair the stock item or part.The management should ensure optimum availability and maintenance of inventory under the "Essential" category too. The unavailability of inventory under this category should not cause any stoppage or delays.

D- Desirable Category

The desirable category of inventory is the least important among the three, and their unavailability may result in minor stoppages in production or other processes. Moreover, the easy replenishment of such shortages is possible in a short duration of time.

(iii)EOQ

Economic order quantity (EOQ) is the ideal order quantity a company should purchase to minimize inventory costs such as holding costs, shortage costs, and order costs. The formula assumes that demand, ordering, and holding costs all remain constant.

Formula and Calculation of Economic Order Quantity (EOQ)

The formula for EOQ is:

$$Q = \sqrt{\frac{2DS}{H}}$$

where:

$Q =$ EOQ units

$D =$ Demand in units (typically on an annual basis)

$S =$ Order cost (per purchase order)

$H =$ Holding costs (per unit, per year)

The goal of the EOQ formula is to identify the optimal number of product units to order. If achieved, a company can minimize its costs for buying, delivery, and storing units. The EOQ formula can be modified to determine different production levels or order intervals, and corporations with large supply chains and high variable costs use an algorithm in their computer software to determine EOQ.

EOQ is an important cash flow tool. The formula can help a company control the amount of cash tied up in the inventory balance. For many companies, inventory is its largest asset other than its human resources, and these businesses must carry sufficient inventory to meet the needs of customers. If EOQ can help minimize the level of inventory, the cash savings can be used for some other business purpose or investment.

The EOQ formula determines a company's inventory reorder point. When inventory falls to a certain level, the EOQ formula, if applied to business processes, triggers the need to place an order for more units. By determining a reorder point, the business avoids running out of inventory and can continue to fill customer orders. If the company runs out of inventory, there is a shortage cost, which is the revenue, lost because the company has insufficient inventory to fill an order. An inventory shortage may also mean the company loses the customer or the client will order less in the future.

(iv) Lead time

The lead time is the sum of the supply delay and the reordering delay. The lead time is the applicable duration to calculate the lead demand, the safety stock or the reorder point through a direct quantile forecast. The longer the lead time, the higher the total inventory level or the larger is the safety stock, resulting in excess of investment in inventories. As far as possible efforts should be made to decrease the lead time for effective inventory control.

(V) Buffer stock

Buffer stock is used in emergency to meet the unforeseen demands . in other words it refers to minimum quantity of a particular item which must be kept in the stores of all time. Buffer stocks can be calculated using the following formula ;

Buffer stocks= (Maximum consumption rate / day average- consumption rate / day)X lead time

Buffer stocks needs following factors to be taken into consideration like;

(i) Lead time

(ii) Nature of item and rate of consumption

(iii) Availability of substitutes

(iv)Re-order level

(v) Stock out cost

Modern Computerization of Inventory Control

Presently national information centre (NIC) is working hard to prepare software which would facilitate proper control of inventory through the implementation of accepted principles of material management such as ABC analysis, "Last is the first out" etc. It would minimize the chances of validity of drugs expiring while in storage by the transfer of stocks from the surplus to deficit depots.

Computerization will serve following purposes:

(i) Less investment

(ii) Less storage

(iii)Fast supply of drug

(iv) Control on Issue of Drugs

(v) Minimum wastage

(vi) Prompt payments

Reorder Level

The reorder level is the level of the stock of a particular item, held by the firm, when an order is needed to be placed for avoiding the risk of being out of stock. It is based on the average time taken by the supplier for replenishment, maximum usage of the item during the replenishment time, and safety stock requirement. It is also known as reorder point. Reorder level is the stock level of a particular item of inventory, at which a firm needs to place an order for the fresh supply or replenishment of the item. It gives a signal regarding when to place a new order for the fresh supply of an inventory item. The internal factors involved in reorder level are maximum usage during the lead time, safety level, and replenishment period. Whereas the external factor involved in reorder level is lead time taken by the supplier. 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 following formula is used for estimation of reorder level:

Reorder level = (Average daily usage rate x Average lead time in days) + Safety level

Investigational Use of Drugs

Syllabus:-Description, Principles involved, Classification, Control, Identification, Role of Hospital Pharmacist, Advisory Committee.

Investigational Drug

Any drug or placebo which is being tested or used as a reference in a clinical trial, including a registered drug used in a different formulation, or used for an unapproved indication, or used in doses outside the approved range is called as investigational drugs. An investigational drug can also be called an experimental drug and is being studied to see if disease or medical condition improves while taking it. Hospitals and other healthcare agencies are the major centers for clinical studies with investigational drugs and pharmacists in these institutions should be involved with policies and procedures for the safe and ethical use of these drugs [1].

Principles

Hospitals are the primary centers for clinical investigations on drugs. By definition these are drugs which have not yet been released by the Federal Food and Drug Administration for general use. Since investigational drugs have not been certified as being for general use and have not been cleared for sale in interstate commerce by the Federal Food and Drug Administration, hospitals and their medical staffs have an obligation to their patients to see that proper procedures for their use are established.

Procedures for the control of investigational drugs should be based upon the following principles:

1. Investigational drugs should be used only under the direct supervision of the principal investigator who should be a member of the medical staff and who should assume the burden of securing the necessary consent.

2. The hospital should do all in its power to foster research consistent with adequate safeguard for the patient.

3. When nurses are called upon to administer investigational drugs, they should have available to them basic information concerning such drugs- including dosage forms strengths available, actions and uses, side effects and symptoms of toxicity etc.

4. The hospital should establish, preferably through the pharmacy and therapeutics committee, a central unit where essential information on investigational drugs is maintained and whence it may be made available to authorized personnel.

5. The pharmacy department is the appropriate area for the storage of investigational drugs as it is for all other drugs. This will also provide for the proper labeling and dispensing in accord with the investigator's written orders [2].

Classification of Investigational Drugs

I. On the basis of hospital research programme the investigational drugs

(a) Class A: should contain all investigational use drugs that are in a preliminary experimental stage. The use of drug in this category is usually restricted to the principal investigator.

(b) Class B: should consist of investigational use drugs which have passed through the preliminary research stage. Usually, drugs in this category are supplied to the department of pharmacy by the principal investigator and are dispensed only upon his written prescription.

(c) Class C: is limited to drugs approved by the USP, NF or passed by the Federal FDA for commercial distribution. Drugs in this category may be used within the hospital or its clinics if the physician complies with some specific procedures.

(d) Class D: drugs are preparations which have been accepted for use in the hospital and are listed in the hospital formulary.

II. On the basis of hospital pharmacy operation

(a) General - An FDA-approved drug which as recommended as essential for good patient care with a well established usage, once accepted, may be prescribed by all members of the attending and house staff.

(b) Conditional – Certain drugs may be approved for a conditional period of trial. A drug approved by the FDA for general use, but which the Committee wishes to evaluate for given period before final consideration, may be prescribed by all members of the attending and house staff.

(c) Investigational – Drugs which are not approved by the FDA for use other than under controlled clinical settings must be approved by the Research Advisory Committee. A protocol of any study involving drugs must be submitted to the pharmacy.

Control of Investigational Use of Drugs

All investigational drugs should be registered with the Pharmacy and Therapeutics Committee. This may be accomplished by a letter from the principal investigator, which provides the following information:

01. New drug number	02. Generic name	03. Manufacturer
04. Chemical Name	05. Proprietary name	06. General Chemistry
07. Pharmacology	08. Toxicology	09. Dose Range
10. Method of Administration	11. Antidote	12. Therapeutic use.

In order to control the use of investigational drugs many pharmacists have developed various forms which may be used to disseminate the above information on an investigational use drug to the various staff doctors and nurses. These forms are usually titled:

Physician’s Data Sheet on Investigational Drugs

Nurse’s Data Sheet on Investigational Drugs

Pharmacist’s Data Sheet on Investigational Drug

(a)Physician's Data Sheet

The Physician’s data sheet must contain following information:

1. Name of the Investigational Drugs:
2. Manufacturer or other source:
3. Strength and Form of Investigational Drug:
4. Amount Received:
5. Date Received:
6. Control or Batch #

7. Pharmacologic and Therapeutic Properties, Dosage, Precautions:
8. Arrangements which have made for its administration
9. Signature of Investigator

(b) Nurse's Data Sheet

The Nurse's data sheet must contain following information:

1. Name of the Investigational Drugs:
2. Manufacturer or other source:
3. Strength and Form of Investigational Drug:
4. Pharmacologic and Therapeutic Properties, Dosage, Precautions to be observed:
5. Arrangements which have made for its administration
6. Signature of Nursing In-charge

(c) Pharmacist's Data Sheet

The Pharmacist's data sheet must contain following information:

1. Investigational Drug:
2. Manufacture:
3. Chief Investigator:
4. Date:
5. Physician
6. Patient
7. Rx.#
8. Amount
9. Ward
10. Signature of Chief Pharmacist

Authorization for Treatment with Drug Under Clinical Investigation

The Law Department of the American Medical Association states that drugs under clinical investigation should be administered only where:

1. The informed consent of the patient or his/her authorized representative has been obtained,
2. The physician is convinced of the reasonable accuracy of his diagnosis and, if necessary, has confirmed it by adequate consultation and
3. Existing methods of treatment have proven unsatisfactory.

The physician is advised to confine his clinical investigations of new drugs to those furnished by the reputable sources who have supplied him with comprehensive written information concerning:

1. Animal experimentation.
2. Previous clinical investigations, if any?
3. Recommended dosages.
4. Contraindication.
5. Possible side effects to be watched for, and
6. The safety and possible usefulness of the drug from existing data.

Authorization Form

I authorize Dr. < Name of the Physician>, the attending doctor /physician to treat Patient Name, with the drug presently identify as <Name of the drug> for the following condition: Describe symptoms of disease. It has been explain to me that the safety and usefulness of the drug in the treatment.

I voluntarily consent to treat with the drug and release the attending doctor/physician for liability from any results that may occurs.

Witness Signature-----

(Patient or Authorized representative of the patient)

Consent Form

Patient's Name:_____Date:- Project title_____

Description of the product to be undertaken:

I have fully explained to the patient…<Name of the Patient>….the nature and purpose of the producer described above and such risks as are involved in its performance.

Physician's Sign.

I have fully informed or the risk and possible consequences involved in the performance of the product described above, have been advised that unforeseen results may occur and nevertheless hereby authorized

Dr._____

Witness Patient Sig./Authorized representative_____

Moreover, the hospital pharmacist is urged to consult the hospital's legal counsel for the law applicable to the area in which the hospital is located.

Identification of Investigational Use of Drugs

Whenever Class A or class B drugs are dispensed from the pharmacy, they should be labeled in such a manner as to differentiate them from routine prescription drugs. In some hospitals, investigational use drug labels are printed in red ink on white paper stock. In

addition to commonly required information are:

(i) Patient's name (ii) Data (iii) Prescription number (iv) Doctor's name and (v) directions for use (vi) a space for the research drug number is provided.

This double set of number provides a two-way control relative to the identity of the product dispensed.

Role of the Pharmacist in the Clinical Evaluation of a Drug

Once the pharmacologist has demonstrated a new compound to be effective and safe in animal test, clinical trials are invariably commenced. These trials usually proceed in two steps-preliminary and extended. During the preliminary stage, the principal investigator cautiously administers the drug to a limited number of selected patients and closely follows the results. After having gained experience and confidence in its use, the investigator is generally ready to conduct an extended comprehensive evaluation of its efficacy.

During this stage, the pharmacist can play an important role by assisting in the development of the protocol and the control of a double blind test/study—having the experimental drug and placebo prepared exactly the same dosage form and presentation. Neither the patient nor the doctor informed as to whether the placebo and the potent article.

The kind and extent of the investigational drug test are crucial to producing the substantial scientific evidence of safety and effectiveness needed to approve the drug for marketing. This evidence is obtained in three phases:

Phase-I: to determine toxicities, metabolism, absorption, elimination.

Phase-II: Initial trial on limited patients for treatment (specific disease)

Phase-III: involve extensive clinical Trial, information obtained from above

Phase – IV: Post marketing surveillance

Advisory Committee for Investigational Use of Drugs

The Pharmacy and Therapeutic Committee (PTC)

FDA advisory committee system

(a) The Pharmacy and Therapeutic Committee (PTC)

The PTC is a group of persons which formulate policies regarding evaluation and therapeutic use of investigational drugs. This committee is composed of Physicians, Pharmacist, and other health professionals with the inclusion of the medical staff. It looks after the safety in handling and administering the investigational drug. It also plays a vital role in monitoring adverse drug reaction. Every case of adverse drug reaction is first reported by the attending physician to the chairman of the PTC. The PTC interacts with various government bodies like drug technical advisory board (DTAB), Central Drug Research Institute (Lucknow), Drugs Controller General of India, All India Institute of Medical

Sciences (New Delhi), Post-Graduate Institute (Chandigarh) for consultation for adverse drug reaction of investigational drugs [3].

(b) FDA advisory committee system

FDA advisory committee provides technical assistance related to the development and evaluation of investigational drugs, biologics, and medical devices. It also lends credibility to its decisions and decision-making processes, and provides a forum for public discussion of certain controversial issues. The primary role of FDA technical advisory committees is to provide independent expert scientific advice to the agency in its evaluation of investigational drugs any stage of consideration by the agency. A related role is to advise the agency on general criteria for evaluation and on broad regulatory issues that are not related to a specific product .

INTERPRETATION OF CLINICAL LABORATORY TESTS

Syllabus:- Blood Chemistry, Haematology, and Urine Analysis

I. Blood Chemistry Tests

Blood chemistry tests are blood tests that measure amounts of certain chemicals in a sample of blood. They show how well certain organs are working and can help find abnormalities. Blood chemistry tests may also be called **chemistry panels**. There are many types of blood chemistry tests. They measure chemicals including enzymes, electrolytes, fats (also called lipids), hormones, sugars, proteins, vitamins and minerals. Often several chemicals are grouped together and measured at the same time.

Reason for conducting blood chemistry tests

Blood chemistry tests are common blood tests. An unusual (higher or lower than normal) amount of a substance present in the blood can be a sign of disease in the organ or tissue that makes it. They are often done as part of a routine checkup, but can be done at any time.

Blood chemistry tests can be done to:

- Learn information about your general health.
- Check how certain organs are working, such as the kidneys, liver and thyroid.
- Check the body’s electrolyte balance.
- Help diagnose diseases and conditions.
- Provide the levels of chemicals (a baseline) to compare with future blood

chemistry tests.

- Check how a treatment is affecting certain organs.
- Monitor cancer or another condition (as a part of follow-up).

Common blood chemistry tests

Different tests may be used to measure different types of chemicals. The following are some common blood chemistry tests.

(A) Basic Metabolic Panel (BMP)

The basic metabolic panel (BMP) is a group of 8 tests that measures several substances in the blood. It is one of the most commonly ordered lab tests. The BMP gives important information about the current status of the body's metabolism (hence the name metabolic panel) to the healthcare practitioner. The BMP provides information on blood sugar (glucose) level, the balance of electrolytes and fluids, and the function of the kidneys. Abnormal results, and especially combinations of abnormal results, can indicate a problem that needs to be addressed and may require additional testing. The reference range for a basic metabolic panel has been shown in Table 5.1.

The BMP includes the following tests:

(i) Blood Glucose Level –

Glucose is the primary energy source for the body's cells and the only energy source for the brain and nervous system. A steady supply must be available for use, and a relatively constant level of glucose must be maintained in the blood. This test is conducted to screen for and diagnose diabetes and prediabetes and to monitor for high blood glucose (hyperglycemia) or low blood glucose (hypoglycemia).

The normal fasting blood sugar level is from 60-100 mg/100 ml. 50 mg of glucose is then taken, blood sample is withdrawn after 2 hours. Blood sugar reaches to a maximum level and then it returns to normal levels within 1-2 hours. If it does not return to normal levels and remains elevated to more than 50 mg above the fasting value, it indicates diabetes mellitus. High blood sugar indicates pancreatic disease, hyperthyroidism, hepatic disorders, hyperglycaemia. Low blood sugar levels are observed in hyper thyroidism, hypo-pituitarism or over dose of insulin.

(ii) Blood Calcium level-

Calcium is the most abundant and one of the most important minerals in the body. It is essential for cell signaling and the proper functioning of muscles, nerves, and the heart. Calcium is needed for blood clotting and is crucial for the formation, density, and maintenance of bones and teeth. This test measures the amount of calcium in the blood or

urine, which reflects the amount of total and ionized calcium in the body.

It is tested whenever there are symptoms of a disorder, or known presence of one, affecting the kidneys, bones, thyroid, parathyroid, or nerves or when symptoms of significantly increased or decreased calcium concentrations are present; when someone has certain types of cancer.

There are two tests to measure blood calcium. The total calcium test measures both the free and bound forms. The ionized calcium test measures only the free, metabolically active form. The reference range for blood calcium level in adult is 8.6-10.2 mg/dL. However in case of child there is no fixed reference range. Higher total calcium level (hypercalcemia) than the reference value may be due to hyperparathyroidism, presence of cancerous cell, hyperthyroidism, sarcoidosis, tuberculosis etc. However the reasons for lower total calcium level (hypocalcemia) may be due to liver disease or malnutrition, hypoparathyroidism, decreased levels of vitamin D, magnesium deficiency, increased levels of phosphorus, acute inflammation of the pancreas (pancreatitis), renal failure etc..

(iii) An electrolyte panel

It is helpful for detecting a problem with the body's fluid and electrolyte balance. The electrolyte panel measures the levels of the main electrolytes in the body such as sodium, potassium, chloride, magnesium, phosphate and bicarbonate etc.

(a) Sodium is an electrolyte present in all body fluids and is vital to normal body function,

including nerve and muscle function. This test measures the level of sodium in the blood. A sodium blood test is used to detect an abnormal sodium level, including low sodium (hyponatremia) and high sodium (hypernatremia). The reference range of sodium in adult is 136-145 mmol/L, however in case of person >90 yrs it is 132-146 mmol/L. The conditions that can cause lower blood sodium (hyponatremia) includes diarrhea, vomiting, excessive sweating, use of diuretics, kidney disease or low levels of cortisol, aldosterone and sex hormones (Addison disease), edema due to heart failure etc. However the condition that cause higher blood sodium (hypernatremia) includes dehydration, cushing syndrome, diabetes insipidus,

(b) Potasium is an electrolyte that is vital to cell metabolism. It helps transport nutrients into cells and removes waste products out of cells. It is also important in muscle function, helping to transmit messages between nerves and muscles. This test measures the amount of potassium in the blood. It is conducted whenever there are symptoms like muscle weakness and/or irregular heart beat (cardiac arrhythmia) or when an electrolyte imbalance is suspected; at regular intervals when somebody is taking a medication and/or have a disease or condition, such as high blood pressure (hypertension) or kidney disease.

The reference range of blood potassium level in adult is 3.5-5.1 mmol/L. The conditions that can cause high potassium levels (hyperkalemia) include kidney disease, dehydration, diabetes, addison disease, injury to tissue, use of drugs like non-steroidal anti-inflammatory drugs (NSAIDs), ACE inhibitors, beta blockers. However the conditions that can cause lower potassium levels (hyporkalemia) include diarrhea and vomiting, primary hyperaldosteronism

(Conn syndrome), complication of acetaminophen overdose, diabetes, use of certain drugs such as corticosteroids, beta-adrenergic agonists etc.

(C) Chloride an electrolyte. It is a negatively charged ion that works with other electrolytes, such as potassium, sodium, and bicarbonate, to help regulate the amount of fluid in the body and maintain the acid-base balance. This test measures the level of chloride in the blood. Chloride is present in all body fluids but is found in the highest concentration in the blood and in the fluid outside of the body's cells. Most of the time, chloride concentrations mirror those of sodium, increasing and decreasing for the same reasons and in direct relationship to sodium. When there is an acid-base imbalance, however, blood chloride levels can change independently of sodium levels as chloride acts as a buffer. It helps to maintain electrical neutrality at the cellular level by moving into or out of the cells as needed.

The reference range of blood Cl^- level in adult is 98-107 mmol/L. Low and high chloride levels can be caused by various conditions and diseases. An increased level of blood chloride (called hyperchloremia) usually indicates dehydration, but can also occur with other problems that cause high blood sodium, such as Cushing syndrome or kidney disease. Increased blood chloride may also occur when too much base is lost from the body (producing metabolic acidosis) or when you hyperventilate (causing respiratory alkalosis). A decreased level of blood chloride (called hypochloremia) may occur with any disorder that causes low blood sodium. Low chloride may also occur with congestive heart failure, diabetic ketoacidosis, aldosterone deficiency, prolonged vomiting or gastric suction, Addison disease, emphysema or other chronic lung diseases (causing respiratory acidosis), and with loss of acid from the body (called metabolic alkalosis).

(d) Bicarbonate is an electrolyte, a negatively charged ion that is used by the body to help maintain the body's acid-base (pH) balance. It also works with the other electrolytes (sodium, potassium, and chloride) to maintain electrical neutrality at the cellular level. This test measures the total amount of carbon dioxide (CO_2) in the blood, which occurs mostly in the form of bicarbonate (HCO_3^-). The CO_2 is mainly a by-product of various metabolic processes.

The reference range of blood bicarbonate (HCO_3^-) level in adult is 23-29 mmol/L. Conditions that can cause a low bicarbonate level include: addison disease, chronic diarrhea, diabetic ketoacidosis, metabolic acidosis, respiratory alkalosis which can be caused by hyperventilation shock, kidney disease etc. Condition that cause a higher biocarbonate level include conditions that can cause a high bicarbonate level include: severe, prolonged vomiting and/or diarrhea, lung diseases, including COPD, cushing syndrome, conn syndrome, metabolic alkalosis.

(IV) Kidney Function Test/ Renal Panel

(a) Blood urea nitrogen (BUN) – Waste product (urea) filtered out of the blood by the kidneys; as kidney function decreases, BUN level rises**.** This test is conducted to evaluate the health of the kidneys; to help diagnose kidney disease; to monitor the effectiveness of dialysis and other treatments related to kidney disease or damage.

The reference ranges of blood urea nitrogen in adult and the person >60 years are 2.1-7.1 mmol/L and 2.9-8.2 mmol/L respectively. The conditions responsible for increase in BUN levels include: kidney disease, dehydration, increased protein in diet, congestive heart failure,

shock, stress, recent heart attack, or severe burns etc. However, the conditions responsible for decrease in BUN levels are liver disease, malnutrition.

(b) Serum Creatinine– Creatinine is the waste product produced in the muscles from the breakdown of a compound called creatine and is filtered out from the blood by the kidneys. This test is conducted to know how well the kidneys are working. Results of creatinine tests are interpreted along with BUN results, and with other tests results that may have been performed at the same time, such as a renal panel.

The reference range male and female of 18-60 yrs age group are 80 - 115 µmol/L and 53 - 97 µmol/L respectively. However in case of male and female of >60 yrs age group have 71 - 115 µmol/L and 53 - 106 µmol/L respectively. Conditions that responsible for higher serum creatinine levels include are glomerulonephritis, pyelonephritis, pyelonephritis, reduced blood flow to the kidney due to shock, dehydration, congestive heart failure, atherosclerosis, or complications of diabetes. Low blood levels of creatinine are not common and are not usually a cause for concern. They can be seen with conditions that result in decreased muscle mass.

Table- 5.1 Reference Range for a Basic Metabolic Panel

Test	**Normal range (Adults 18-60 years old)**	**Normal range (Adults >60 years old)**	**Category**
Glucose	70-99 mg/dL	70-99 mg/dL	Sugar Metabolism
Ca+ (calcium)	8.6-10.2 mg/dL	8.6-10.2 mg/dL	Electrolyte Panel
Na+ (sodium)	136-145 mEq/L	132-146 mEq/L (adults over 90 years old)	Electrolyte Panel
K+ (potassium)	3.5-5.1 mEq/L	3.5-5.1 mEq/L	Electrolyte Panel
Cl- (chloride)	98-107 mEq/L	98-111 mEq/L (adults over 90 years old)	Electrolyte Panel
CO_2 (Carbon dioxide or bicarbonate)	23-29 mEq/L	23-31 mEq/L (Adults 61-90 years old); 20-29 mEq/L (Adults over 90 years old)	Electrolyte Panel

BUN (Blood urea nitrogen)	6-20 mg/dL (milligrams per deciliter of blood)	8-23 mg/dL of blood	Renal Panel
Creatinine	0.9-1.3 mg/dL for men; 0.6-1.1 mg/dL for women	0.8-1.3 mg/dL for men; 0.6-1.2 mg/dL for women	Renal Panel

(B) Blood Cholesterol

Normal range is from 100-240 mg/100 mL in healthy young adults. It rises slowly with age. A high serum cholestrol 300 mg/0 l in young adults is a serious indicator of coronary disease.

Significance: An Increase in serum cholesterol is observed in various pathological conditions like nephrosis, lipemia, diabetes mellitus, hyperthyrodism, heaptitis. Decrease in serum cholesterol is found in hyperthyrodism, pernicious anaemia, wasting disease, acute infections, hepatocellular damage.

II. HAEMATOLOGICAL PARAMETERS

1. Erythrocytes (Red Blood Cells): Total RBC count of blood is expressed as number of cells per mm^3. The normal RBC count in men, women and children is mentioned in Table 5.2.

Significance: A relative or absolute increase in the number of circulating R.B.C. Leads to polycythaemia (erythrocytosis) and is observed in various pathological conditions like chronic heart disease, cholera, burns. A decrease in number of R.B.C. is observed in pregnancy anaemia etc.

2. Leucocytes (White blood cells): The total leucocytes count is expressed as number of W.B.C. in a cubic mm of whole blood.

Significance: An Increase in W.B.C's indicates an infection like bacterial infection, fever, tonsillitis, diptheria, smallpox, cold, etc. Physiological leucocytosis (increase W.B.C count) is observed in pregnancy, newborn infants, emotional disturbances, menstruation, fear etc. Great increase shows leukaemia.

W.B.C. differential analysis gives the distribution of various types of leucocytes. Their normal ranges are mentioned in the table 5.2

Significances:

(i) Basophils: An increase in basophil number is indicated in various pathological conditions like mumps, chickenpox, viral hepatitis, tuberculosis, pertusis, granulocytic leukaemia, lymphocytic leukaemia, breast cancer.

(ii) Eosinophils: Increase in eosinophils (Eosinophilia) is indicative of allergic disorders (bronchial asthama, eczema, food allergy), skin diseases (pruritis, leprosy, exfoliative dermatitis), cholera, scarlet fever, tumours of ovary and uterus, ulcerative colitis, etc. Decrease in eosinophils found in stress, cushing disease and in acute infections.

(iii) Monocytes: These are phagocytic cells. A marked increase in monocytes (Monocytosis) is found in tuberculosis, monocytic leukemia, ulcerative colitis, malaria and various bacterial infections.

(iv) Lymphocytes: Lymphocytosis (increase in lymphocytes) is observed in children with viral infection (measles and mumps), whooping cough. Other pathological conditions are syphilis, tuberculosis, breast cancer, etc.

Lymphocytopenia (Decrease in lymphocytes) is indicative of Hodgkin's disease, cardiac failure, stress, AIDS virus, terminal renal failure, etc.

(v) Neutrophils: Neutrophils leukocytosis (an incrase in neutrophil) is seen in rheumatic fever, rheumatoid arthiritis, gout, myocardial infraction, gangrene, etc.

Neutropenia (decrease in neutrophils) is seen in malaria, dengue, infective hepatitis, tuberculosis, typhoid, paratyphoid, etc.

3. Thrombocytes (Platelets): Platelets are very small bodies (3µ diameter). They play a vital role in blood coagulation.

Significance: Thrombocytosis (increase in number of thrombocytes) is observed in various conditions like tuberculosis, cirrhosis of liver, acute haemorrhage, iron deficiency anaemia, Hodgkin's disease.

Thrombocytopenia (decrease in platelet count) is indication of miliary T.B., myeloproliferative disorders, spleen enlargement, septicemia, Gaucher's disease, massive haemorrhage, microangiopathic haemolytic anaemia etc.

4. Haemoglobin: Haemoglobin gives the idea of oxygen carrying capacity of red blood cells. Anaemia is the condition where the haemoglobin percentage is low. They are above normal in dehydration and polycythaemia. Normal values are mentioned in Table 5.2.

5. E.S.R. or Erythrocyte Sedimentation Rate: In this erythrocytes (RBC's) are allowed to settle in whole blood under the force of gravity over a period of time (usually 1 hr). The speed of their fall is called sedimentation rate and is measured in mm/1 hr. E.S.R. is very useful for detection of tissue damage in various conditions like myocardial infarction, angina pectoris, etc.

An increase in E.S.R. is observed in myocardial infarction, rheumatoid arthritis, rheumatic fever, T.B., renal disease, cancer, anaemia, pneumonia, mensuration, etc. A decrease in E.S.R. is indicative of sickcle cell anaemia, polycythemia vera, etc.

6. Clotting time of blood: It is the time required for coagulation of blood, where fibrinogen is converted into fibrin to form matrix for fixation of cellular portion. Normal range of whole body clotting time is 4-9 minutes at 37^0C.

Significance: It is used to diagnose haemophilia, Vitamin K deficiency anaemia, leukaemia,

obstructive jaundice etc. Prolonged clotting time indicates haemophilia (factor VIII

deficiency). Before surgeries, clotting time is generally recorded so as to prevent excessive loss of blood.

Table 5.2 Normal Values Showing Haematological Parameters

Sl No	Types of parameters	Men	Women	Children
1.	R.B.C. Counts	4.5 to 5.5 million/mm^3	3.5-5.5 million/mm^3	4.0 to 5.5 million/mm^3
2.	W.B.C Counts	4000 to 11000 Cells /mm^3		
	W.B.C differential analysis gives the distribution of 5 major leucocytes			
	W.B.C	**% count**	**Actual Count**	
(i)	Basophils	0-1%	0-100	
(ii)	Eosinophils	1-4%	40-400	
(iii)	Monocytes	4-8%	160-800	
(iv)	Lymphocytes	23-35%	1000-3500	
(v)	Neutrophils	60-70%	2500-7000	
3.	**Thrombocytes (Platelets)** The normal range of platelets is 1,50,000 to 3,00,000/mm^3			
4.	**Haemoglobin**	13-18g/dl	11.5-16.5 g/dl	7.5-14.5 g/dl
5.	**E.S.R**	0-15 mm/1 hr	0-20 mm/1 hr	0-10 mm/1 hr
6.	**Cloting time of the blood** is 4-9 minutes at 37^OC			

III. URINE EXAMINATION

Abnormal constituents appear in the urine sample whenever there is pathological condition of the body. The following table (Table-5.3) shows the abnormal constituents and their related disorders.

Table 5.3 Abnormal constituents of urine and the disorders

Sl No	Abnormal constituents	Disorder
1	Sugar (glucose)	Diabetes mellitus, endocrine disorder
2	Proteins (Albuin) Normal (50-80 mg/mL)	If albumin present in urine, It can be due to kidney damage
3	Bile pigments like bilirubin	Jundice
4	Ketone bodies	Diabetes mellitus, starvation, ketosis
5	Blood cells	Haematoria, T.B, cancer, Acute inflammation of urinary organ, haemolysis

Generally urine is examined physically, chemically and microscopically. Various physical tests like volume, appearance, pH, Specific gravity are performed to obtain basic information of certain systemic diseases. Various physical examinations of urine, their normal values and associated disorders are shown in Table 5.4

Table 5.4 List of various physical examinations of urine, their normal values and associated disorders

Test	Normal Value	Related Disorder
1. Volume	700-2500 ml	Increase in polyurea, diabetes mellitus, diabetes insipidus, Decrease in diarrhoea
2. Appearance	Clear form, Colour ranges pale yellow to deep gold	Red color indicates the presence of blood, yellow with tetracycline, It becomes cloudy due to presence of pus or phosphate
3. Specific gravity	Normal range is 1.003 to 1.025	Increase in Diabetes mellitus, Nephrosis Decrease in Diabetes insupidus
4. pH	4.5-9.0 is the normal value (Acidic)	Alkaline pH shows alkalosis or use of certain drug

IV. GENERAL STOOL EXAMINATION

(A) Macroscopic observation of the fecal sample:

Macroscopic appearance of the stool can give a clue to the type of organisms present. (i)**Consistency:** Normal stools are well formed. In diarrhea and dysentery the stools are semi solid or watery in nature. The cysts have been mostly found in the formed stools, while trophozoit have been most abundantly found in watery stools.

(ii) Color: the normal adult stool is brown due to bile pigments, and the color of stool is affected by the type of food. Infant feces are yellow-green and semi formed.

Abnormal types of feces color:

1-Watery (like rice water): the patient infected with cholera (Vibrio cholerae)

2- Clay or white colored: Obstructive jaundice or presence of barium sulfate

3-Reddish colored: Blood from lower gastrointestinal tract, beef consumption

4-Black: Bleeding from upper gastrointestinal tract (melena), Iron, charcoal.

5- Green: Ingestion of Spinach, antibiotics.

The presence of blood, mucus or pus

Blood and mucus: it is a case of amoebic dysentery caused by *Entameoba histolytica.*

Blood and pus: the case is bacillary dysentery, caused by *Shigella, Compylobacter or E.coli.*

Only blood: the diarrhea caused by *Salmonella or E.coli or Clostridium difficile*

The **presence of adult worms** can also be seen in a freshly passed stool eggs adult stages of ***Ascaris lumbricoides*** and ***Enterobius vermicularis***. ***Proglottid of Taenia*** species can also be seen.

(B) Microscopic examination

Examine fecal specimens under (10X and 40X objectives) of light microscope and report the presence of:

1. Large numbers of pus cells:

Clumps of pus cells of > 50 cells per high power field along with macrophages and erythrocytes are typical of shigellosis.

A smaller number of pus cells of < 5 cells per high power field are present in cholera, EPEC and ETEC and viral Diarrhoea

2-RBCs

3-Amoebas, flagellates

4-Eggs, larvae & cysts

(C) Chemical Examination of Stool

(i) pH: normal stool pH is week acidic (pH 6).The pH of stools is acidic in amoebic dysentery and is alkaline in bacillary dysentery.

(ii) Occult blood: Occult blood may be present in a number of diseases Including malignancy of the gastrointestinal tract (colon, rectum, stomach).

(iii) Reducing factors: mono sugar and di sugar ,there level in stool (6mg/g) any increase in that level indicate disturbance in enzymes that digest sugar (e.g.Lactase, Sucrase).

Various examination of stool and their significance are shown in Table 5.5

Table 5.5 Stool Examination and the Significances

Sl no	Test	Significance
1	Semi solid consistency is normal	If watery stools are there chances of infection
2	Brownish color is normal	Color may change according to diet and drug
3	Putrefective actions of bacteria leads to an odour	Very foul order is present in ulceration, malignant lesion in rectum
4	Very small amount of mucous in normal conditions	Large amount of mucousseen in dysentry, colitis, amoebiasis, nematoda, round worms, hook worms, entamoeba, histolytica, E. col are observed in various pathological conditions
5.	Microscopic examination is done for the presence of RBC, pus cells and common parasite	In case of amoebic dysentery R.B.C., mucus, and pus cells are present. Tape worm, flat worm, nematode, round worms, hookworms, entamoeba histolytica, E.Coli are observed in various pathological conditions.

V. EXAMINATION FOR COMMON ENZYMES

(i) Phosphatases: These are the enzymes which catalyse the splitting of phosphoric acid from mono phosphoric acid esters. There are two types of Phosphatases present in serum. Alkaline phosphatases with maximum activity at about pH 10 and acid phosphatase with maximum activity at about pH 5.

The normal range of serum acid phosphatase is 1-5 KA units/100ml. It increase in prostratic cancer. Normal range of serum alkaline phosphatase is 29-92 IU/L. Higher levels are observed in rickets, osteomalacia, impaired absorption of vitamin D, calcium and jaundice.

(ii)Serum Glutamate Oxaloacetate Transminase (SGOT): Normal levels of this enzyme is upto 35 SF units/100 ml. SGOT levels increase in infective, toxic hepatitis, cirrhosis, obstructive jaundice, cardiac diseases (myocardial infarction) and muscle damage.

(iii) Serum Glutamate Pyruvate Transminase (SGPT) or Alanine Transminase (ALT): It catalyzes the conversion of L-alanine to pyruvate at a temperature of 37^0C.

The normal range of SGPT is 35 SF units/100mL (sigmafrankel units). The level is increased in liver cell damage.

(iv) Diastase in Urine: The enzyme diastase is present in urine which acts upon starch and converts it into maltose. Normal Level of urine diastase is 3-32 units. Urinary diastase activity increase in pancreatitis.

(v) Lactic Acid Dehydrogenase (LHD or LD): This enzyme catalyzes the interconversion of lactate and pyruvate. There are 5 isoenzymes of LHD which are described as under:

-LHD_1 and LHD_2 present in heart

-LHD_3 in the lungs

-LHD_4 and LHD_5 mainly in liver and skeletal muscle

Their distribution helps in diagnosing various pathological conditions like myocardial infaraction, and hepatic diseases.

(vi) Creatine Phosphokinase (CPK): It is found in heart muscle, and skeletal muscle. There are three isoenzymes of CPK like CPK-MH, (Muscle), CPK-BB (brain), CPK-MB (Heart). Measurement of their level differentiate their source of damage.

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