

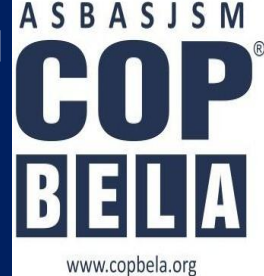


Amar Shaheed Baba Ajit Singh Jujhar Singh Memorial

# COLLEGE OF PHARMACY

(An Autonomous College)

BELA (Ropar) Punjab



<b>Program</b>	:	B. Pharmacy
<b>Name of Unit</b>	:	Drug Store management
<b>Subject /Course name</b>	:	Pharmacy Practice
<b>Subject/Course ID</b>	:	BP 703T
<b>Class: B.Pharm. Semester</b>	:	VII
<b>Module</b>	:	V
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## Learning Outcome of Unit

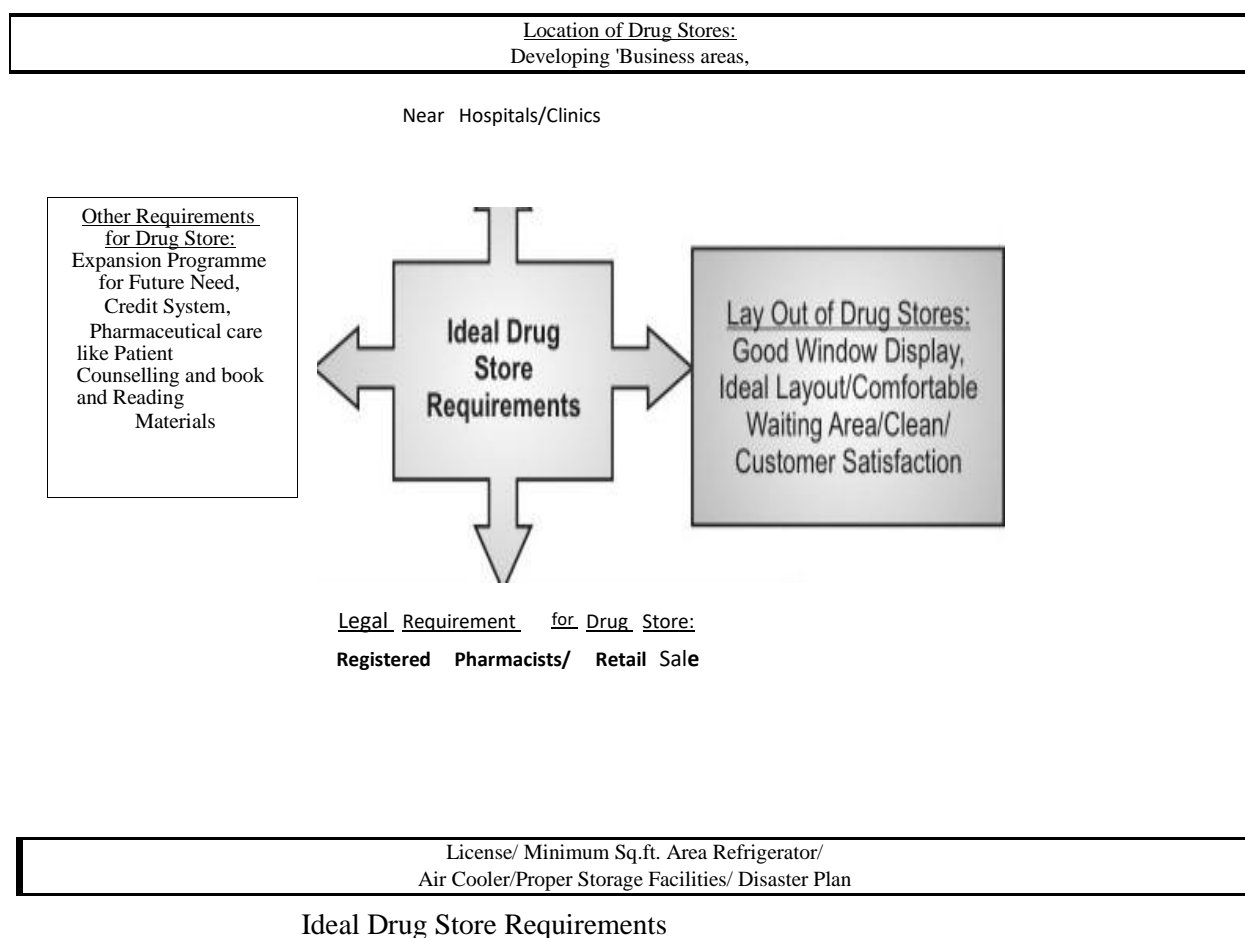
LO	Learning Outcome (LO)	Course Outcome Code
LO1	Students able to understand Ideal Drug Store Requirements, Importance and Types of Inventory Control	BP703.5
LO2	Students learn about record maintenance for dispensing of investigational drugs	BP703.5
LO3	Student able to understand role of principle investigator for use, control and supervision of investigation drugs in hospital.	BP703.5
LO4	Students learn about various biochemical tests and their clinical significance	BP703.6
LO5	Student learn about importance Of clinical laboratory testing.	BP703.6

**MODULE CONTENT TOPIC**

NO.	TOPIC
1	Drug store management and inventory control:- Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurements and stocking, Economic order quantity, Reorder quantity level, and methods used for the analysis of the drug expenditure.
2	Investigational use of drugs:- Description, Principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.
3	Interpretation of Clinical Laboratory Tests:- Blood chemistry, hematology and urinalysis.

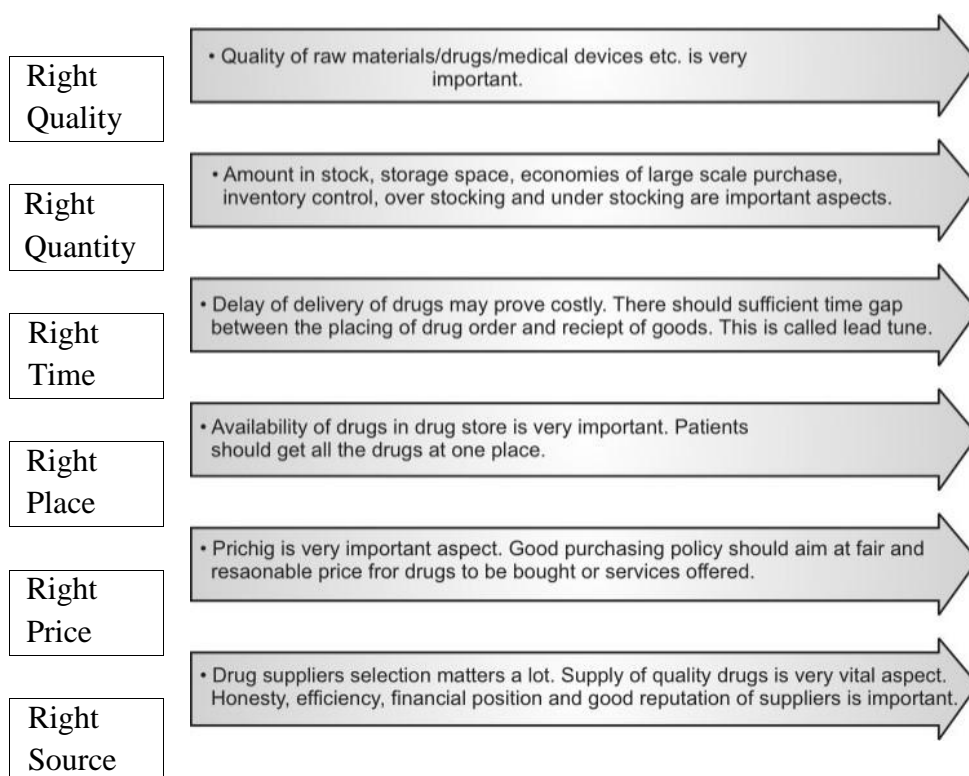
## A. DRUG STORE MANAGEMENT

Drug store management is one of the important aspects in pharmaceutical business. It is also called as retail pharmacy, which consists of final activity and is a place where drugs will be in the hands of the patients/consumers or to provide services to the patients/consumers. The word retail is derived from the French word Retailer, meaning to cut a piece off or to break bulk. For successful of any retail firm, some important factors are taken into consideration. As pharmacy is specialized field, some of factors are different compared to other retail outlets. Ideal drug store requirements are mentioned below:



### Purchasing of Materials

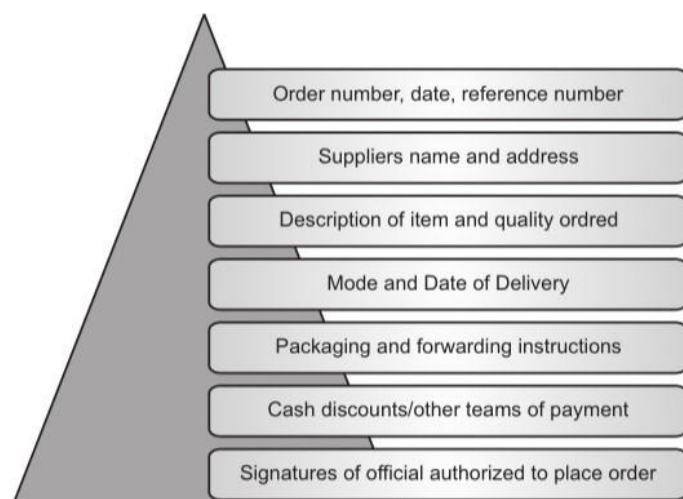
Purchasing or procurement is an important aspect of material management in pharmaceutical field. Purchasing of any materials/equipments related to pharmacy should be a genuine activity. A well planned and sound purchasing policy ensures sufficient purchases to meet all anticipated needs but avoids either over stocking or under stocking. Economical, efficient and timely purchases should be an objective of a sound purchasing policy.



#### Six R's of Scientific Purchasing of Pharmaceuticals Purchasing Procedure:

Once the selection of suppliers is done, then purchasing of drugs is done based on drug store requirements. Orders can be placed from single supplier or multiple suppliers. For continuity of supply of drugs most reputed, trusted supplier need to be selected. Mode of payment for purchase depends on supplier and buyer. It may be through credit, online or cash transactions.

**Purchase Order:** An order may be defined as an offer to buy specific drug product from suppliers. Order should be clear and free from any errors. It is one of the important written documents for future references. The particulars mentioned in purchase orders are:



**Fig. 19.3: Particulars Used in Purchase Order of Pharmaceuticals**

## 19.2 TYPES OF MATERIALS STOCKED AND STORAGE CONDITIONS

Drug stores are used to store all kind of products/materials like; capsules, tablets, liquid dosage forms, injections, antibiotics, narcotics and psychotropic substances, biologicals, medical devices, etc.

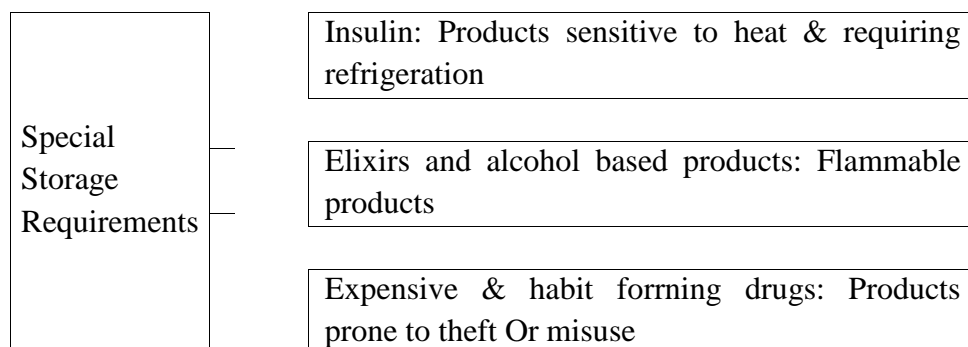
Storage/Store keeping is directly concerned with physical storage of goods. Proper storage offer protection against fire, damage, deterioration, theft, losses, etc. It helps in identifying and locating drugs through indexing, labels and identification marks. Another important aspect of storage is; it helps in effective inventory control. Storage conditions of pharmaceuticals should possess the following:

- Adequate temperature.
- Sufficient lightning.
- Clean conditions.
- Humidity control.
- Cold storage facilities.
- Adequate shelving to ensure integrity of the stored drugs.

### Storage Conditions as per Indian Pharmacopoeia

Storage Conditions	Indian Standards as per IP-1996
Cold	Temperature not exceeding $8^{\circ}\text{C}$ (between $2^{\circ}\text{C}$ - $8^{\circ}\text{C}$ ).
Cool	A temperature between $8^{\circ}\text{C}$ — $25^{\circ}\text{C}$ .
Warm	A temperature between $30^{\circ}\text{C}$ — $40^{\circ}\text{C}$ .
Excessive Heat	A temperature above $40^{\circ}\text{C}$ .
	Temperature between $-25^{\circ}\text{C}$ to $-10^{\circ}\text{C}$ .
Room Temperature	Temperature prevailing at workin area.
Place	Average relative humidity not exceeding 40%.

Vaccines and Sera: Products to be stored at a certain temperature.



Nitroglycerine and Expensive and habit forming drugs are t

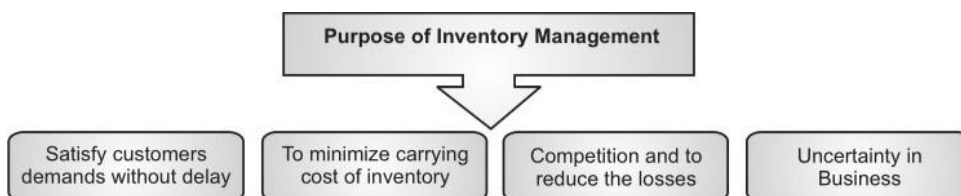
exchanged places

### Special Storage Requirements Inventories in Drug Store

Inventory means stock. To stay ahead in the market, drug stores need to take into consideration about demand and supply. Buying the right quantity is important to the success of the business in a number of ways. Inventory is required to satisfy future demands and plans of the drug store. One of the most important aspects of inventory is to have the items in stock at the moment they are needed. Inventory is the availability of goods or materials at any given time. Inventory system controls and monitors levels of inventory and regulates what levels should be maintained, when stock should be refilled, and how large orders should be placed. Inventories are affected by fluctuations in demand and manufacturing lead times which are covered by reserve stock or safety stock. Inventory is in the form of money and asset for organization. The purchase and holding of minimum supply of item will give better return on investment and inventory turnover. Many active ingredients like antibiotics and vitamins deteriorate very fast if they are not properly stored. Hence, these materials should be produced as and when required. A well-managed inventory can help in cost reduction of the organization. Thus, the savings can be invested by the organization for other profitable ventures. The various types of materials which are kept as inventories are all types of drugs, over the counter drugs and medical devices as per schedules mentioned in Drugs and Cosmetic Act, 1945.

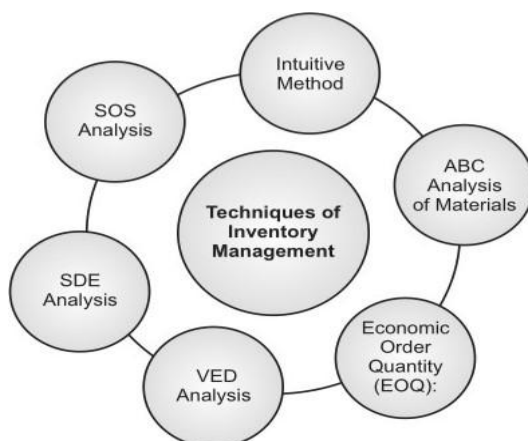
### Purpose of Inventory Management:

The main objectives of Inventory management are:



1. Satisfy customers demands without delay: The main objective of inventory management is to satisfy customers' demands by supplying drugs/medicines without endless delay.
2. To minimize carrying cost of inventory: Another important objective Of inventory management is to reduce investment in inventory at minimum level to maximize productivity.
3. Competition: To stay ahead in competitive market, drug store needs to dispense drugs as per requirement in the market.
4. To reduce the losses: There may be unexpected loss of goods due to theft, obsolescence and wastage, etc.

Uncertainty in Business: In rapidly changing environment, market (business) is facing multiple challenges in all means. To standardize the market, drug store has to go for inventory management



**Intuitive Method:** The in-built method is aided by the well-known want book. This is the most common method in practice today and surely the least effective. Items are recorded in the book when the number of units in stock reaches one to three, and the amount ordered is the best estimate of the person in charge of inventory.

**ABC Analysis of Materials:** It enables the management to plan efforts to get. It is a powerful approach in the direction of cost reduction, as it helps to control items required for production

with a selective approach. Proper color codification may be adopted for ABC categories of items. ABC analysis is called as always better control.

Class	Cost	Percentage	Quantity (%)	Procurement order
	High	75	10	Frequent order
B	Medium	15	15	Once in three months
c	Low	10	75	Once in six months (Bulk Order)

What are Class ABC Items?

**Class A:** These are fundamental items. They are bulk drugs which are costly. The cost of procurement of these items is high. In terms of quantity, they are only 10%. Class A items are antibiotics and costly drugs. Searching for many sources of supplier for class A item will be more economical. As the Class A items are very costly accurate forecast is needed for these items.

**Class B:** These are not so costly items as compared to Class A items. Class B items constitute for 15% in terms of quantity. They are usually excipients used for drugs. These are not fundamental items compared to Class A items.

**Class C:** These are also not fundamental items. These are economical items. They are excipients used for drugs. Class C items constitute for 75% in terms of quantity. The procurement order is made once in Six months. ABC analysis helps in reducing clerical costs and rationalizes the number of orders and reduce overall inventory.

### ECONOMIC ORDER QUANTITY

The EOQ is one of important method of inventory management. In pharmaceutical industry, high cost is invested on materials with longer procurement time. EOQ is represented by the formula:

$$= \sqrt{\frac{2AS}{I}}$$

= Annual

EOQ =

Where,

A = Annual usage in rupees

S = Ordering cost in rupees

I = Inventory

EOQ is based on inter-relationship of costs which shows carrying costs. As order quantities go up, so do carrying cost, but ordering costs go down. Conversely, as order quantities go down, so do carrying costs, but carrying costs go up. EOQ analysis determines whether these costs are in balance. The EOQ equation shows that the most economic lot size is the function of the square root of the annual usage of items expressed in rupees. Material manager should decide how much to buy and when exactly to buy. Excess of inventory will increase chances of



obsolescence. Purchasing of materials should be done in right time, using efficient forecasting methods carefully. Ordering to nearest trade quantity or quality may be essential, as low demand and supply will be uneconomic to produce and quote. The order quantity could be altered to get certain benefits of transportation and discounts offered for bulk purchase of materials. In case of perishable goods, the quantity has to be adjusted to shelf life of the item. When price fluctuates, dynamic programming technique has to be used to determine the quantity of purchase.

## **VED Analysis:**

VED is one of important type of inventory management. VED analysis is done to control critical inventory situation. VED analysis is called Vital Essential Desirable.

V-Vital: Item without which production will completely stop.

E-Essential: These items are also called as alternative items.

Desirable: These items can be endured for a long period.

## **SDE Analysis:**

SDE analysis is based on spares availability of an item:

S-Scarce items: These items are especially imported and those which are very much in short supply. Due to scarcity of these items, they are procured on yearly interval.

D-Difficult items: These are difficult for availability.

E-Easy items: These items are easily available. They are produced locally. Due to their easy availability, firms may not require to hold these items in large volume in their stock.

**SOS Analysis:** SOS Analysis is done, keeping in view the seasonality or non-seasonality of the item.

- S - Seasonal Items
- OS - Non-seasonal Items

Depends on seasonality and non-seasonality of the items, procurement actions vary. Example: Sales of certain commodities, such as; cough and cold products, increase between rainy and winter season due to the cold and flu season whose procurement is seasonal, these companies need to procure their requirement for a longer duration so as to adjust their production plans. Non-seasonal items are available throughout the year without any major price variation. Since seasonal items, which are available for a limited period, are procured in bulk to manage the production process throughout the year.

## **Recent Trend in Inventory Management:**

Use of computers in inventory control. As computerization of inventory control will provide effective control and increase profitability. Computerization has reformed inventory management with the help of technology company can trace their goods till it reaches in the hands of a customer. Reports which can be generated by computer like:

- Forecasting: Reports can be generated for sales history, sales forecast and forecasting techniques.
- Material planning reports can be maintained for material requirement and bills of material.
- Inventory management: Reports regarding Maximum inventory level, Minimum inventory level and ABC analysis can be maintained.

**B. INVESTIGATIONAL USE OF DRUGS**

Investigational drugs are those drugs or mixture or chemical which are not released and certified by the food and drug administration (FDA) for the general use and sale for the commercial concern. These drugs usually stand the statement on their labels as "Caution: New Drug — Limited by Federal Law to Investigational use". They are released only to the principle investigator who is the member of medical staff of hospital after obtaining consent by duly sign the food and drug release form for the manufacture of respective investigational drugs.

**CLASSIFICATION OF INVESTIGATIONAL NEW DRUGS**

Class A	This class should contain all investigational use drugs which are under the preliminary experimental stage. These drugs are restricted to used only by principle investigator.
Class B	This class of investigational drugs has passed through preliminary experimental research stage. In this class, the investigational drugs are supplied to pharmacy department by principle investigator and are only dispensed after obtaining of his written prescription which is duly sign.
Class C	This class of investigational drugs are approved by the USP, NF or passed by the Federal FDA for use and sale as commercial concern. These drugs may be used only in hospital setup for their patients under the supervision of medical staff after fulfillments of specific procedure
Class D	These classes of the drugs have been accepted for use in hospital and are listed in the hospital formulary.

**PRINCIPLES INVOLVED**

Investigational drug should be used only in hospital setup, which is the primary center for the clinical investigations. As per the definition, these are not the general-purpose use and these are not yet to release or certified by FDA for general use or for sale in commercial interest. It is responsibilities of hospital and medical staff to check and establish the proper procedure for the use of investigational drugs for their patient's benefits. The procedure and the control on the use of investigational drugs are based on the following principles:

1. The investigational drugs should be used under strict medical supervision, mainly under the supervision of principal investigator who is supposed to be a member of medical staff and having responsibilities of obtaining of necessary consent.
2. Hospital should do these procedures for short term research purpose in most critical cases such as; advanced stage of cancer with aim at beneficial and protection for their patients.
3. When the nurse is called for drug administration and is a part of the procedure, then nurse should have detailed information of investigational drug such as; dosage form, available strength, action of drug, its uses, side effects and toxicities, etc.

4. It is responsibility of hospital to establish a central unit with the help of pharmacy and therapeutic committee for the maintenance and availability of essential information on the investigation drugs to authorized personnel.
5. Pharmacy department should find appropriate place for the storage of such investigation drugs. The department will also responsible for provision of proper labelling and dispensing in accordance to written order of the principle investigator.

#### Advisory Committee and their Responsibilities:

In the view of drugs which are used in the investigational purpose in the hospital are subjected to review by advisory committees which are nothing but the committee on the human use in research; and Pharmacy and Therapeutics Committee (PTC). In which the principle investigator should provide all the information related to investigational drugs to the PTC and should letter for intention to use of investigation drugs in patients. It is the responsibilities of hospital and members of PTC to develop procedures and policies for the handling of investigational drugs in the hospital for the patient's benefits.

The committee on the human use in the clinical research is the standing committee of hospital and is responsible for the providing the guiding principles and policies issues in association with the use of human/patients for the clinical research investigations.

Following are some important policies which are need to be implemented in hospital where enforcing the use of investigational drugs for the safeguard the rights and welfare of human subjects.

- The use of investigational drug in patient must be approved from the human subject committee, pharmacy and therapeutic committee and if applicable isotope committee before the use for the patients in the hospital.
- The principle investigator shall be informed in the written that, neither the hospital nor other hospital staff will be responsible for any legal liabilities which may occur during the use of investigational drugs.
- Investigator should not proceed to use the investigational drug before obtaining of the consent form from the patient or legally responsible person.
- The principle investigator is responsible for to register each investigational drug in pharmacy department and provide all the related information to prepare investigational drug data sheet and drug formulary.

#### CONTROL AND SUPERVISION OF INVESTIGATIONAL USE OF DRUGS

All investigational drugs which are in use, are under the strict supervision of principle investigator and are registered with the Pharmacy and Therapeutics Committee (PTC). The following information must be given by principle investigator to PTC with letter indicating the intension to use such investigational drug in patient in his supervision.

- |                     |                      |
|---------------------|----------------------|
| 1. New drug number  | 2. Generic name      |
| 3. Manufacturer     | 4. Chemical name     |
| 5. Proprietary name | 6. General chemistry |
| 7. Pharmacology     | 8. Toxicology        |

9. Dose range

10. Method of administration

11. Antidote

12. Therapeutic use

The above information on each investigational drug usually found in the brochure which is provided by the manufacturer and supplier to the principle investigator after fulfilment of official procedure.

Pharmacy department may use this information in the form of Physician Data Sheet on the Investigation drugs for circulation various medical staff and nurses dealing with use of particular investigational drugs.

Hospital can design drug report form for use of investigational drugs. Such form may provide all information required for the handling and dispensing procedure for the investigational drug by the medical staff, nurse and pharmacist. This form must be kept in such place where it can easily accessible to staff associated with handling of investigational drugs. Each staff dealing with the procedure of investigation drug use must comply with the guidelines frame by the hospital and maintain the record in duplicate entries. Similarly, pharmacist should maintain records (separate file) for the dispensing of each investigational drug along with receipt of written prescription of principle investigators.

#### IDENTIFICATION OF INVESTIGATIONAL USE OF DRUGS

Pharmacist must ensure to label each class of investigational drugs before they are going to dispense. Labelling of class A and class B drugs in such a manner that, these class drugs should be differentiate from routine prescription drugs. In some hospital, for proper differentiating with other class, hospital use printed label in red ink on the white paper stock. In addition to this label information, hospital also provide the above printed layout format for the dispensing record of the investigational drugs.

ROLE OF HOSPITAL INVESTIGATIONAL DRUGS	PHARMACIST	IN HANDLING	OF
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#### 1. Assisting in the Development of the Study Design:

Pharmacists provide his support in the development of the new protocol and control on the use of investigational drugs in the hospital. The investigational drugs are assigned to pharmacist for dispensing purpose according to written order from principle investigator in predetermined pattern.

#### 2. Acting as Independent Collaborator:

Pharmacist act as an independent collaborator by maintaining all the records and codes in the handling of investigational drugs in the hospital. This would give the investigators the advantages of having code information available for 24 hours a day and 7 days a week and the ability to break the code for an individual patient without exposing the rest of the study.

Collecting, Storing and Distributing Essential Information Concerning the Investigational Drug Being Studied: As per the brochure provided by the manufacturer, the pharmacist should prepare data sheet on the investigational drug which provide the all information about

the investigational drugs. This drug data sheets gives information to the medical, pharmacy and nursing staff. This form should contain:

- (a) Drug designation and common symptoms.
- (b) Dosage form and strengths available.
- (c) Dosage schedule and route of administration.
- (d) Indicators.
- (e) Expected therapeutic effects.
- (f) Expected and potential untoward effects.
- (g) Contraindications.
- (h) Storage requirements.
- (i) Instructions for dosage preparation and administration.
- (j) Instructions for disposition of unused doses.
- (k) Names and Telephone numbers of principal and authorized co-investigators.

The data sheet on the investigational drug is reviewed by the principal investigator and then the copies are distributed to the appropriate pharmacy staff and all the patient care units whenever the drug will be used.

### 3. Packaging and Labelling of Investigational Dugs for Multiple or Unit Dose Containers:

Investigational drugs must be properly packaged in accordance with all applicable regulatory standards for example: F. D. A, C.P. Packaging act.

### 4. Preparing Dosage Forms:

The pharmacist can provide a valuable service to the new drug researcher by formulating new dosage form from the pure chemical.

### 5. Dispensing of Investigational Drugs to both Inpatients and Outpatients:

Dispensing of investigational drugs should be incorporated with the rest of the drug distribution system. The pharmacist should maintain the inventory record for the dispensing of investigational drug. This form should contain name of drug, dosage form, and strength, batch number and name of manufacturer along with complete address. In this form there is need to maintain the record of other information which are essential for the drug order. It is essential to provide the sufficient information on proper dosage, route of administration, possible toxic reactions and side effects, precautions and proper labelling is available to them.

## C. INTERPRETATION OF CLINICAL LABORATORY TESTS

**INTRODUCTION:** The importance of the clinical laboratory tests is in detection of abnormal biochemical constituents present. In biological fluid and organ specimen, there are several biochemical constituents available and they contribute to perform important physiological and biochemical functions. An abnormal value of these constituents indicates when the people are suffered from any medical conditions. Several diagnostic testings are essential to performed for recognition of the abnormal biochemical and hematological constituents in the management of patient care, monitoring of the effects of prescribed therapy and allowing detecting of abnormal condition of patient earlier. Below are describing the basic principles of the reactions relating to the most widely used qualitative tests.

Importance of Laboratory Testing:

Following are the importance of laboratory testing in detection and solving of several issues of the patients:

- Laboratory testing helps in finding of basic information of health of patients.
- Ability to provide the information of normal or abnormal functioning of the health.
- Provides the information about the medical condition before showing any kind of symptoms.
- Helps in the identification of cause of the abnormal function of health or symptoms.

Helps in decision making process in working of medicine and accordingly provide the direction to choose correct medications.

**HEMATOLOGY AND BLOOD CHEMISTRY :** Hematological testing is related with blood only. The test includes blood and its components such as blood cells, haemoglobin, protein, bone marrow, platelets, etc. The conditions such as; hemophilia, thrombus formation, bleeding disorders, leukemia, multiple myeloma etc. affects the process of blood formation and functions of each components reflected by abnormal laboratory values. Following are describing various hematological parameters used in laboratory investigation.

Hematological Test:

### 1. WBC:

It is a test to count the number of white blood cell (WBC) in body and it is a part of complete blood count. High or low number of counts indicates underlying medical condition. Laboratory testing for WBC count helps to detect hidden infection within body and it will help for doctors to diagnose the medical condition such as; immune deficiency, UTI infections, blood disorders, etc. It will also help to monitor the effectiveness of medications such as effectiveness of chemotherapy in cancer patients, effectiveness of antibiotics in UTI infections.

### 2. Hematocrit:

The hematocrit is also known by other name i.e. percentage of red blood cells. Estimation of RBC level helps to diagnose or monitor the response of treatment. Lower number of hematocrit



value indicates anemia while higher than normal indicates dehydration, polycythemia, etc. Generally, a normal range of RBC is considered to be 38.3 to 48.6 percent for men while 35.5 to 44.9 percent for women.

### 3. Erythrocyte Sedimentation Rate (ESR):

It is a type of blood cells and used to measure how fast erythrocyte get settle at the bottom of test tube of blood sample. Generally, erythrocytes are settling slowly but, in some conditions, there is faster rate of sedimentation than normal indicates the underlying condition associated with inflammation. There is clump/stick formation of RBC due to inflammation results into cells become heavier and get settle earlier compared to normal condition. This test does not indicate the cause of inflammation or where is inflammation. The results of ESR are estimated by measuring the volume of clear plasma in tube containing heparinized blood sample. In which, low value indicates a smaller number of cells are settle while large values indicate a greater number of cells are settle.

Generally, the results of this test are used along with other test results. The higher ESR rates indicate joint pain, pain in neck and shoulder, headache, abnormal weight, digestive problems, fever etc.

### 4. Haemoglobin:

It is protein in red blood cells associated with carries of oxygen to organ and tissue of the body. It also transports carbon dioxide from the organ and tissue to lungs. If the laboratory test results reveal low concentration of haemoglobin than normal indicates there is low level of red blood cell and high chances of anaemia. There are so many reasons for anaemia including; deficiency of vitamin, chronic disease or bleeding. Similarly, if the laboratory test results reveal high concentration of haemoglobin indicates blood disorders such as; polycythemia vera, may be living in high altitude, dehydration. Generally, the normal level of haemoglobin is 13.5 to 17.5 gm/dl in men while in female the range is 12.0 to 15.5 mg/dl.

Types of Blood Chemistry (Biochemical Test):

#### 1. Blood Glucose Estimation:

It is also called blood sugar test and mostly the test is performed after patient have fasted or randomly (called random glucose test). The test is generally used to monitor the glucose level in diabetes patients. The test detects conditions of hypoglycemia as well as hyperglycemia. Most of the diabetic patients do this test by their own by using rapid test kit with special machine for reading of glucose concentration in blood by simple finger-prick test. The normal range of fasting (10-16 hours) blood glucose is below 100 mg/dl. Range of 100-109 mg/dl indicates prediabetes and such individual may be at higher risk of diabetes so in such cases, OGTT (oral glucose tolerance test) should be performed for continuous monitoring of blood glucose level.

#### 2. Folate Test:

It is nothing but the folic acid (vitamin B-9) test and it is measured the amount of folic acid in the blood. Folic acid is essential for the production of RBC and repairing of the nerve tissue in the body. These cells are associated with carrying of the oxygen to entire body so this test is important for maintaining the overall health of person.

Generally, folate is found in green vegetables, dry beans, peas, cereals and in fruits. It is very

essential in normal growth, particularly for development of babies in pregnancy.

Several reported literatures indicate that deficiency of folic acid associated indicates the condition of anemia, neural tube defects in new babies, etc.

### 3. hA1c:

It is also name as glycated or glycosylated haemoglobin. HbA1c indicates the haemoglobin is joined together with glucose. The main function of haemoglobin is carrying of oxygen. The amount of HbA1c in blood directly reflects how much amount of glucose available in blood. The life of RBC is 4 months. So, this test results reflect how much amount of sugar is present since 4 months in the blood. This test is different than blood sugar test which indicates presence of sugar at that moment only.

Other biochemical analyses are given in below separate liver and kidney functions test.

## LIVER FUNCTION TEST

### Determination of Bilirubin:

Bilirubin is the byproduct of the heme. In the liver bilirubin is conjugated with diglucoronide and is excreted in bile. There is specific reaction by which identification for increased in the level of bilirubin can done. This reaction called Van den Bergh reaction and it is mixture of sulfanilic acid and sodium nitrite in equal concentration. The principle of the reaction is based on diazotization reaction. In which diazotized sulfanilic acid get reacts with bilirubin to produce azobilirubin which is in purple color form and that can be measured by colorimeter or Spectrophotometrically. High laboratory test values represented for the various form of bilirubin such as; conjugated, unconjugated and mixture of both indicates the medical condition of obstructive form of jaundice, hemolytic jaundice and hepatic jaundice respectively.

### Determination of SGPT and SGOT:

Another name of SGPT is alanine transaminase (ALT) and it is specifically increased in the hepatic disease such as liver damage, hepatic jaundice, liver cirrhosis, metastatic carcinoma, drug induced liver diseases, etc. SCOT is gold/direct marker for the identification of hepatocellular damage or injury. While SGOP, name by aspartate transaminase (AST) which is useful and count as indirect marker for the identification of liver injury.

The basic principle or reaction associated with estimation is SGPT produces pyruvate and SGOT produces oxaloacetate and this get reacts with 2, 4-dinitrophenyl hydrazine to produced dinitrophenyl hydroazone which shows brown in colour in alkaline medium and that can be measured at colorimeter or spectrophotometer at 505 nm. Higher laboratory test results for SGPT compared to SGOT indicates chronic liver disease while higher test results for SGOT represents chances of cirrhosis and acute alcoholic hepatitis.

### Alkaline Phosphatase:

Alkaline phosphatase (ALP) is an enzyme and mainly it is obtained from bone and liver cells. The normal level of ALP is 3 -13 KA units/dl. Increased in the level of ALP indicates the bone resorption process which may leads to osteoporosis. Elevated level of ALP is also another indicator of high level of bilirubin due to biliary obstruction which is observed in hepatic



jaundice, liver cirrhosis and hepatic tumor.

**Gamma Glutamyl Transpeptidase (GGT):**

GGT is a microsomal enzyme and it is widely distributed in body tissues, including liver. The normal level of GGT is 5-40 IU/D. Elevated level of GGT indicated in condition of biliary obstruction and alcoholism.

**Galactose Tolerance:**

Galactose is a monosaccharide and exclusively metabolized by the liver. Thus, the liver function can be assessed by estimating the utilization of galactose. In this high level of galactose indicates poor functioning of liver and vice-versa. Generally, the test of galactose is performed by blood withdrawal at the interval of 10 minutes for next 2 hours of food ingestion. The half-life of galactose in normal individual is around 10-15 minutes. The elevated level of galactose is also an indicator of hepatocellular damage, liver cirrhosis and infective jaundice.

**Serum Albumin:**

It is a protein and it is an important indicator for testing of liver function. A low value of protein indicates the damaging of liver while high level of albumin indicates impairment of liver functions.

**Prothrombin Time:**

Clotting factors are essential for blood clot process and these factors are synthesized in the liver. Impairment of liver function demonstrated by increased in bleeding tendency which is associated with decreased in the concentration of clotting factors. So, this can be assessed by estimating of prothrombin time. The test is generally performed on the non-heparinized blood sample. Prolong in prothrombin time indicates impairment in the liver function or liver damage compared to normal.

**Hippuric Acid Synthesis:**

Synthesis of hippuric acid takes place in liver and it is product of benzoic acid and glycine. Liver is the major source of organ for the detoxification and estimation of hippuric acid synthesis is an ideal method for assessing the function of liver. Increased in the concentration of hippuric acid indicates the hepatic damage. Normally around 60% of sodium benzoate which is equivalent to 4.5 gm of hippuric acid is eliminated in urine. The normal concentration of hippuric is less than 3 gm.

**KIDNEY FUNCTION TEST:** Kidney function tests are normally performed to assess the renal function. These are simply estimated by using blood sample or/and urine analysis. In several medical conditions such as diabetes as well as in elderly person there is need to estimate or monitor the renal function test. Following are describing the various types of kidney functions test.

**Clearance Tests:**

Estimation of rate of clearance for the substance which is already present in the blood is mostly preferred for the assessment of kidney function. There are two compounds namely urea and creatinine that are present in blood as well as in urine and can be used for assessment of kidney function. Decreased in the concentration of these compounds in urine reflected high concentration of these compounds indicates renal problem.

Rate of creatinine clearance is 145 ml/min which is marginally higher than glomerular

filtration rate (125 ml/min) because creatinine is secreted by the renal tubule. While the clearance rate for the urea is 75 ml/min while is comparatively lower than GFR due to partially reabsorbed by the renal tubules. The rate of creatinine production and elimination is equal i.e. 1:1 ratio, so any fluctuation/difference in the reading can be used for interpretation and conclusion of results. Creatinine estimation is widely used laboratory test for assessment or detection of renal impairment. This test is useful for an early detection of impairment before the clinical manifestation likely to produce.

#### Urea Clearance Test/Blood Urea Nitrogen:

Urea Nitrogen is the end product of protein metabolism and its rate of clearance is lesser than GFR due to its partial reabsorbed by renal tubules. Further urea clearance is also influenced by protein contents of the diet. Due to this reason, urea clearance is not much sensitive than creatinine clearance for assessing of kidney function. The normal range of urea clearance is 12 to 20 gm/24 hours in urine. Lower values of urea clearance indicate insufficient concentration of protein in diet or renal problem. As such the urea clearance fall below the level of 50% of normal then only the blood urea level found to detect thus the creatinine clearance is a better indicator for the assessment of renal function.

#### URINE ANALYSIS

It is analysis or test of urine used for diagnosis of various kinds of disorders, such as renal disease, diabetes and urinary tract infection. In urine analysis, there is checking of appearance of urine, concentration (pH), and content of urine. An abnormal result of urine analysis indicates the disease or some kind of illness. For example, in urinary tract infection, the color of urine looks cloudy instead of clear. Increased in the concentration of protein of in urine also indicates the sign of kidney disease. There requires more testing of urine analysis to reveal the source of the problem.

#### Visual Examination:

Typically, the urine is clear and laboratory technician examine the appearance of urine. If the appearance of urine is looks cloudy and unusual odor indicates infections and may other problems. Blood in urine make the red or brown color of urine. Urine color influenced by type and varieties of food eaten for example- beet root make urine red tint to urine.

#### Dipstick Test:

Dipstick test is used to identify the abnormality or the bacterial infections. In this test there is use of thin plastic stick with impregnated chemical or strip of chemical on the stick. If the certain substance or abnormality is available in urine or available at above normal range then their results into change in the color of strip. The test is used to detect or evaluate the following indices.

- It is used to detect the acidity (pH) in urine. Abnormal pH levels may see in a kidney or urinary tract disorder.
- The test is used to estimate the concentrated (higher molarity) or diluted urine or specific gravity of urine. The result of higher than normal concentration indicated the dehydration or not drinking enough of fluid.

- This test is also used to estimate the protein in urine sample. In the urine low level of protein is normal. Even though small increased in the concentration of protein is not so much concerned while larger quantity of protein in urine indicates the major renal problem,
- This test is also used for bilirubin determination which is a byproduct of RBC after its breakdown. After formation of bilirubin it get transported to liver for its removal and become a part of bile. Detection of bilirubin indicates the liver damage or diseases.
- Sugar estimation. Normally there is presence of sugar in urine in very small quantity, which is very low to detectable range. While observance of sugar in urine in detectable range indicates the chances of diabetes and there is need of follow up of testing for diabetes.
- Ketones determination. Similar with the glucose, any detectable concentration found in urine may call for diabetes and there require follow-up of testing.
- Presence of blood in urine may need of some additional testing because it may be sign of infection, blood disorders, kidney damage, bladder/kidney stone, and cancer of kidney/bladder.

Evidence of infection can be detected by this test by simple observance of WBC and it indicates the sign of urinary tract infection

#### Microscopic Examination:

In this test, some drops of urine are observed under microscope. If following are observed at above average range, then additional testing may require for detail diagnosis and confirmation of laboratory analysis and medical conditions.

1. Presence of white blood cells may indicate the sign of an infection.
2. Presence of red blood cells may indicate the sign of renal disease, hemolytic condition/blood disorder or any another underlying medical condition, such as bladder cancer.
3. Presence of bacteria or yeasts indicates the probability of infection Presence of tube-shaped proteins in urine may indicate the kidney disorders.
4. Presence of crystals in the urine sample may be a sign of kidney stones.

**QUESTION BANK**

**A. 2 MARKS QUESTIONS**

1. Define inventory and inventory control?
2. Enlist methods to determine EOQ.
3. Enlist factors affecting inventory control.
4. Give formula of EOQ Analysis.
5. Give the purpose of investigational use of drugs (IUD) in hospitals.
6. Enlist different classes of drugs used in hospitals research program.
7. Give the four phases used in clinical investigation of drugs.
8. What is blood?
9. Enlist physical characteristics of blood.
10. Give the characteristics of plasma.
11. What is urinalysis?
12. What is hematology?

**B. 5 MARKS QUESTIONS**

1. Describe dipstick urinalysis.
2. Write a note on interpretation of urinalysis.
3. Describe IUD and its principle involved in hospital.
4. Describe documents used to amend in IND.
5. Write a short note on lead time, safety stock method, re-order level.
6. Write a short note on organization of drug store.
7. Write about VED analysis.

**C. 10 MARKS QUESTIONS**

1. What are the features of good layout design? Write objective of inventory control.
2. Define purchasing, its principle and procedure for purchasing of materials.
3. Write role of hospital pharmacist in the clinical evaluation of a drug and give classification of drugs according to the adoption in hospital.
4. What is hematology? Write a note on interpretation of laboratory tests in hematology.
5. Write in detail about liver and kidney function test.