Unit-5
Pharmacy Practice

B.Pharma 7 Sem Notes

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, procurement 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

Drug Store Management and Inventory Control

Introduction

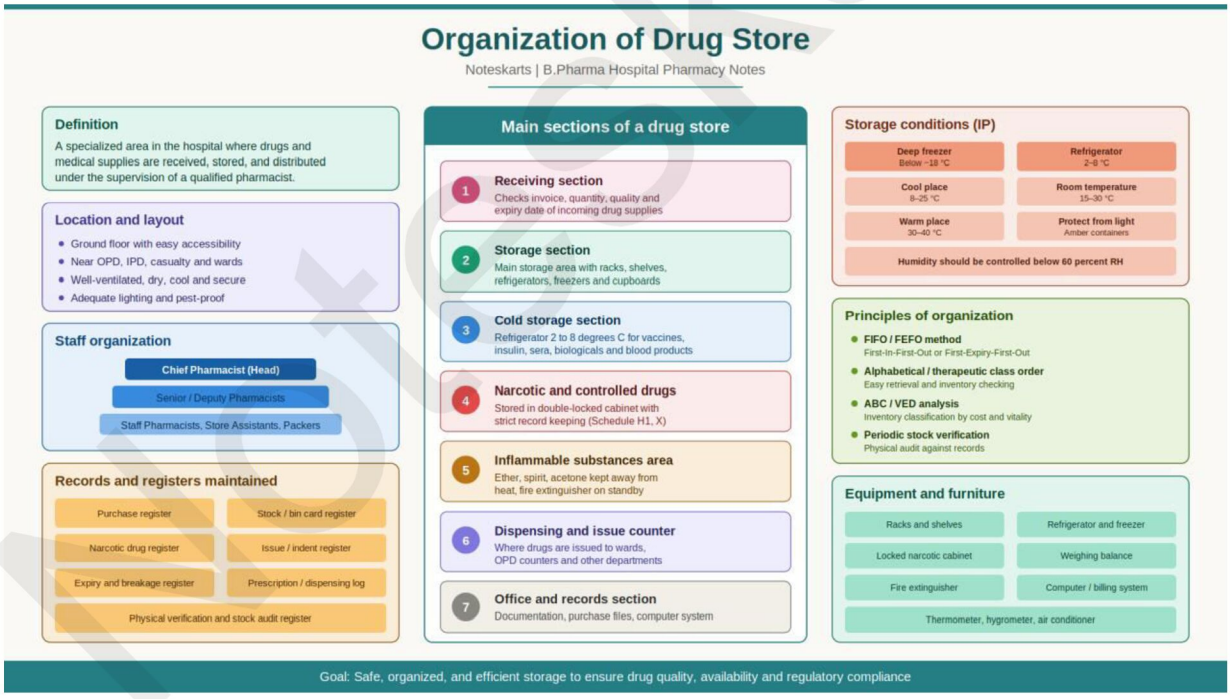
DEFINITION

Drug store management refers to the systematic planning, organizing, and controlling of all activities in a hospital drug store, including procurement, storage, distribution, and record keeping of medicines and medical supplies. Inventory control is the process of maintaining the right quantity of stock at the right time to avoid shortage, wastage, or overstocking.

Proper drug store management is critical because medicines are expensive, perishable, and directly linked to patient safety. A well-managed drug store saves money, prevents drug shortages, and ensures quality.

Organization of Drug Store

A hospital drug store is a central location where all medicines and medical supplies are received, stored, and distributed. It is organized under the chief pharmacist and works closely with the purchase department and hospital administration.



Sections of a Hospital Drug Store

◆ Organization of Drug Store

- ▶ Receiving Section — receives and checks incoming supplies
- ▶ Main Store — bulk storage of medicines

- Sub-Store / Ward Store — small stores in each ward / department
- Dispensing Section — distribution to inpatients and outpatients
- Narcotic / Controlled Drug Section — separate locked area
- Cold Storage — refrigerator / cold room for thermolabile drugs
- Surgical Store — surgical instruments, sutures, and disposables
- Record / Office Section — registers, files, and computer records

The drug store should ideally be located on the ground floor, near the receiving dock for delivery trucks, and connected to the dispensing pharmacy. It should have proper lighting, ventilation, pest control, and fire safety equipment.

Types of Materials Stocked

Category	Examples
Drugs & Medicines	Tablets, capsules, injections, syrups, ointments, IV fluids
Surgical & Disposable Items	Syringes, gloves, catheters, bandages, sutures, dressings
Diagnostic Reagents	Laboratory chemicals, test kits, blood grouping reagents
Radiological Supplies	X-ray films, contrast media
Dental Supplies	Filling materials, dental instruments, anaesthetics
Ophthalmic Supplies	Eye drops, eye ointments, contact lens solutions
Nutritional Products	Enteral feeds, infant formula, protein supplements
Disinfectants & Antiseptics	Alcohol, chlorhexidine, glutaraldehyde, bleach
Gases	Oxygen cylinders, nitrous oxide, carbon dioxide
Stationery & Packaging	Labels, prescription pads, bottles, containers

Storage Conditions

Different drugs require different storage conditions. Failure to store drugs properly leads to loss of potency, degradation, and patient harm.

Storage Condition	Temperature	Examples
Room temperature (Controlled)	15–30°C	Most tablets, capsules, syrups

Storage Condition	Temperature	Examples
Cool place	8–15°C	Suppositories, some creams
Refrigeration (Cold storage)	2–8°C	Vaccines, insulin, sera, eye drops
Freezer	Below -10°C	Blood products, some biologicals
Protected from light	Amber containers	Nifedipine, sodium nitroprusside
Protected from moisture	Airtight containers	Aspirin, hygroscopic powders
Flammable storage	Separate fire-proof area	Alcohol, ether, acetone
Narcotic storage	Double-locked cupboard	Morphine, pethidine, codeine

Purchase and Inventory Control

A) Principles of Purchasing

Purchasing is the process of buying medicines and supplies from manufacturers or wholesalers. The main principles are:

- **Right Selection:** Buy the right drug in the right quantity at the right time.
- **Right Price:** Purchase at the lowest possible cost without sacrificing quality.
- **Right Source:** Buy only from licensed and reliable suppliers.
- **Right Quality:** Maintain quality standards by buying drugs from WHO-GMP, ISO certified firms.
- **Right Delivery:** Drugs should reach the store on time to avoid stock-outs.

B) Purchase Procedure

The purchase procedure in a hospital follows these steps:

STEP 1: Identify the need — check stock levels and consumption data

↓

STEP 2: Prepare indent / requisition from the drug store

↓

STEP 3: Send enquiry / tender to approved suppliers

STEP 4: Receive quotations and compare prices and quality

↓

STEP 5: Select the best supplier and issue Purchase Order (P.O.)

↓

STEP 6: Receive the goods and inspect quality, quantity, and expiry

↓

STEP 7: Record in the stock register and arrange payment

↓

STEP 8: Store the goods properly and distribute to wards / dispensary

C) Purchase Order (P.O.)

A purchase order is a written document sent to the supplier, authorizing the supply of specific drugs at an agreed price. A purchase order usually contains:

- Hospital name and address.
- Supplier name and address.
- Purchase order number and date.
- List of items with name, strength, quantity, and unit price.
- Delivery date and terms of payment.
- Terms and conditions (penalty for late delivery, return policy).
- Authorized signature of the purchase officer.

D) Procurement Methods

Hospitals use various methods to procure drugs:

- **Open Tender:** Advertised publicly; open to all suppliers. Used for large government purchases.
- **Limited Tender:** Sent to a select group of pre-approved suppliers.
- **Single Tender:** Only one or two suppliers are contacted for urgent or specialized items.
- **Rate Contract:** An agreement to buy fixed quantities over a period of time at a fixed price.
- **Local Purchase:** Directly buying from local market in emergency or for small items.

- **Central Purchase / Pooled Procurement:** Pooled purchase by multiple hospitals to get bulk discounts.

E) Stocking

Stocking means keeping adequate quantity of drugs so that there is no shortage and no excess. Good stocking follows these principles:

- Organize drugs alphabetically or by therapeutic class.
- Apply FIFO (First In, First Out) and FEFO (First Expiry, First Out) methods.
- Monitor expiry dates and remove expired items regularly.
- Keep buffer stock for emergencies.
- Store drugs away from direct sunlight, moisture, and heat.
- Conduct periodic physical stock verification.

Economic Order Quantity (EOQ)

DEFINITION

Economic Order Quantity (EOQ) is the ideal order quantity that a hospital should purchase at a time, so that the total cost of ordering plus total cost of holding the inventory is minimum. It is the most cost-effective quantity to order.

FORMULA — Economic Order Quantity (EOQ)

$$EOQ = \sqrt{(2 \times D \times S / H)}$$

D = Annual demand (units/year) | S = Ordering cost per order (₹) | H = Holding/carrying cost per unit per year (₹)

Example: If annual demand (D) = 10,000 units, ordering cost (S) = ₹100 per order, and holding cost (H) = ₹5 per unit per year, then:

$$EOQ = \sqrt{(2 \times 10{,}000 \times 100 / 5)} = \sqrt{(4{,}00{,}000)} = 632 \text{ units (approx.)}$$

So the hospital should order 632 units at a time for minimum total cost.

Reorder Quantity Level (ROL)

DEFINITION

Reorder Level (ROL) is the stock level at which a new order should be placed so that the fresh supply arrives before the existing stock runs out. If the order is placed at the right reorder level, there will be no stock-out.

FORMULA — Reorder Level (ROL)

ROL = (Average daily consumption) × (Lead time in days) + Safety stock

Lead time = time between placing order and receiving goods | Safety stock = extra buffer for unexpected demand

Example: If daily consumption = 50 units, lead time = 7 days, and safety stock = 100 units, then:

ROL = (50 × 7) + 100 = 350 + 100 = 450 units

So when the stock reaches 450 units, a new order should be placed immediately.

Other Important Stock Levels

Level	Formula / Meaning
Minimum Stock Level	ROL − (Normal consumption × Normal lead time)
Maximum Stock Level	ROL + EOQ − (Min. consumption × Min. lead time)
Average Stock Level	(Minimum level + Maximum level) / 2
Danger Level	Average consumption × Emergency lead time

Methods for Analysis of Drug Expenditure

To control cost and manage inventory efficiently, the hospital pharmacy uses special analysis methods. The most important ones are:

A) ABC Analysis (Always Better Control)

This classifies drugs into three categories based on their annual consumption value (cost × quantity):

Category	% of Items	% of Cost	Control Level
A (High value)	10–15%	70–80%	Tight control, frequent ordering, strict monitoring

Category	% of Items	% of Cost	Control Level
B (Medium value)	15–20%	15–20%	Moderate control
C (Low value)	65–75%	5–10%	Minimum control, bulk ordering

Example: Expensive drugs like anticancer drugs, immunosuppressants, and biologicals fall in Category A, while common drugs like ORS and paracetamol fall in Category C.

B) VED Analysis (Vital, Essential, Desirable)

This classifies drugs based on how critical they are for patient care, regardless of cost:

Category	Meaning	Example
V — Vital	Must always be available; shortage is life-threatening	Adrenaline, insulin, anti-snake venom
E — Essential	Important but short shortage can be managed	Antibiotics, antihypertensives
D — Desirable	Useful but their absence does not harm the patient	Vitamins, skin creams, cough drops

C) FSN Analysis (Fast, Slow, Non-Moving)

Based on the rate of consumption:

- **Fast-moving (F):** Used regularly in large quantities (e.g., paracetamol, amoxicillin).
- **Slow-moving (S):** Used less often (e.g., specialty drugs).
- **Non-moving (N):** Rarely or never used; risk of expiry (e.g., outdated formulations).

Non-moving items should be returned, exchanged, or disposed of to prevent dead stock losses.

D) HML Analysis (High, Medium, Low)

Based on the unit price of the drug:

- **High (H):** Unit price is very high (e.g., biological drugs, cancer drugs).
- **Medium (M):** Moderate unit price.
- **Low (L):** Unit price is very low (e.g., ORS, multivitamins).

E) XYZ Analysis

Based on the value of inventory actually held in the store at a given time:

- **X:** Items with highest inventory value.
- **Y:** Items with moderate inventory value.
- **Z:** Items with low inventory value.

F) Combination Matrix (ABC-VED)

For best results, hospitals combine ABC and VED analysis to create a matrix:

Priority	Combination	Action
Category I (Highest)	AV, AE, AD, BV, CV	Maximum control, no stock-out allowed
Category II (Medium)	BE, BD, CE	Moderate control
Category III (Low)	CD	Minimal control

Investigational Use of Drugs

Description

DEFINITION

An investigational drug (also called an Investigational New Drug or IND) is a pharmaceutical substance or biological product that is being studied in clinical trials but has not yet been approved by the regulatory authority (like CDSCO in India or FDA in USA) for marketing and general use. It is a drug under investigation to determine its safety, efficacy, dosage, and side effects in humans.

Investigational drugs are used only in controlled clinical trial settings with proper approval and informed consent. They play an important role in developing new treatments for diseases that have no current cure or inadequate treatment.

Principles Involved

The use of investigational drugs is governed by strict ethical and scientific principles:

- **Scientific validity:** The study must be designed properly to give reliable scientific results.

- **Informed consent:** Participants must be told about risks, benefits, and alternatives and must sign an informed consent form.
- **Patient safety:** The health and safety of participants is the top priority at all times.
- **Ethics committee approval:** The study must be approved by the Institutional Ethics Committee (IEC) before starting.
- **Fair subject selection:** Participants should be selected fairly without bias. No exploitation of vulnerable groups.
- **Favorable risk-benefit ratio:** The risks should be minimized and should always be less than the expected benefits.
- **Regulatory compliance:** The trial must follow Declaration of Helsinki, ICH-GCP guidelines, and ICMR guidelines.
- **Data monitoring:** Data must be monitored and any serious adverse event must be reported immediately.

Classification of Clinical Trials

Investigational drugs go through a series of phases before approval:

Phase	Subjects	Purpose	Sample Size
Pre-clinical	Animals	Safety, toxicity, dosing in animals	Variable
Phase I	Healthy volunteers	Safety, tolerability, pharmacokinetics	20–100
Phase II	Patients with disease	Efficacy, dose finding, side effects	100–500
Phase III	Large patient group	Confirm efficacy, compare with standard drug	500–5000
Phase IV	General population	Post-marketing surveillance, long-term effects	Thousands

Other Types of Clinical Trials

- **Open-label trial:** Only one group gets the drug; no control group.
- **Single-blind trial:** Patients don't know if they get the drug or placebo.
- **Double-blind trial:** Neither the patient nor the doctor knows the assignment.
- **Randomized controlled trial (RCT):** Patients are randomly assigned to groups to avoid selection bias.
- **Crossover trial:** Patient receives both drug and placebo in separate periods.

Control of Investigational Drugs

Investigational drugs must be handled under strict control to ensure safety and data integrity:

- Must be approved by CDSCO in India or FDA in the USA before use in humans.
- Must be approved by Institutional Ethics Committee (IEC).
- Must follow Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP).
- Drugs must be stored separately from regular stock with clear labelling.
- Access limited to authorized persons only.
- Complete accountability — record every tablet received, dispensed, returned, and destroyed.
- All adverse events must be reported within defined timelines.
- Only qualified principal investigator can prescribe investigational drugs.

Identification of Investigational Drugs

All investigational drugs must be clearly identified and labelled to avoid confusion with regular medicines.

- Label must say "For Investigational Use Only" or "Not for Commercial Sale".
- Label should contain study protocol number, drug code, batch number, expiry date, and storage conditions.
- Drug may be coded or blinded — the actual name may not be on the label.
- Drug must be distinguishable from regular pharmacy stock.
- Kept in a separate locked area in the pharmacy.
- Returns and unused stock must be documented and returned to the sponsor.

Role of Hospital Pharmacist

The hospital pharmacist plays a key role in the management of investigational drugs. Main responsibilities include:

◆ Role of Pharmacist in Investigational Drug Use
▶ Receiving, storing, and distributing investigational drugs
▶ Maintaining accurate drug accountability records
▶ Dispensing only on the investigator's written order
▶ Ensuring proper storage as per protocol
▶ Preparing and labelling blinded study medication
▶ Counseling trial participants about drug usage

- Monitoring for adverse drug reactions
- Returning unused drugs to the sponsor
- Assisting the IEC and Principal Investigator
- Maintaining confidentiality of trial data

Advisory Committee / Institutional Ethics Committee (IEC)

Before any investigational drug can be used on humans, it must be reviewed and approved by an advisory body called the Institutional Ethics Committee (IEC) or Institutional Review Board (IRB).

Composition of IEC (as per ICMR guidelines):

- At least 7 members.
- Chairperson — a person from outside the institution.
- One or two experts from the relevant medical field.
- One legal expert.
- One social scientist or community representative.
- One lay person from the community.
- One philosopher or ethicist.

Functions of IEC:

- Review and approve or reject research proposals.
- Ensure informed consent is properly obtained.
- Protect the rights and safety of participants.
- Monitor ongoing trials for compliance with protocol.
- Review serious adverse event reports.
- Suspend or terminate trial if risks are too high.

Interpretation of Clinical Laboratory Tests

Introduction

DEFINITION

Clinical laboratory tests are investigations performed on patient samples (blood, urine, etc.) to help in the diagnosis of diseases, monitor drug therapy, and assess overall health. The clinical pharmacist needs to understand these tests to detect drug-related problems, monitor therapeutic outcomes, and advise dose adjustments.

Laboratory tests are broadly divided into three major categories: Blood Chemistry, Hematology, and Urinalysis. The pharmacist should know the normal values and their clinical significance.

Blood Chemistry (Biochemistry)

Blood chemistry tests measure the concentration of various chemicals in the blood. They help in assessing the function of liver, kidney, heart, thyroid, and glucose metabolism.

A) Blood Glucose

Test	Normal Range	Clinical Significance
Fasting Blood Sugar (FBS)	70–110 mg/dL	↑ in Diabetes Mellitus; ↓ in Insulin overdose
Post-Prandial (PP)	<140 mg/dL	↑ in Diabetes Mellitus
Random Blood Sugar	70–140 mg/dL	Used for quick diabetes screening
HbA1c	4–6% (Normal); <7% (Diabetic goal)	Shows average glucose over 2–3 months

B) Kidney Function Tests (KFT / RFT)

Test	Normal Range	Clinical Significance
Blood Urea	15–40 mg/dL	↑ in renal failure, dehydration
Blood Urea Nitrogen (BUN)	7–20 mg/dL	↑ in kidney disease, high protein diet
Serum Creatinine	0.6–1.2 mg/dL	↑ in kidney damage; most reliable KFT marker

Test	Normal Range	Clinical Significance
Creatinine Clearance (CrCl)	80–120 mL/min	↓ indicates decreased kidney function
Uric Acid	3–7 mg/dL	↑ in Gout, kidney stones

Kidney function tests are important for pharmacists because many drugs need dose reduction in renal impairment. Creatinine clearance is used to calculate dose adjustments.

C) Liver Function Tests (LFT)

Test	Normal Range	Clinical Significance
SGOT / AST	5–40 U/L	↑ in liver damage, heart attack
SGPT / ALT	7–56 U/L	↑ in liver disease; more specific for liver
Alkaline Phosphatase (ALP)	44–147 U/L	↑ in bone disease, bile duct obstruction
Total Bilirubin	0.1–1.2 mg/dL	↑ in jaundice, liver disease, hemolysis
Direct Bilirubin	0–0.3 mg/dL	↑ in obstructive jaundice
Total Protein	6–8 g/dL	↓ in malnutrition, liver disease
Albumin	3.5–5.5 g/dL	↓ in liver disease; affects drug binding
Globulin	2–3.5 g/dL	↑ in infections, inflammation

LFT is important for pharmacists because hepatotoxic drugs (like paracetamol overdose, rifampicin, isoniazid) can damage the liver, and liver disease requires dose adjustment of drugs metabolized by the liver.

D) Lipid Profile

Test	Desirable Level	Clinical Significance
Total Cholesterol	<200 mg/dL	↑ risk of heart disease
LDL (Bad cholesterol)	<100 mg/dL	↑ increases atherosclerosis risk
HDL (Good cholesterol)	>40 mg/dL (M); >50 (F)	↓ increases heart disease risk
Triglycerides	<150 mg/dL	↑ in obesity, diabetes, pancreatitis

E) Electrolytes

Test	Normal Range	Clinical Significance
Sodium (Na+)	135–145 mEq/L	↓ hyponatremia; ↑ hypernatremia
Potassium (K+)	3.5–5.0 mEq/L	↓ with diuretics; ↑ with ACE inhibitors
Calcium (Ca++)	8.5–10.5 mg/dL	↓ causes tetany; ↑ in hyperparathyroidism
Chloride (Cl-)	98–106 mEq/L	Altered in acid-base disorders
Bicarbonate (HCO3-)	22–26 mEq/L	Important in acid-base balance

Electrolyte monitoring is crucial in patients receiving diuretics, cardiac drugs, corticosteroids, and IV fluids. Potassium levels are especially important for patients on digoxin and ACE inhibitors.

F) Other Blood Chemistry Tests

Test	Normal Range	Clinical Significance
Thyroid — TSH	0.5–5.0 mIU/L	↑ in hypothyroidism; ↓ in hyperthyroidism
T3 / T4	T3: 80–200 ng/dL; T4: 5–12 mcg/dL	Used in thyroid disorders
Serum Iron	60–170 mcg/dL	↓ in iron deficiency anaemia
C-Reactive Protein (CRP)	<10 mg/L	↑ in inflammation, infection, autoimmune

Hematology

Hematology tests examine the blood cells and their components. The most common is the Complete Blood Count (CBC).

A) Complete Blood Count (CBC)

Parameter	Normal Range	Clinical Significance
Hemoglobin (Hb)	Males: 13–17 g/dL; Females: 12–15 g/dL	↓ in anaemia; ↑ in polycythemia
RBC Count	Males: 4.5–5.5 M/uL; Females: 3.8–4.8	↓ in anaemia, hemorrhage
WBC Count (TLC)	4,000–11,000 /uL	↑ in infection; ↓ in immunosuppression

Parameter	Normal Range	Clinical Significance
Platelet Count	1.5–4.0 Lakh /uL	↓ in dengue, drug-induced thrombocytopenia
Hematocrit / PCV	Males: 40–54%; Females: 36–48%	↓ in anaemia; ↑ in dehydration
MCV	80–100 fL	↓ microcytic; ↑ macrocytic anaemia
MCH	27–33 pg	Helps classify type of anaemia
MCHC	32–36 g/dL	Helps classify type of anaemia
ESR	Males: 0–15 mm/hr; Females: 0–20	↑ in inflammation, infection, TB, cancer

B) Differential Leukocyte Count (DLC)

Cell Type	Normal %	↑ in (Increase)	↓ in (Decrease)
Neutrophils	40–70%	Bacterial infection	Viral infection, drug toxicity
Lymphocytes	20–40%	Viral infection, TB	HIV/AIDS, corticosteroid therapy
Monocytes	2–8%	Chronic infection, TB	Bone marrow suppression
Eosinophils	1–6%	Allergy, parasitic infection	Corticosteroid therapy
Basophils	0–1%	Chronic myeloid leukemia	Allergic reactions (consumed)

C) Coagulation Tests

Test	Normal Range	Clinical Significance
Prothrombin Time (PT)	11–13.5 seconds	Monitors warfarin therapy
INR	0.8–1.2 (Normal); 2–3 (on warfarin)	Standardized PT; target 2–3 for anticoagulation
aPTT	25–35 seconds	Monitors heparin therapy
Bleeding Time (BT)	2–7 minutes	↑ in platelet disorders
Clotting Time (CT)	5–15 minutes	↑ in hemophilia, heparin therapy

Coagulation tests are very important for pharmacists to monitor patients on anticoagulants like warfarin (PT/INR) and heparin (aPTT). Dose adjustments are made based on these values.

Urinalysis

Urinalysis is the examination of urine to detect and manage a wide range of disorders including UTIs, kidney disease, and diabetes. It is a simple, non-invasive test.

A) Physical Examination of Urine

Parameter	Normal	Abnormal Findings
Color	Pale yellow to amber	Red (blood), dark brown (liver disease), milky (infection)
Appearance	Clear	Turbid / cloudy (infection, crystals)
Volume	800–2000 mL/day	↑ polyuria (diabetes); ↓ oliguria (renal failure)
Odor	Slightly aromatic	Fruity (diabetes ketoacidosis); foul (infection)
Specific Gravity	1.005–1.030	↑ dehydration; ↓ overhydration, renal tubular disease
pH	4.5–8.0 (avg. 6.0)	Alkaline in UTI; acidic in diabetic ketoacidosis

B) Chemical Examination of Urine

Test	Normal	Significance of Abnormal Result
Glucose	Absent (Nil)	Present in uncontrolled diabetes (Glycosuria)
Protein (Albumin)	Absent (Nil)	Present in kidney disease (Proteinuria / Albuminuria)
Ketone Bodies	Absent	Present in diabetic ketoacidosis, starvation
Blood / RBCs	Absent	Present in kidney stones, UTI, cancer (Hematuria)
Bilirubin	Absent	Present in liver disease, obstructive jaundice
Urobilinogen	0.1–1.0 mg/dL	↑ in liver disease, hemolytic anaemia
Nitrites	Absent	Present in bacterial UTI
Leukocyte Esterase	Absent	Present in UTI (indicates WBCs in urine)

C) Microscopic Examination of Urine

Finding	Normal	Clinical Significance
RBCs	0–2 per HPF	↑ in kidney stones, trauma, cancer
WBCs / Pus cells	0–5 per HPF	↑ in UTI (pyuria)
Epithelial cells	Few	↑ in contamination or kidney tubular damage
Casts	None / rare hyaline	Granular / cellular casts in kidney disease
Crystals	Few	↑ in kidney stones (uric acid, calcium oxalate)
Bacteria	None	Present in UTI

Urinalysis helps the pharmacist monitor drug therapy in conditions like diabetes (urine glucose), kidney diseases (proteinuria), liver diseases (bilirubin), and UTIs (nitrites, pus cells). Some drugs can also change urine color (e.g., rifampicin makes urine orange-red, nitrofurantoin makes it brown).

Thank You for Reading!

We hope this book helped you in your studies.

If you want to access complete notes, PDFs, and study material for your course, scan the QR code below.

Scan & Download All Notes

What You'll Get:

- B.Pharm & D.Pharm Notes
- Exam-Oriented PDF Materials
- Regular Updates & New Content

Stay Connected for More Updates

Visit: https://noteskarts.com/

Contact: noteskartsconnect@gmail.com

One Scan = All Notes at Your Fingertips!