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**Important Instructions to examiners:**

- 1) The answers should be examined by key words and not as word-to-word as given in the model answer scheme.
- 2) The model answer and the answer written by candidate may vary but the examiner may try to assess the understanding level of the candidate.
- 3) The language errors such as grammatical, spelling errors should not be given more Importance (Not applicable for subject English and Communication Skills).
- 4) While assessing figures, examiner may give credit for principal components indicated in the figure. The figures drawn by candidate and model answer may vary. The examiner may give credit for any equivalent figure drawn.
- 5) Credits may be given step wise for numerical problems. In some cases, the assumed constant values may vary and there may be some difference in the candidate's answers and model answer.
- 6) In case of some questions credit may be given by judgement on part of examiner of relevant answer based on candidate's understanding.
- 7) For programming language papers, credit may be given to any other program based on equivalent concept.



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**Q1. Attempt the following:**

**20M**

**(a) Define the following (any four) ( 1 mark each)**

**(i) Hospital Pharmacy** - It is service department of hospital which receives drugs and supplies, stores, dispenses them to inpatients and outpatients under supervision of legally qualified registered pharmacist.

**(ii) Drug Information service-** It is provision of written and/ or verbal information about drugs and drug therapy in response to request form, from health care professionals, patients or public.

**OR**

Drug information services is any objective, scientifically derived and documented data or knowledge ,involving the pharmacological ,toxicological and therapeutic use of drug.

**(iii) Patient Compliance-** WHO defines patient compliance as ‘faithful adherence by the patient to prescriber’s instructions’.

**(iv) Drug Interaction-** Drug interaction may be defined as an alteration in the therapeutic effects of one drug by prior or concurrent administration of another drug.

**(v) Hospital Formulary-** It is a continuously revised compilation of pharmaceuticals & ancillary information used in hospital by that reflects current clinical judgment of medical staff.

**(b) What advice will you give to the patient taking: (any four) (1 mark each)**

**(i) Diazepam** - This drug may cause drowsiness so do not work with dangerous machinery and do not drive a heavy vehicle and do not drink alcoholic beverages.

**(ii) Tetracycline-** Do not take this medication with milk or antacid.

**(iii) Phenolphthalein-** This laxative may colour the urine and feces pink.



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(iv) **MAO Inhibitors** - Avoid cheese, chocolate, alcoholic beverages and liver or yeast extract.

(v) **Boric acid**- Contraindicated in children under 12 years old. Not for internal use.

c) **Give the normal values of : (any four) (1 mark each)**

(i) **Heart rate** : 60-80 beats/minute

(ii) **RBC**: In Male: 4.5 to 6.0 millions/cu.mm.

In female: 4.0 to 5.5 millions/cu.mm

(iii) **ESR**

Normal Value: **Westergren Method**: Male 0-15mm at end of one hour

Female 0-20 mm at end of one hour

**Wintrobe Method** : Male 0-9mm at end of one hour

Female 0-20mm at end of one hour

(iv) **Sperm Count**: Normal Value: 60 -150 million/ml of seminal fluid

(v) **Blood Sugar**: 80-120 mg/100ml

(d) **Translate into English : (any four) (1 mark each)**

(i) **Guttae** – drops

(ii) **Bis in die**-two times a day / twice a day

(iii) **Nebula**- nasal spray /a spray solution

(iv) **Omni nocte**- every night

(v) **Collutorium**- mouth wash



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**(e) Explain the following: (any four) (1 mark each)**

**(i) Lithotripsy-** is the non-invasive treatment of stones in kidney, in the gallbladder in the liver using an acoustic pulse

**(ii) Drug habituation-** Drug habituation: It is a condition resulting from the repeated consumption of a drug. There is desire but not compulsion to continue taking the drug to improve a sense of well being.

**(iii) Idiosyncrasy-** The term idiosyncrasy (Greek idios means 'one's own and synkrisis, a mixture together') is used to denote abnormal drug response. Idiosyncrasy covers unusual, bizzare or unexpected drug effects which cannot be explained or predicted in individual recipients. It also includes drug induced foetal abnormalities, e.g. phocomelia which developed in the offspring's of mothers exposed to thalidomide.

**(iv) PTC and Drug safety- ( ½ mark each)**

Pharmacy Therapeutics Committee is a policy framing & recommending body (pharmacy and medical staff on matters related to rational and safe use of drugs in the hospital.

**Drug safety** - The PTC can play an effective role in ensuring drug safety on a continuous basis by creating safety awareness in all departments of the hospital. This committee provides guidelines for hospital which ensures drug safety in the hospital.

**(v) Triple roller ointment mill-** The mill consist of three rollers which are arranged in such a way that the material coming between the rollers is crushed depending on gap between them. This mill is used for homogenization of semisolid preparations.

**Q2. Attempt any THREE of the following; (4 marks each)**

**12M**

**(a) Define modern hospital and write it functions. (Definition 1 mark, any three functions 3 marks)**

Modern Hospital is a educational and social service institution with a single purpose of restoration and maintenance of good health .It provide special facilities (like accommodation, colleges and day night medical stores) with a trained professional staff.



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**Functions of Hospital:-**

1. **Patient care:** It includes services for diagnosis, prophylaxis and treatment of diseases to the sick or injured patients. It is a centre of community health and contributes a great deal to preventive and social medicine.
2. **Public health:** The hospitals are required to support all the activities carried out by various public health and voluntary agencies such as immunization programme, blood donation camps, social and economics rehabilitation, health education etc by providing facilities and advice.
3. **Medical research:** Research is an important activity in the hospital that helps in developing the new methods of treatment and improving the hospital services. Some of the common areas of research in the hospital are development of new techniques in surgery, laboratory diagnostic procedures, evaluation of investigational drugs in diseases.
4. **Educational training:-** This facility , particularly for medical students , pharmacist , nursing , medical technologist and allied health professional helps to fulfill their curriculum requirement. Hospital also educates the general public through lectures and demonstrations on the preventive aspects of common and serious diseases. Hospital provides the methods by which the persons can work together in groups with the object of care of patient and community.
5. **Counseling and patient advice:** It is a modern concept adopted in big hospitals for the well being of the patients. During these counseling sessions pharmacist educate people on communicable diseases, epidemics and family welfare etc.

**(b) Explain the abilities and competence required for a hospital pharmacist. ( Any 4 of the following -1 mark each)**

The hospital pharmacist should possess following abilities and competencies:

1. **Administrative ability-**Hospital pharmacist should be thoroughly familiar with organization of hospital, with staff and with appropriate channel of communication. Hospital pharmacist should be capable of planning and integrating services, budgeting, inventory control, cost-review, cost-effectiveness, audit, maintenance of records and preparation of reports.



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**2. Technical ability-** Hospital pharmacist must have ability to use his basic knowledge of effect of drug on biological systems, in assessing drug absorption, distribution, metabolism and excretion. He/she knows the storage condition of various drugs and their stability. He has to assure quality of pharmaceutical products used in the hospital.

**3.Manufacturing ability-**Hospital pharmacist must be able to develop manufacturing section .Hospital pharmacist should possess an adequate understanding of the principles involved in formulations and preparation of dosage forms. In manufacturing process he requires control over quality of raw material, supply, cost of drug and equipment installation.

**4.Research ability-**Hospital pharmacist must be prepared to participate in clinical research initiated by medical staff and to conduct pharmaceutical research himself. Hospital pharmacist must be able to establish database for drugs being used and patients participating in studies. Hospital pharmacist must have ability to collect appropriate data interpret them and make conclusion from data.

**5. Teaching/Training ability-** Hospital pharmacist is responsible for training of new personnel and for carrying out continuous educational programme for pharmacist and pharmacy supportive personnel. Hospital pharmacist must be able to develop well planned and coordinate training programme and able to deliver lectures.

**6. Ability to Control-**Hospital pharmacist must be able to develop quality assurance programme for quality services of pharmacy department and products dispensed. Hospital pharmacist must be able to develop control programme for distribution of drugs throughout the hospital.Hospital pharmacist have to check on inventories of drugs that are brought in the hospital.

**(c) Explain receipt and issue system in outpatient dispensing.( 4 marks)**

**Ans.** 1.Patient in his first visit to OPD goes to registration counter .Take case paper after paying nominal fees.



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2. Then patient goes to general check up counter –guided for medical department on the basis of clinical symptom.
3. Physician write prescription for patient and he submitted it to pharmacy dept. where Rx is compounded and dispensed by pharmacist.
4. Pharmacist number the Rx ,monitor it and assemble the materials and equipment for compounding.
5. Pharmacist gives token to the patient so patient and Rx can be identified.
6. Compounded Rx filled in suitable container, packaged, labeled and priced reasonably.
7. Pharmacist record Rx in a register for accounting purpose .
8. While dispensing and compounding the drug correct delivery is ensured by checking token number. For his next visit Rx is given back to the patient.

**(d) Define clinical pharmacy and describe its scope. (Definition 1 mark, Scope- any 3 points 1 mark each)**

**Ans.** Definition of Clinical pharmacy – Clinical pharmacy is a new born discipline that carries traditional hospital pharmacist from his product oriented approach to more healthier patient oriented approach, so as to ensure maximum well-being of the patient while on drug therapy.

**OR**

It is the branch of pharmacy which is concerned with various aspects of patient care & deals not only with dispensing of drug but also advising the patients on safe & rational use of drugs

**Scope of clinical pharmacy—**

1. Medication history- it includes past and present of prescription and non – prescription drug, dietary supplements, dietary habits, drug and estimate of patient compliance with the drug therapy.



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2. Monitoring drug therapy- it includes evaluation of patient pharmacokinetics and pharmacodynamics parameters, lab. Findings medical problems and communicating relevant findings to physician.
3. Participation in ward rounds- The clinical pharmacist with physicians should participate in ward rounds, observe individual patient and decide the drug therapy.
4. Drug information- The clinical pharmacist establish drug information center. The drug info. Is available at this center and utilized suitably. This data is send to physician as per their requirements.
5. Patient counseling- it involves providing information to the patient about drug therapy and illness. The pharmacist acts as resource for information about health promotion and disease prevention.
6. Participation in new drug investigation- clinical pharmacist along with physician participates in investigation of new drugs. Data of this investigation is complied, analyzed and maintained at drug information center.
7. ADR management- Along with physician clinical pharmacist's activity is involved in reporting of management of ADR.
8. Educational programs- clinical pharmacist organized educational programs for nursing and education related to safe and effective use of drugs.
9. Tailoring drug therapy- the clinical pharmacist after the diagnosis of physician formulates drug therapy to need of patient.

**(c) Write the 'Consequences of Non- Compliance'.**

Non compliance occurs due to

**1. Under utilization of medications ( 2 marks-1mark for reasons and 1 mark for any 1 example)**

It may happen due to following reasons

- i). Taking less than the prescribed dose.





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ii).Discontinuing the drug before completing the course.

iii).Omitting 1 or more doses.

**Underutilization may result in : (any 1 example)**

a) Risk of toxicity:- If the physician unaware of the patient's noncompliance, in the treatment of hypertensive patient, the doctor may increase the dose or prescribe more potent antihypertensive drugs, which result in toxicity.

B) Danger of death:- underutilization of anticonvulsant drug results in uncontrollable seizures and death.

C) In patient with C.C.F digoxin and hydrochlorthiazide should also take potassium chloride to replace potassium. ( $K^+$  loss occur due to diuretic action). if patient stop taking potassium chloride, The  $k^+$  depletion results, making heart more sensitive to digoxin and activity of cardiac glycoside occurs.

d) Patient with antibiotic therapy if stop taking the drug when symptoms disappears this will result in recurrence of the infection. e.g. Tuberculosis

e) Omitting a single dose of contraceptive pill may results in unwanted pregnancy

**2. Overutilisation of medication: ( 1mark)**

Excessive dose of drug may cause serious adverse drug reactions and toxicity in the patients.

It may happen due to following reasons

i). Taking more amount/quantity than the prescribed dose.

ii). Taking more than prescribed number of doses.

iii). Taking a dose at a time other than when needed.



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iv) Taking the same medication from two or more different dosage form simultaneously.

**3. Miscellaneous: ( 1mark)**

It may arise due to following factors

- i) Improper technique of drug administration
- ii) Using medication for wrong purpose
- iii) Use of out dated drugs without knowledge.

**3. Attempt any THREE of the following:**

**12M**

**a) Write pathophysiology, signs and symptoms of 'Myocardial Infarction' or 'Rheumatoid arthritis'.**

**Myocardial Infarction: Pathophysiology ( 2 marks)**

Some pathophysiological conditions may lead to the development of heart failure . These includes

- a) Pressure overload the heart e.g. hypertension or aortic stenosis;
- b) Volume overload e.g. valvular regurgitation
- c) Loss of viable myocardium e.g. myocardial infarction or
- d) Decrease in myocardial contractility e.g. cardiomyopathy.

In some patients, heart failure results when the cardiac output is greater than the normal output, this is called as high output heart failure. This occurs when metabolic demands of the tissue are greatly increased as in hyperthyroidism or pregnancy.



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**Sign and symptoms: ( Any 4 for 2 marks)**

1. Coughing and shortness of Breath (pulmonary congestion) due to increase in extracellular and plasma volume.
2. The skin turns bluish i.e. cyanosis.
3. The patient may cough up a frothy, pinkish ,blood tinged material at night
4. Enlargement and tenderness of liver
5. Kidneys are congested and unable to excrete excess fluid from the body
6. Presence of albumin and casts in urine
7. Distressing symptoms such as gas, constipation, lack of appetite and distension of the bowel.
8. Fatigue , weakness , nocturia , impairment of memory , confusion , insomnia and anxiety
9. Increase in both serum creatinine and nitrogen.

**Rheumatoid arthritis**

Rheumatoid arthritis is a chronic disorder characterized by inflammation of connective tissues.

**Pathophysiology: ( 2 marks)**

Rheumatoid arthritis is an autoimmune disease. In these diseases, body's immune system no longer accepts certain body proteins and reacts as if they were foreign antigen and produces antibodies against them. It is observed that patient's body considers human gamma globulin (IgG) as the antigen and produces antibodies against them, known as 'Rheumatoid factors'. The antigen reacts with antibody to form immune complex, which then reacts with complement. Complement is a series of proteins, which helps to stimulate the inflammatory process. Thus, the immune complex reacts with the complement in the joints, which leads to the inflammatory response.



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**Sign and symptoms.( any 4 Sign and symptoms- 2 marks)**

Fatigue, anorexia, weight loss and fever

- 1) Inflammation of peripheral joints, most frequently the small joints of hand and feet, and the wrists, larger joints may also be involved.
- 2) Morning stiffness is a common symptom. The stiffness generally lasts more than 30 minutes and may last for many hours.
- 3) Chronic inflammation of joints results in erosion at the margins of the bones.
- 4) Deformities may develop, mainly of the fingers and neck etc. Joints may be ankylosed with complete loss of motion.
- 5) Around 20- 30 % patients show formation of rheumatoid nodules. They occur commonly in the elbow or along the extensor surface of forearm.
- 6) Inflammation of organs than joints like heart, lungs, eyes, may also occur.

**b) Explain' Drug Food Interaction'.( any 4 example -1 mark each)**

- i) Milk reduces absorption of tetracycline by forming an insoluble complex.
- ii) Solubility of Griseofulvin increases when it is taken with milk or fatty food, because ionization of Griseofulvin is high in presence of fatty food.
- iii) Mono amine oxidase( MAO) is an enzyme which breaks down catecholamines such as Nor-epinephrine. When the enzyme is inhibited, there are increased level of Nor-epinephrine. Thus MAO- inhibitors are used as antihypertensives. if MAO inhibitors administered with tyramine containing food like cheese and butter, alcoholic beverages ,Tyramine is metabolized by MAO. When patient being treated with MAO-inhibitors also take tyramine containing food, Tyramine reaches systemic circulation causing severe hypertension.
- iv) If drugs like Oral contraceptives/Phenytoin taken with Folic acid they inhibit the enzyme intestinal conjugase which is responsible for conversion of poorly absorbed form of folic acid i.e polyglutamate into readily absorbed form of folic acid .i.e monoglutamate. This results into deficiency of Folic acid (Anemia)



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v) Absorption of some drugs reduces in presence of food e.g. ampicillin, Rifampicin, Aspirin, Isoniazide, Tetracycline, Benzylpenicillin, Levodopa.

Iron absorption is reduced if food has been taken within the previous two hours. If Iron is taken on empty stomach it can cause nausea. Therefore Iron tablets are often given with food.

vi) Absorption of drugs like- riboflavin, spironolactone, Lithium, citrate, Carbamazepine increases in presence of food.

Nitrofurantoin is given with food to avoid GIT irritation this also increases drug absorption.

**c) Define Unit dose dispensing. Write its benefits. (Definition -1 mark, any 6 benefits - 3marks )**

**Definition** - It can be defined as those medicines which are ordered, packaged, handle, administer and charge in multiples of single dose unit containing a predetermined amount of drug for one regular dose or application or use.

**Benefits: (any 6)**

1. The patients are charged for those which are administered to them.
2. It reduces the medication error since the pharmacist checks the copy of physician's original order.
3. It avoids drug losses, no pilferage of drug.
4. Less space is required as compared to bulky floor stock.
5. Patients receives the nursing service 24 hrs a day.
6. It avoids duplication of orders and extra paper work.
7. It enhances more efficient utilization of personnel
8. It eliminates labeling error .



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9. Drug accounting become easier.

10. Better financial control means credits are eliminated.

**d) Define Central services. Give various administrative patterns or Central services.**

**(Definition -1 mark, 3 administrative patterns -1 mark each)**

**Definition:** Central services is alternatively called central supply department which provides essential supplies and equipment. Both sterile and non sterile –to all specialized departments.

There are three different patterns of the administrative structure of the central service departments.ss

1) Dept. under PHARMACY control:

a) Well trained & qualified pharmacist handle various function- Procure, storage & distribution of medical supplies. b) Operate & maintain different sterilizer. c) Ability of Mfg. various parenteral preparation aseptically.

2) Dept. under NURSING control:

a) Senior nurse is in charge of this department. b) Nursing in charge handle various functions like-Cleaning, packaging, & distribution of medical supplies & equipment & majority of items supplied by CSS are used by nurses for their patients & they are familiar with these items.

3) Dept. under dual control of PHARMACY & NURSING: Dual function-

1) Procure, storage, & distribution of medical supplies b) Operate & maintain different sterilizer c) Ability of Mfg. various parenteral preparation aseptically under pharmacy control\_2) Cleaning, packaging, & distribution of medical supplies & equipment under nursing control.



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**e) Discuss four important factors governing make or buy decision.( 1mark each)**

Following factors affect make or buy decision in hospital manufacturing:

**1. Quality 2.Quantity 3.Cost and 4.Service.**

**1) QUALITY**-The quality of outside purchases & the quality that could be possibly achieved when manufactured within the hospital are compared. If there are no wide variations between these two, it is not an important consideration .if there is a wide variation, it becomes a crucial factor. If a better quality results from in-house manufacturing, the matter should be probed further. Why do the outsiders fail to come up to the desired quality level? Also, is the hospital competent to produce the desired quality? Does it have the necessary infrastructure?

Most of the times, as in case of large volume fluids, the hospital favours in-house manufacturing as it has a legitimate apprehension that an outsider may compromise with the quality of his supplies.

**2) QUANTITY**-Generally, those items whose orders are too small to purchase it from an outside supplier are manufactured within the hospital.

Similarly, items which are required every day for use in hospitals, in large quantities, are generally decided to be manufacture. Break-even analysis gives the hospital the break-even quantity of production. Break-even is at a point where there are no profits and no losses.

**3) COST**-Here we compare the costs of buying from outside with the cost of in-house manufacturing. The cost of manufacturing the items within the hospital is estimated by drawing up a cost-sheet. It is important to allocate over-heads correctly.

Cost and quantity together considered for making the decision.

**4) SERVICE**: Generally, a supply is more assured when a hospital makes an item then when it buys it. Assured supply is often a valid reason for manufacturing. Interruption in supplies may affect the major clinical series of the hospital. Unfair practices of outsider make a hospital opt for making rather than buying.



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**4. Attempt any THREE of the following: ( 4 marks each)**

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**a) Name and explain the various additives used in parental formulation.( any four-1 Mark each)**

i) **To adjust the tonicity:-** some injections are required to isotonic with blood plasma or other body fluids .e.g. NaCl or borax but must be compatible with other ingredient of preparation. various methods are used to estimate the amount of adjusting substance .e.g Freezing point depression or NaCl equivalent.

ii) **Antioxidants:-** It prevent the oxidative degradation of product.e.g Sodium bisulphate-0.1%, sodium formaldehyde, Thiourea, acetone, sodium metabisulphite, ascorbic acid for oral injections :- Tocopherol,BHA(beta hydroxy anisole),BHT(tolene) and propyl gallate.

iii) **Antimicrobials:-** These are used in the parental product to prevent the microbial growth during storage especially in multidose containers. It should not be toxic and must be compatible with medicament.

Cresol - 0.3%, Chlorcresol -0.2%, Benzalkonium chloride - 0.001%, Chlorobutanol - 0.5%, Phenyl mercuric nitrate -0.002%, Phenol -0.5%

iv) **Stabilizers/Buffering agent** -They are added to maintain to maintain the required pH of many products .They are employed to stabilize the solution against chemical degradation due to change in pH.

Phosphate, Acetate, Phthalate etc is used to maintain the pH of product.

v) **Suspending Agent:-**These agent improve the viscosity of parentral suspensions.

Acacia,Methyl cellulose,Gelatin, Tragacanth,CMC etc.

vi) **Emulsifying agent**- It maintain the stable emulsion. E.g- Lecithin

vii) **Wetting agent**- It reduces interfacial tension between solid and liquid particles so as to prevent the formation of cake.e.g- Tween-80, Sorbiton Trioleate





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**viii) Chelating agent-** It chelates or complex the metallic ion present in formulation and forms the soluble complex.e.g-EDTA and its salt.

**b) Describe procurement or purchase procedure step by step. (4 marks)**

In hospital following procedure for procurement of materials is followed:

**1. Purchase request form-**Pharmacist or person authorized by him prepare and fill purchase request form. This form provides information to purchase dept. regarding description, packaging, specifications, price, quantity needed; inventory balanced and anticipated monthly use.

The original copy of this form is sent to administrator for approval. After his approval it is forwarded to purchasing officer. A copy of this form is retained by pharmacist for his record to indicate that the process of procurement is going on.

**2. Quotation invitation-**On the receipt of purchase request form, purchasing officer invites quotations from different suppliers.

**3. Purchase order form-** Purchasing officer scrutinizes the quotations received. He checks the quantity to be supplied in consultation with pharmacist and prepare purchase order form.

Purchase order form consists of many pages 'snap out'-

First copy-it is send by post or by hand to supplier.

Second copy- Send to accounts dept. It is held till invoice is received from supplier. It is completed after receiving report from purchase dept. then only payment is done.

Third copy-It is kept with purchasing officer as department file. This copy served as source of information.

Fourth copy-It is kept with Hospital pharmacy dept. This copy is compared with purchase request form for accuracy.



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Fifth & Sixth copy\_ These copies serve as receipt report. When goods arrive in full consignment then fifth copy is used. If order is received partially then sixth copy is used and send to account dept.

Seventh copy- This copy is known as history copy. It is kept by purchasing dept.

**4.Return of goods-** When the ordered goods comes in dept. the quantities and prices are checked. Received goods bill sent to the account section where bill is entered in purchase record register.

**5. Release of payment to supplier.**

**c) Define Adverse drug Reaction. Explain the various reasons for adverse reactions.**

**(Definition -1 mark, any 3 reasons 1 mark each)**

**Definition-** Adverse drug reactions (ADR) - “ Any response to a drug which is noxious and unintended, and which occurs at doses used in man for prophylaxis, diagnosis or therapy”.

**1. Medication errors:**

- a) Self medication of OTC drugs by patient leads to over use or misuse of drug. It may result into excess pharmacological action or complications.
- b) Over prescribing of potent medicament to the patient e.g oral hypoglycemic, antihypertensives etc.

**2. Inadequate monitoring of the patient:** Drugs like cardiotonics ,Diuretics,corticosteroids needs therapeutic monitoring with continuing the administration beyond therapeutic end point which leads into adverse reactions.

**3. Sudden withdrawal of drugs:** Therapy with drugs like corticosteroids and hormones can not be suddenly stopped. Such drugs therapy is gradually stopped by decreasing the dose.

**4. Bio-availability variations:** There are number of brands of the same drug which leads to variations in bio-availability of drugs.

**5. New potent drugs :** The ever increasing number of new potent drugs along with brands ,may cause hypersensitivity reactions in particular individuals.



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- 6. Drug interaction and drug food interaction:** This type of interaction occurs when two or more drugs or presence of food may inactivate or alter the absorption of drug results in inactivation.
- 7. Some drug having narrow margin of safety:** Difference between therapeutic dose and toxic dose is very narrow in some drugs, e.g. Digitalis if not prescribed carefully leads to its toxicity.
- 8. Patient factors:**
- a) **Age:** Young and old patients are more susceptible to adverse drug reactions as compared to the adults, because of pharmacokinetics pattern at this age.
  - b) **Disease state:** Mainly patients with hepatic or renal dysfunctioning are prone to adverse effect of drugs.
  - c) **Discontinuation of therapy /treatment due to :**
    - i) High cost of medicine.
    - ii) Lack of faith on physician.
    - iii) Noncompliance.
  - d) **Classify Poisons with examples**

**Classification-**

Depending upon mechanism of action of poison, these are classified as

**1) Corrosives-**

- a) Strong acids- sulphuric acid, nitric acid, hydrochloric acid
- b) Organic acids- oxalic acid, carbolic acid
- c) Concentrated alkalies- caustic potash, caustic soda, carbonates of sodium, calcium and potassium

**2) Irritants =**

- a) Inorganic:
  - 1. Non-metallic- Phosphorous, chlorine, bromine, Iodine
  - 2. Metallic- Lead, Mercury, copper, zinc, arsenic, manganese
- b) Organic:
  - 1. Animal origin- Snake, scorpion, Insects, Cantherides
  - 2. Vegetable origin- Ergot aloe, capsicum, castor oil seeds etc.



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c) Mechanical- Powdered glass

**3) Neurotics-**

a) Cerebral poison- opium, sedatives and hypnotics, insecticides, cocaine and hyoscyamus

b) Spinal poisons- Nux vomica

c) Peripheral poisons- curare alkaloids, conium

4) **Cardiac:**e.g. Digitalis , stropanthus, aconite, tobacco

5) **Pulmonary depressants:** Substances acting on lungs e.g. Gases such as carbonmonooxide, coal gas

6) **Miscellaneous-** Analgesics, antipyretics, stimulants, antidepressants, antihistamines, hallucinogens.

**e) Give medical complications,withdrawal symptoms and treatment of Alcoholism.**

**(Medical complications-1 mark, withdrawal symptoms- 1mark and treatment- 2 marks)**

**Medical complications:** Acute Hepatitis,Cirrhosis of liver, pancreatitis ,Gastritis, fatty liver chronic diarrhea ,beri- beri ulcers, delirium, convulsive disorders ,hypoglycemia .

**Withdrawal symptoms-** Hangover, delirium, anxiety, course tremors, weakness, sweating, insomnia, headache, muscle twitching, tachycardia, hallucination, disorientation and seizures. G.I disturbances like chronic gastritis, pancreatitis. The termination of alcohol can lead to fever, tremors, tachycardia, agitation .It also results in myopathy , bone marrow suppression and gout.

**Treatment:** 1.Antidote treatment- Use of Disulfiram in a dose of 500mg daily.

2. For nutritional deficiencies- Vitamin B complex or thiamine injections are given.

3. Use of sedatives: Effective medical supportive therapy , like alcoholic anonymous and psychological counselling is effective.

4. Emetin or apomorphine is given together with alcoholic drink to make the patient vomit.

5. Phenobarbitone is given to prevent tremors.

6. Behaviour therapy – It gives relaxation training , assertiveness training and self control skills.



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**5. Attempt any THREE of the following.( 4 marks each)**

**12M**

**a) What is Bioavailability? Discuss physiological factors affecting bioavailability of drugs ( Definition-1 mark, Any 3 factors 1mark each)**

**Bioavailability-** Bioavailability may be defined the amount or percentage of drug is absorbed from the administered dosage form, that reaches to the systemic circulation.

OR

The extent to which the active ingredient in the drug product is taken by the body in the form in which it is physiologically active.

**Physiological factors:-**

**a) Effect of GIT fluids-**

-Acidic drugs are rapidly absorbed from stomach because in the acidic medium of stomach these remain in the unionized form.e.g. Salicylates and Barbiturates.

- Basic drugs are not absorbed from the stomach. The alkaline medium of small intestine enhances the absorption of these drugs because these remain in the unionized form e.g. Pethidine, Ephedrine.

-Mucin forms a thin layer over the gastric and epithelium. It may form complexes with various drugs and reduce their bioavailability. E.g - Hypertensive and Anticholinergic drugs form complexes and hence are poorly absorbed.

**b) G.I. transit time and gastric motility-**

- Presence of food and the volume, viscosity and tonicity of gastric contents, can influences drug absorption by altering gastric emptying time.

- Some drugs show better bioavailability when they are given before meals.

- Some drugs like Salicylates, iron preparations are administered after food, because they cause GIT irritation.

- Increased peristaltic activity of stomach reduces bioavailability. E.g. sustained released drugs.

- Anti-cholinergic drugs, which promote gastric emptying time also reduce the bioavailability.



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- Metoclopramide increase gastric emptying and so increase the absorption of ethanol, paracetamol, Tetracyclines; while Propantheline reduce the absorption of riboflavin, sulfamethoxazole, ethanol and paracetamol.

**c) First pass-effect-**

First pass effect means the drug degradation occurring before the drug enters the systemic circulation.

-It, means, all drugs taken orally, first pass through GIT and then through the portal system, before reaching systemic circulation.

- Hence, bioavailability of such drugs decreases; and this diminishes the therapeutic response by first pass effect, e.g. levodopa, morphine, nitroglycerine, Isosorbide dinitrite and Propranolol have less bioavailability if given orally.

**d) Diseased state-**

- Absorption of drugs can be affected by diseased state of GIT, like malabsorption, thyrotoxicosis, achlorhydria, and liver cirrhosis.

- In achlorhydric conditions of GIT, absorption of acidic drugs like aspirin increases.

- Some drugs like amoxicillin show decreased bioavailability in diseased state.

- In chronic inflammation of ileum absorption of trimethoprim decreases while that of sulphamethaxazole increases.

**e) Presence of other drug-**

- If two or more drugs, having different bioavailability, are administered together, one drug can affect the bioavailability of another, e.g liquid paraffin decreases the bioavailability of Vit. A, as it emulsifies the fat, and therefore causes, deficiency of fat soluble vitamins A,D,E and K.

**b) What are antidotes? Classify them with examples.( Definition -1 mark, Any 3 classes-1 mark each)**

**Definition-** An antidote is an agent that counteracts the poison,

Antidote are classified according to mechanism of action.

**Classification:**

**i).Mechanical antidote-** These antidote prevents the absorption of poison by forming the coat over the mucous membrane of the stomach, e.g, fats, oils, egg albumin, activated charcoal etc.



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**ii). Chemical antidote**-These antidote convert the poison into harmless or insoluble compounds  
E.g. Sodium thiosulphate for cyanide poisoning,  $KMnO_4$  used in opium poisoning, MgO or Calcium oxide used to neutralize the acids.

**iii). Physiological antidote**- These antidote produce the opposite action to that of poison and nullify the adverse effects of the poisons, E.g Caffeine against morphine, Atropine against pilocarpine, Chloroform against strychnine.

**iv)Universal antidote-**

These are given in combination. They are used in situation where the nature of poison is not known

E.g 1) Powdered Charcoal -2 parts

2) Magnesium oxide- 1 part

3) Tannic acid- 1part.

**v) Systemic antidote/ Specific antidote -**

<b>Antidote</b>	<b>Poison</b>
Pecicillamine	Lead, Mercury.
Calcium edentate(EDTA)	Magnese, Lead ,Iron
Desferrioxime	Iron
BAL	Mercury, Arsenic

**c) What are the guiding principles while using a hospital formulary? (Each point carries ½ mark)**

**Guideline principles for preparation of Hospital Formulary:**

The following principles will serve as guide to all those utilizing the formulary system:

1. The medical staff of the hospital shall appoint P and T Committee and outline its scope, purpose, organization and function.



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2. The formulary system will be sponsored by medical staff based upon recommendations of P and T Committee.
3. The medical staff shall adopt the written policies and procedures of the formulary system.
4. Drugs should be included in the formulary by their nonproprietary names and should be prescribed by the same name.
5. Limiting the number of drugs available from pharmacy can produce substantial patient care and financial benefits. These benefits can be greatly increased by using generic equivalents.

Generic equivalent- The drugs containing identical active compounds. e.g. Two brands of tetracycline.

Therapeutic equivalent- The drugs differing in composition but having very similar pharmacological or therapeutic effects. .e.g: two different antacid products.

6. The management of the hospital shall inform all the medical and nursing staff about the existence of the formulary system, procedures of the operation of the system and any changes in those preparations. Copies of formulary must be readily available at all times.
7. Provision shall be made for the use of drugs not included in the formulary, by the medical staff.
8. The pharmacist shall be responsible for specification as to quality, quantity, and source of supply of all the drugs used in the diagnosis and treatment of patients.

**d) Write any four tests to evaluate 'Absorbent cotton Wool I.P.'( any 4 tests-1 mark each)**

**Tests for evaluation of Absorbent cotton IP –**

1. To 15 gm of drug add 150 ml of water, macerate for 2 hrs in a closed vessel, decant the liquid, carefully squeezing out the residual liquid.

**a) Alkalinity or Acidity:** To 25 ml of the solution sample add 0.1 ml of dilute phenolphthalein solution to another 25 ml add 0.05 ml of methyl orange solution.





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No pink colour develops in acidity and alkalinity test

**b)Surface active substances:** Into 25 ml, graduated, stoppered cylinder, with external diameter 18- 22 mm . Previously rinsed with sulphuric acid and then with water, add 10 ml of solution sample, shake vigourously 30 times in 10 seconds. Allow it to stand for 1 min.and shake again 30 times in 10 seconds. After 5 mins the height of froth should not exceed 2 mm above the surface of liquid

**3. Sinking time :** Weigh the basket. Take 5 samples each of approximately 1 gm,pack loosely in the basket. Hold the basket with its long axis in the horizontal position, and drop it from a height of about 10 mm into the water at 25<sup>0</sup> c, obtained in a beaker at least 12 cm in diameter and filled to a depth of 10 cm. Measure with a stopwatch the time taken by the basket to sink below the surface of water,

Should not be more than 10 seconds.

**4. Water holding capacity:**

After the sinking time has been recorded in the test, remove the basket from the water and allow it drain for exactly 30 seconds. With its long axis in the horizontal position transfer it to the tared beaker and weigh. Calculate the weight of the water retained by the sample. Not less than 23gram of water/gram of cotton.

**5. Neps:** Spread thin layer of 0.5 gm of absorbent cotton for an area of 450 sq.cm.uniformly between two glass plates. View by the naked eye under transmitted light. Repeat the test three times

Should not be more than 500 neps/gm of absorbent cotton.

**6.Water soluble substances:** Boil 5 gm with 500ml water for 30 mins, stirring frequently, and replacing the water lost by evaporation .Decant the liquid into the beaker, squeeze the residual liquid from the material carefully, with a glass rod, mix the liquid and filter the extract. Evaporate the 400 ml of the filtrate and dry the residue to constant weight at 105<sup>0</sup> c

Not more than 0. 5 %

**7. Ether soluble substances:** : Not more than 0. 5 %

**8. Loss on drying:** : Not more than 8.0 % w/w

**9. Residue on ignition:** : Not more than 0.2% residue remain.



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**e) Explain the use of computers in purchasing and inventory control.**

The computer can be effectively used for purchasing and inventory control in the hospital pharmacy as follows:

**i) Periodic inventory control system-** In this system, inventory of goods are manually checked, the amount of stock in hand, minimum and maximum, can be found out by feeding the data to the computer. Once the stock is entered in the computer, it is helpful for placement of order to each supplier.

**ii) Perpetual inventory control-** In this system, computer maintains running balance of all drugs in the stock. All drugs are entered into the database. When they arrive in the pharmacy, they are added in the initial stock, so as to update the current stock. The current level of each drug is found out by subtraction from the inventory balance.

Thus, the computer can list out minimum order quantity of each drug. In this way computer can help in inventory control-

- To detect the items those have reached minimum order level.
- To prepare the list of drugs to be ordered and their quantities.
- To prepare the purchase order and avoid duplicate orders.

**6. Attempt any THREE of the following.( 4 marks each)**

**12M**

**a) Give a short account of hospitals classified on the basis of size.( Each class carries 1 mark)**

i) **Large Hospitals:** Beds available 1000 or above 1000, e.g. J.J.group of hospital, K.E.M. hospital

ii) **Medium hospitals:** Beds available 500-1000, e.g, Bombay hospital (700 bed hospital)

iii) **Small Hospital:** Beds available 100-500, E.g- Breach candy hospital and Hinduja a hospital.

iv) **Very small hospital:** Beds less than 100.e.g Private ownership hospital/ Nursing home

**b) Explain the following. (Each term – 1Mark)**

**i) Heamatinics-** Agent which improves the quality of the blood, increasing the hemoglobin level and the number of erythrocytes. They are used in the treatment of aneamias.



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**ii) Anesthetics:** An agent which produces a state of reversible loss of consciousness and sensation.

**iii) Cholagogue:** An agent that enhances the flow of bile into the intestine. OR An agent that produces evacuation of gall bladder.

**iv) Tranquilizer:** A drug which acts to reduce mental tension and anxiety without interfering with normal mental activity.

**c) Explain the 'Floor stock system' (Charge floor stock system- 1 Mark, Non charge floor stock system- 3 Marks)**

Ans- The medicines or drugs are stored in pharmacy and supplied ,or distributed to the wards or rooms on order and kept under the supervision of registered nurse at nursing station .It is classified further into-

**a) Charge floor stock drug:-** Drugs which are stocked on the nursing station at all time and are charged to the patient account . An envelope is used to dispense the drugs to the nursing station.

**Dispensing of charge floor stock drugs ( Envelope method)**

The patients are charged mostly because of high cost of the drugs. These include injections or other single dose preparations. An envelope is used to dispense the drug to the nursing station which is used as charge ticket. The pre- labeled envelopes are filled with specific drugs in specified quantity and placed at the disposal of nursing unit.

When the drug is administered, the patient's name and room number is entered on the envelope and sent to the pharmacy where it is priced & forwarded to account department for billing.

**b) Non Charge floor stock drug:-** Drugs which are placed at the nursing station at all time and for which there may not be direct charge to patient's account. The cost is calculated in the per day cost of hospital room.

There are different methods for dispensing of Non Charge floor stock drug.



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1. Drug Basket method.    2. Mobile Dispensing unit

**1) Drug basket method-** The night nurse check the medicine closet, utility room, and drug supplies against a master list provided by the pharmacy. The nurse places a check mark on the number required for each drug on the requisition for floor stock supplies. She also places the empty containers in the drug basket. After completing the procedure, the empty containers and requisition for floor stock supplies is then sent to the pharmacy. In the next morning, The pharmacy staff fills each container and dispense with suitable label.. Once the basket is completed, it is delivered to the floor through the messenger service.

**2) Mobile dispensing unit-**It is specially constructed stainless steel Trolley use to carry the drugs/ medicines and containers. The carbon copy of the requisition for floor stack supplies is left on the nursing station as a record of the delivery and original is returned to the pharmacy. The pharmacist checks nursing station or a drug stock and refill container according to requisition slip.

So, In this method night duty nurse need not check drug stock. By this method pharmacist come out of the pharmacy and go to the nursing station to check the drug stock. This increase interaction between pharmacist and nursing staff.

**d) Explain the role of pharmacist in monitoring the adverse drug reactions.( Each point carries 1 mark)**

Pharmacist with better knowledge of pharmacological action, adverse reactions, and Pathophysiology of diseases can make the drug therapy safer. He is involved in following steps of identification and monitoring of adverse drug reactions

**1) Literature review:** Published literature and information inserted in the packages on relevant data, on the suspected adverse effect are reviewed by the pharmacist and physicians

**2) Patient history:** Pharmacist should check whether the patient has a history of allergic disorders or medication allergy to related compounds; time from which the drug has been started. He should also note other patient related factors like concurrent medications, disease states. etc.



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**3) Drug level studies:** If possible, the pharmacist should check the drug level in biological fluids by which it can be understood whether the adverse effects are dose dependant.

**4) Therapeutic decision making:** Taking into consideration intensity and seriousness of the reaction, the pharmacist can advice if immediate discontinuation of therapy is required. He must weigh the risk/ benefit ratio of the continued administration of the drug against the availability of other drugs.

**e) Explain 'Pyrogen testing' (SHAM test- 3marks, LAL test- 1 mark)**

**SHAM test:**

**Conditions:**

- 1) For this test, initially three rabbits are selected.
- 2) These three rabbits must be healthy and their weight not less than 1.5 kg
- 3) They should not have undergone any testing for the previous two weeks.
- 4) Needles, glassware's, syringes etc.to be used for this test should be Pyrogen free and washed with water for injection. Then heated in hot air oven, at  $250^{\circ}\text{c}$ , for one hour.
- 5) The three rabbits are injected 10 ml/ kg normal saline solution. Any animal showing a rise in temperature of  $0.6^{\circ}\text{c}$  is rejected.
- 6) The test is carried out in an air-conditioned room.

**Procedure:**

- 1) During the test, food and water is withheld from rabbits overnight.
- 2) Clinical thermometers are inserted into the rectum of each rabbit, to a depth of not less than 75 cm for recording the body temperature.



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- 3) Two normal reading of rectal temperatures should take before the test, at an interval of half an hour and the mean of two calculated. This is called as initial temperature
- 4) Then intravenous injection of 10ml/ kg body weight is warmed at  $38^{\circ}\text{c}$  and injected slowly through the ear vein.
- 5) Rectal temperature readings are then recorded at an interval of half an hour till six readings.

**Result:**

- 1) The response of each rabbit can be calculated by subtracting the initial temperature from maximum temperature, which is the highest temperature recorded.
- 2) Addition of three responses from three rabbits gives sum of responses.
- 3) If the sum does not exceed  $1.4^{\circ}\text{c}$ , and if the responses of any individual rabbit are less than  $0.6^{\circ}\text{c}$ , the sample passes the test.
- 4) If the sum is more than  $1.4^{\circ}\text{c}$  or response of any individual rabbit is  $0.6^{\circ}\text{c}$  or more, continue the test, for five more rabbits.
- 5) Again if, sum of all rabbits is less than  $3.7^{\circ}\text{c}$ , the sample passes the test.

**Limulus Amoebocyte Lysate:**

- 1) It is another method for determination of pyrogen endotoxin.
- 2) In this method, The test solution is combined with cell lysate from the blood cell of horseshoe crab
- 3) Any pyrogen endotoxin if present will coagulate with protein fraction or blood cell and result in formation of gel.