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341651(41)

B. Pharmacy (Sixth Semester) Examination, April-May 2020

(PCI Scheme)

MEDICINAL CHEMISTRY-III

THEORY (BP601T)

Time Allowed : Three hours

Maximum Marks : 75

Note *: Attempt all parts as directed.*

Part-A **1×20=20**

Note *: Attempt all questions.*

1. Multiple Choice Questions :

(i) Which of the following drug is an aminoglycoside drug :

(a) Erythromycin

(b) Kanamycin

(c) Doxycycline

(d) Ethambutol

(ii) Neomycin drug isolated from ..... :

(a) Streptomyces griseus

(b) Streptomyces fradiae

(c) Streptomyces lividans

(d) Streptomyces ambofaciens

(iii) Azithromycin is semisynthetic derivative of which drug :

(a) Streptomycin

(b) Clarithromycin

(c) Erythromycin

(d) Gentamicin

(iv) Macrolide compounds act by inhibiting protein synthesis of bacteria after binding with ..... :

(a) 30 S ribosomal subunit

(b) 50 S ribosomal subunit

(c) Transpeptidase enzyme

(d) None of the above

(v) Natural penicillin which is the precursor for synthetic penicillin is ..... :

(a) Phenethicillin

(b) Phenoxy methyl penicillin

(c) Piperacillin

(d) Benzyl penicillin

(vi) Which of the following drug is β-lactamase inhibitor :

(a) Salbactam

(b) Aztreonam

(c) Cloxacillin

(d) Tabtoxin

(vii) Penicillins are contain which of the following heterocyclic ring :

(a) Dihydro metathiazine

(b) Tetrahydrothiazine

(c) Dihydrothiazole

(d) Tetrahydrothiazole

(viii) Which of the following drug is an example of fourth generation cephalosporins :

(a) Cephaloridine

(b) Cefoxitin

(c) Cefpirome

(d) Cefoperazone

(ix) The antimalarial drug belongs to 8-aminoquinoline category is :

(a) Chloroquine

(b) Mefloquine

(c) Primaquine

(d) Quinine

(x) The synthetic precursor the synthesis of chloramphenicol is :

(a) P-amino acetophenone

(b) P-nitroacetophenone

(c) P-chloroacetophenone

(d) P-nitrobenzophenone

(xi) Which of the fluoroquinolones not belongs the first generation :

(a) Ciprofloxacin

(b) Ofloxacin

(c) Norfloxacin

(d) Levofloxacin

(xii) Nitrofurantoin contains which of the heterocyclic ring :

(a) Imidazolidinedione

(b) Oxazolidinedione

(c) Thiazolidinedione

(d) Pyrazolidinedione

(xiii) Ciprofloxacin act by inhibiting ..... enzyme :

(a) DNA helicase

(b) DNA polymerase

(c) DNA gyrase

(d) Reverse transcriptase

(xiv) Which of the following antifungal drug is a natural drug :

(a) Fluconazole

(b) Tolnaflate

(c) Griseofulvin

(d) Flucytosine

(xv) Antiprotozoal agents are used for the treatment of :

(a) Emesis

(b) Dysentry

(c) Malaria

(d) Tuberculosis

(xvi) Which of following drug not used as anthelmintics :

(a) Thiabendazole

(b) Niclosamide

(c) Ivermectin

(d) Tinidazole

(xvii) Cotrimoxazole is the combination of the following :

(a) Trimethoprim + Sulfamethoxazole

(b) Trimethoprim + Sulfamethizole

(c) Trimethoprim + Sulfisoxazole

(d) Trimethoprim + Sulfatriazole

(xviii) Fluconazole contains which heterocyclic ring :

(a) Imidazole

(b) Pyrazole

(c) Triazole

(d) Pyridine

(xix) Acyclovir is ..... :

(a) Adenin analog

(b) Cytosin analog

(c) Guanin analog

(d) Thiamin analog

(xx) Hammett's value indicate the following physico chemical property :

(a) Partition coefficient

(b) Steric property

(c) Molar refractivity

(d) Dissociation constant

Part-B 2×10=20

Note : *Attempt any* ***two*** *questions.*

2. Discuss the malaria cycle. Give the classification of antimalarial drugs along with MOA and synthesis of chloroquine.

3. Describe the classification, MOA, chemistry and SAR of penicillins.

4. Write the classification of sulphonamide along their SAR. Discuss the MOA and synthesis of sulfacetamide.

Part-C 7×5=35

Note : *Attempt any* ***seven*** *questions.*

5. Give the structural classification and MOA of tetracyclines.

6. Write a note on monobactams.

7. Discuss the structural requirements and MOA of macrolides.

8. Write the synthesis and action of Isoniazide.

9. Explain the MOA and synthesis of acyclovir.

10. Discuss the classification of antifungal drugs along with the MOA and structure of miconazole.

11. Describe the synthesis and MOA of chloramphenicol.

12. Write a note on Hansch analysis.

13. Discuss the approaches of combinatorial chemistry.

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B. Pharmacy (Sixth Semester) Examination, April-May. 2020

(PCI Scheme)

PHARMACOLOGY-III

(Theory) (BP602T)

Time Allowed : Three hours

Maximum Marks : 75

Note : *Attempt all questions as directed. Distribution of marks is given with sections.*

Part-'A' **20×1=20**

1. Multiple choice questions (MCQs). Answer all the questions :

(i) Indicate the drug which is a leukotreine receptor antagonist :

(a) Sodium cromoglycate

(b) Zafirlukast

(c) Zileuton

(d) Triamcinolone

(ii) Gastric acid secretion is under the control of the following agents EXCEPT :

(a) Histamine

(b) Acetylcholine

(c) Serotonin

(d) Gastrin

(iii) All of the following drugs are proton pump inhibitors EXCEPT :

(a) Pantoprazole

(b) Omeprazole

(c) Famotidine

(d) Rabeprazole

(iv) Which drug is an analogue of prostaglandin E_1?

(a) Misoprostol

(b) De-nol

(c) Sucralfate

(d) Omeprazole

(v) Bactericidal effect is :

(a) Inhibition of bacterial cell division

(b) Inhibition of young bacterial cell growth

(c) Destroying of bacterial cells

(d) Formation of bacterial L-form

(vi) Which of the following groups of antibiotics demonstrates a bacteriostatic effect?

(a) Carbapenems

(b) Macrolides

(c) Aminoglycosides

(d) Cephalosporins

(vii) Tick the drug belonging to antibiotics-monobactams :

(a) Ampicilin

(b) Bicillin-5

(c) Aztreonem

(d) Imipenem

(viii) Sulphonamides are effective against :

(a) Bacteria and Chlamidia

(b) Actinomyces

(c) Protozoa

(d) All of the above

(ix) Sulphonamides have the following unwanted effects :

(a) Hematopoietic disturbances

(b) Crystalluria

(c) Nausea, vomiting and diarrhoea

(d) All of the above

(x) Tick the antimycobacterial drug belonging to first-line agents :

(a) PAS

(b) Isoniazid

(c) Kanamycin

(d) Pyrazinamide

(xi) Mechanism of Cycloserine action is :

(a) Inhibition of mycolic acids synthesis

(b) Inhibition of RNA synthesis

(c) Inhibition of cell wall synthesis

(d) Inhibition of pyridoxalphosphate synthesis

(xii) The mechanism of fluroquinolones action is :

(a) Inhibition of phospholipase C

(b) Inhibition of DNA gyrase

(c) Inhibition of bacterial cell synthesis

(d) Alteration of cell membrane permeability

(xiii) The drug of choice for syphillis treatment is :

(a) Gentamycin

(b) Penicillin

(c) Chloramphenicol

(d) Doxycycline

(xiv) Methotrexate is :

(a) A purine antagonist

(b) A folic acid antagonist

(c) An antibiotic

(d) An alkylating agent

(xv) Tick the anticancer drug belonging to inorganic metal complexes :

(a) Dacarbazine

(b) Cisplatin

(c) Methotrexate

(d) Vincristine

(xvi) Which of the following toxicity can occur due to single exposure?

(a) Acute toxicity

(b) Sub-acute toxicity

(c) Sub-chronic toxicity

(d) Chronic toxicity

(xvii) If two organophosphate insecticides are absorbed into an organism, the result will be :

(a) additive effect

(b) synergistic effect

(c) potentiation

(d) subtraction effect

(xviii) In humans, a surge of melatonin release occurs :

(a) During the night

(b) During the morning

(c) During late afternoon

(d) During the evening

(xix) The part of the brain that has been shown to function like a 'biological clock' is the :

(a) Optic chiasm

(b) Superchiasmatic nucleus

(c) Nucleus of the solitary tract

(d) Gigantocelluar tegmental field

(xx) Tick the drug, inhibiting viral DNA synthesis :

(a) Interferon

(b) Saquinavir

(c) Amantadine

(d) Acyclovir

Part-'B' **2×10=20**

2. Long answer Type Questions. Attempt any two questions :

(i) Define peptic ulcer classify the drugs use for treatment of peptic ulcer and explain their mechanism of action.

(ii) Define antibiotics, classify penicillin and discuss mechanism of action of penicillin.

(iii) What is biological clock? Discuss in detail about Circadian rhythms.

Part-'C'

(Short Answer Type Questions) **7×5=35**

Note : Answer any seven questions. Each question carry 5 marks.

3. Short answer type questions. Attempt any seven questions :

(i) Define and classify expectorant and enumerate its mechanism of action.

(ii) Discuss the pathophysiology of asthma and classify the drug use for treatment and explain their mechanism of action.

(iii) Classify the drugs use for treatment of diarrhoea and discuss their mechanism of action.

(iv) Wha is cotrimoxazole and discuss its mechanism of action?

(v) Classify antileprotic agents and discuss their mechanism of action.

(vi) Explain in brief about sub-acute and chronic toxicity.

(vii) Clinical symptoms and management of barbiturates poisoning.

(viii) Write notes on immunostimulants.

(ix) Discuss in detail about chemotherapy of sexually transmitted diseases.

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B. Pharmacy (Sixth Semester) Examination, April-May 2020

(PCI Scheme)

(Pharmacy Branch)

HERBAL DRUG TECHNOLOGY - THEORY

(BP603T)

Time Allowed : Three hours

Maximum Marks : 75

Note : *Questions paper has three parts A, B, C. All the questions in Part-A are compulsory. Part-B is long answer type questions. It contains 3 questions of which attempt any two questions. Each question carries 10 marks. (2×10 = 20 marks). Part-C is short answer type questions. It contains 9 questions, of which attempt any seven questions. Each question carries 5 marks. (7×5=35 marks).*

Part-A

1. Multiple Choice Questions (MCQs) : Answer all the questions : 20×1=20

(i) Asian ginseng is native to what countries

(a) Japan and Hong Kong

(b) China and Taiwan

(c) Korea and China

(d) Thailand and Japan

(ii) The triterpene glycoside, glycyrrhizin from *Glycyrrhiza glabra* ..... times sweeter than sucrose.

(a) 100

(b) 50

(c) 250

(d) None of the aboye

(iii) *Stevia rebaudiana* leaves contain which compounds that are 200-300 sweeter than sucrose :

(a) Steviol alkaloids

(b) Steviol glycosides

(c) Both (a) & (b)

(d) None of the above

(iv) In the Rig Veda, Aryuvedic medicine describes treating snakebites with reserpine. What plant is reserpine derived from?

(a) Aconitum

(b) Rauwolfia serpentine

(c) Sassafras albidum

(d) Gingko biloba

(v) The chemical obtained from chrysanthemum that has insecticidal properties is called a :

(a) pyrethrum

(b) pyrethroid

(c) pathogen

(d) parasite

(vi) Pest control measures are best implemented :

(a) Before fruiting starts

(b) After plants flower

(c) After the pest starts to destroy the plant

(d) Before the destructive stage of the pest

(vii) A herbicide applied to the soil before planting a crop is called a :

(a) Preplant herbicide

(b) Preemergence herbicide

(c) Postplant herbicide

(d) Postemergence herbicide

(viii) Who is traditionally regarded as the founder of Ayurveda?

(a) Kamadhenu

(b) Shri Laxmi

(c) Airavata

(d) Dhanvantari

(ix) A homeopathic remedy becomes stronger :

(a) The less diluted it is

(b) The more diluted it is

(c) When mixed with other homeopathic remedies

(d) After you swallow it

(x) What are the life forces, which influence the functioning of the body?

(a) Vata dosha (space and air)

(b) Pitta dosha (fire and water)

(c) Kapha dosha (water and earth)

(d) All of the above

(xi) The term "WIPO" stands for :

(a) World Investment Policy Organization

(b) World Intellectual Property Organization

(c) Wildlife Investigation and Policing Organization

(d) World Institute for prevention of Organized Crime

(xii) Patent application can be filed in India by :

(a) True and First Inventor

(b) Assignee of the Inventor

(c) Legal representative of the Inventor

(d) All the above

(xiii) The first legislation in India relating to patents

was enacted in :

(a) 1856

(b) 1911

(c) 1970

(d) 2005

(xiv) ..... is used in hair tonic preparation :

(a) Capsicum

(b) Cantharides

(c) Resorcinol

(d) All of the above

(xv) Carotenoids are lipid-soluble :

(a) Yellow-orange pigments

(b) Yellow-orange-red pigments

(c) Yellow-red pigments

(d) Red-orange pigments

(xvi) What is called for the illegal collection of indigenous plants by corporations to patent them for their own use?

(a) Biopiracy

(b) Biomagnifications

(c) Biodegradation

(d) Biodiversity

(xvii) Phospholipids are abundant in :

(a) Egg Yolk

(b) Plant seeds

(c) Both (a) & (b)

(d) None of the above

(xviii) What are called for the value of nature's products that are consumed directly?

(a) Productivity value

(b) Indirect value

(c) Non-consumptive value

(d) Consumptive value

(xix) Which of the following is an organic farming practice that helps maintain soil health?

(a) Sewage Sludge

(b) Synthetic Fertilizers

(c) Monoculture

(d) Crop Rotation

(xx) The herb andrographis paniculata, popular in Ayurvedic medicine, is sometimes known as "Maha-tita", which translates into English as what?

(a) King of Bitters

(b) Baby-Blood

(c) Lady-Bosom

(d) Deadly Nightshade

Part-B

2. Long answer type questions :

(Answer **two** out of three) 2×10=20

(i) Write an illustrative essay on WHO guidelines for good agricultural practices for medicinal plants?

(ii) Describe history, basic principles and philosophy of Siddha system of medicine?

(iii) Define IPR, write about its components. Also discuss about stability testing of herbal drugs

according to ICH guidelines.

Part-C

3. Short Answer Type Questions : (Any Seven) 7×5=35

(i) Herbal cosmetics

(ii) Plant sweeteners

(iii) Plant bitters

(iv) Alfaalfa and Spirulina as nutraceuticals

(v) Herb-Food Interactions

(vi) Herbal colorants and flavouring agents

(vii) Case study of Curcuma

(viii) Phytosomes

(ix) Authentication of herbal materials

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B. Pharmacy (Sixth Semester) Examination, April-May 2020

(PCI Scheme)

(Pharmacy Branch)

BIOPHARMACEUTICS and PHARMACOKINETICS

THEORY (BP604T)

Time Allowed : Three hours

Maximum Marks : 75

Note : *Questions paper has three parts A, B, C. Part-A has* ***two*** *sections. (i) Attempt all questions. Each question carries 2 marks (5 questions × 2 = 10 marks). (ii) 10 Multiple choice questions each of 1 mark. All the questions in Part-A are compulsory. Part-B is long answer type questions. It contains 3 questions of which attempt any* ***two*** *questions. Each question carries 10 marks. (2×10 = 20 marks). Part-C is short answer type questions. It contains 9 questions, of which attempt any* ***seven*** *questions. Each question carries 5 marks. (7×5=35 marks).*

Part- 'A'

1. Attempt all questions. Each questions carries 2 marks :

Define : 2×5=10

(a) Bioavailability (Absolute and Relative)

(b) Compartment Models

(c) Absorption

(d) Biotransformation

(e) Protein binding

Multiple choice Questions : 1×10=10

(i) The drinking force for the passive diffusion is :

(a) Electrochemical gradient

(b) Concentration gradient

(c) Both

(d) None

(ii) Cell eating process is also known as :

(a) Phagocytosis

(b) Pinocytosis

(c) Transcytosis

(d) None

(iii) The rate limiting step for oral absorption of any

drug is :

(a) Disintegration

(b) Disaggregation

(c) Absorption

(d) Dissolution

(iv) With the increase in surface area the dissolution rate :

(a) Increaes

(b) Decreases

(c) No change

(d) All of the above

(v) Which vitamin molecules will bind to alpha 2 globulin :

(a) Vitamin B complexes

(b) Vitamin A and Vitamin B

(c) Vitamin A, D, E, K

(d) None of the above

(vi) If a drug is weak acid then in the stomach it will be in which form :

(a) Ionized form mostly

(b) Non ionized form mostly

(c) Partially ionized

(d) Will aggregate

(vii) What does the word "open" mean in the One compartment open model :

(a) The drug easily enters

(b) The drug readily mixes with the blood

(c) Unidirectional input and output

(d) Easy absorption

(viii) What is the equation to find out the apparent volume of distribution :

(a) Amount of drug in the body/plasma drug concentration

(b) Plasma drug concentration/amount of drug in the body

(c) 1 / plasma drug concentration

(d) 1 / Amount of drug in the body

(ix) Which organ comprise the Central Compartment in a two compartment model :

(a) Muscles

(b) Skin

(c) Adipose

(d) Liver

(x) Michaelis Menton equation is related to :

(a) Non linear pharmacokinetics

(b) Linear Pharmacokinetics

(c) Pharmacodynamics

(d) None of the above

Part- 'B'

(Long Type Questions)

*Note : Attempt any **two** questions. Each question carries 10 marks.* 2×10=20

2. Define bioavailability and discuss methods of determination of bioavailability.

3. What is compartment modelling classify them and discuss any one in detail?

4. Discuss in detail non linear pharmacokinetics.

Part- 'C'

(Short Type Questions)

*Note : Attempt any **seven** questions. Each question carries 5 marks.* 7×5=35

5. Discuss clinical signifiance of protein binding of drugs?

6. Discuss invitro-invivo correlations.

7. Explain one compartment open model for intravenous injection (bolus).

8. Explain biotransformation of drugs with examples.

9. Explain factors influencing drug absorption through GIT.

10. Explain non-renal routes of drug excretion of drugs.

11. Write about renal excretion of drugs.

12. Discuss tissue permeability of drugs.

13. Explain bioequivalence studies.

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B. Pharmacy (Sixth Semester) Examination, April-May 2020

(PCI Scheme)

PHARMACEUTICAL BIOTECHNOLOGY

THEORY (BP605T)

Time Allowed : Three hours

Maximum Marks : 75

***Note** : Attempt all parts as directed.*

Part-A **1×20=20**

***Note** : Attempt all questions.*

1. Multiple Choice Questions :

(i) What is the clinical application of monoclonal antibodies?

(a) Biosensors

(b) Transplant rejection

(c) Infectious disease

(d) Purification of drugs

(ii) Restriction endonucleases are most widely used in recombinant DNA technology. They are obtained from :

(a) Bacteriophages

(b) Bacterial cells

(c) Plasmids

(d) All prokaryotic cell

(iii) Sterilization of tissue culture medium is done by :

(a) Mixing the medium with antifungal agents

(b) Filtering the medium through fine sieve

(c) Autoclaving of medium at 120° for 15 min

(d) Keeping the medium at –20°C

(iv) Micropropagation is a technique :

(a) For production of many plants that are clones of each other

(b) For production of haploid plant

(c) For production of somatic hybrids

(d) For production of somaclonal plants

(v) Plasmids are suitable vectors for gene cloning because :

(a) These can shuttle between prokaryotic and eukaryotic cells

(b) These are small circular DNA molecules with their own replication origin site

(c) These are small circular DNA molecules, which can integrate with host chromosomal DNA

(d) These often carry antibiotic resistance genes

(vi) Double stranded DNA denaturation with specified limit of temperature is :

(a) Reversible reaction

(b) Irreversible reaction

(c) Either (a) or (b)

(d) None of these

(vii) In a PCR reaction after four cycles, each molecule of a duplex DNA give rise to :

(a) 16 double stranded DNA

(b) 16 single strands of DNA

(c) 18 single stranded of DNA

(d) 18 double stranded DNA

(viii) The PCR, polymerase chain reaction is becoming the method of choice for :

(a) Alteration of gene

(b) Screening gene

(c) Sterilization of gene

(d) All of these

(ix) The first immunoglobulin heavy chain class to be expressed on the surface of a newly produced B-cell is :

(a) IgA

(b) IgD

(c) IgG

(d) IgM

(x) The cytoplasmic region of surface IgM consists of :

(a) A single H chain constant region domain

(b) A light chain

(c) 110 amino acids

(d) 3 amino acids

(xi) Which of the following is considered an autoimmune disease :

(a) Rheumatoid arthritis

(b) AIDS

(c) SCID

(d) Agammaglobulinemia

(xii) A transplant between individuals of different animal species is termed as :

(a) Allograft

(b) Isograft

(c) Enterograft

(d) Xenograft

(xiii) HIV has a high mutation rate due to the imprecise operation of its :

(a) Viral membrane

(b) Reverse transcriptase

(c) Protease

(d) Dismutase

(xiv) Electroporation is also used for taking up the DNA by the cell. It constitutes of ..... :

(a) Inserting the DNA into the cells via an electric shock

(b) Increased efficiency than both natural and chemical methods

(c) Causing the least amount of damage in comparison to other methods

(d) Decreased efficiency than both natural and chemical methods

(xv) Which of the statements hold true for conjugation?

(a) Conjugation is the natural process of transferring DNA from one species to another

(b) It is the artificial process in case the cells are not able to take them up naturally

(c) The plasmids are transferred from one cell to another by physical contact

(d) The plasmids are transferred from one cell to another by chemical means

(xvi) The addition or deletion of a nucleotide base pair involves :

(a) Point mutation

(b) Silent mutation

(c) Nonsense mutation

(d) Frame shift mutation

(xvii) The final electron acceptor in lactic acid fermentation is :

(a) Oxygen

(b) Lactic acid

(c) Pyruvate

(d) NAD

(xviii) Pasteur effect discovered in 1857, is :

(a) Inhibiting effect of oxygen on the fermentation process

(b) Aerating yeasted broth causes yeast cell growth to decrease, while conversely, fermentation rate increase

(c) (a) and (b)

(d) All of these

(xix) EFB class 4 consists of ..... :

(a) Low-risk microorganisms

(b) High-risk microorganisms

(c) Medium-risk microorganisms

(d) Environmental-risk microorganisms

(xx) Which of the following fermenters are characterized by height to diameter ratio :

(a) Tower fermenter

(b) Airlift fermenter

(c) Hollow fibre

(d) Perfusion bioreactor

Part-B

Long Answer Questions **2×10=20**

Note : *Attempt any **two** questions.*

2. Describe methods of enzyme immobilization and applications.

3. Explain in detail application of r-DNA technology and genetic engineering in the production of hepatitis vaccine.

4. Discuss and illustrate production of penicillin by fermentation technology.

Part-C

Short Answer Questions **7×5=35**

Note : *Attempt any **seven** questions.*

5. Write a note on types of mutants.

6. Explain southern blotting.

7. What is hybridoma technology? Discuss in brief.

8. Define immunity and discuss types of immunity in short.

9. What is microbial biotransformation? Clarify.

10. Briefly elucidate about PCR.

11. Discuss in short about storage conditions and stability of officials vaccines.

12. Give details of design of a fermenter and its various controls.

13. Write in short about biosensors.

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B. Pharmacy (Sixth Semester) Examination, April-May 2021

(PCI Scheme)

(Pharmacy Branch)

PHARMACEUTICAL QUALITY ASSURANCE

(Theory)

(BP606T)

Time Allowed : Three hours

Maximum Marks : 75

Note : *Questions paper has three parts A, B & C. All the questions in Part-A are compulsory. Each question carries 1 marks. Part-B is long answer type questions. It contains 3 questions of which attempt any two questions. Each question carries 10 marks. (2×10 = 20 marks). Part-C is short answer type questions. It contains 9 questions, of which attempt any seven questions. Each question carries 5 marks. (7×5=35 marks).*

Part-A

(Multiple Choice Questions)

Note : Answer all the questions from MCQs. Each question carries 1 mark.

1. Identify the correct options : 20×1=20

(i) According to WHO, QC is a part of :

(a) GLP

(b) GMP

(c) GCP

(d) None of the above

(ii) TQM does not work in an environment where employee ..... each others.

(a) Appreciate

(b) Criticize

(c) Support

(d) None of the above

(iii) The aim of the pharmaceutical development is to design a ..... product.

(a) Optimized

(b) Effective

(c) Quality

(d) None of the above

(iv) Warehouse serve as a key connection between manufacture and ..... for finished product.

(a) Employee

(b) Storage facilities

(c) Customers

(d) Warehouse

(v) FEFO stand for :

(a) First in first out

(b) Far in far out

(c) First invent first out

(d) First enventory first outstanding

(vi) According to USFDA guidelines, the three stages of process validation involve :

(a) Process design

(b) Process qualification

(c) Continued process verification

(d) All of the above

(vii) Master formula record for each drug product describe all aspects of its :

(a) Manufacture

(b) Package

(c) Control

(d) All of the above

(viii) ICH a unique project that bring together the regulatory authorities of Europe, Japan and .....

(a) USA

(b) Brazil

(c) Australia

(d) India

(ix) ICH Q2 guidelines are for :

(a) Cleaning validation

(b) Analytical validation

(c) Calibration

(d) None of the above

(x) It is also called as pre market validation :

(a) Restrospective validation

(b) Concurrent validation

(c) Design qualification

(d) Prospective validation

(xi) The closeness of an agreement between the value, which is accepted either as a conventional true value or accepted reference value. The value found is known as :

(a) Accuracy

(b) Precision

(c) Ruggedness

(d) Robustness

(xii) Good distribution practice is a part of :

(a) QC

(b) QA

(c) IPQC

(d) None of the above

(xiii) Storage area should be :

(a) Clean

(b) Filthy

(c) Free from accumulated waste and vermin

(d) Both (a) and (c)

(xiv) Climate controlled warehousing space including control of :

(a) Temperature

(b) Humidity

(c) Both (a) and (b)

(d) None of the above

(xv) Complaint about product is an indication of the product :

(a) Quality

(b) Safety

(c) Efficacy

(d) None of the above

(xvi) In ABC analysis, "C" item have :

(a) Tight control

(b) Ordinary control

(c) Moderate control

(d) None of the above

(xvii) GMP ensures which of the following parameters :

(a) Quality

(b) Safety

(c) Efficacy

(d) All of the above

(xviii) Many warehouses utilize a ..... to receive, store and retrieve product.

(a) Serial process

(b) Storage system

(c) Warehouse management system (WMS)

(d) Bill of lading

(xix) Document verification of a proposed design's ability to meet the requirement it needs to fulfill is called as :

(a) Design qualification

(b) Operational qualification

(c) Installation qualification

(d) Performance qualification

(xx) A printed form used by the physician to request a laboratory test for a patient is :

(a) Action value

(b) Procedure

(c) Requisition

(d) Manual

Part-B

(Long Answer Type Questions) **2×10=20**

*Note : Answer any **two** questions. Each question carries 10 marks.*

2. What do you mean by analytical method validation? Discuss the importance and type of validation.

3. Define ICH guidelines. Discuss the objectives of ICH guidelines and process of harmonization in detail.

4. Why document maintenance is essential in pharmaceutical industries? Elaborate on the master formula record and parts of the documentation.

Part-C

(Short Answer Type Questions) **7×5=35**

*Note : Answer any **seven** questions. Each question carries 5 marks.*

5. Discuss the comparative overview of quality assurance and quality control.

6. Define the principle of organization. Explain the key elements of personnel responsibilities.

7. Describe the design, construction and plant layout of premises.

8. Define complaints. Discuss the evaluation of complaints.

9. What is the general principle of calibration? Discuss the calibration of the pH meter.

10. What is GLP? Describe the organization and facilities of GLP.

11. Define TQM. Discuss the key elements of TQM.

12. What is SOP? Why it is essential?

13. What is the role of quality control in packing materials? Discuss the quality control for the glass container.