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341651(41)

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

(PCI Scheme)

MEDICINAL CHEMISTRY-III

THEORY (BP601T)

Time Allowed : Three hours

Maximum Marks : 75

Note *: Attempt specified number of question from each section.*

Section-A **1×20=20**

(Multiple Choice Questions)

Note *: Attempt all questions.*

1. Multiple Choice Questions :

(i) The streptomycin structure is containing .....

(a) Streptidine

(b) Streptose

(c) N-methyl glucosamine

(d) All of the above

(ii) Which of the following is not a natural aminoglycoside :

(a) Streptomycin

(b) Netilmicin

(c) Neomycin

(d) Kanamycin

(iii) The heterocycle present in the β -lactam ring is ..... :

(a) Aziridinone

(b) Azapine

(c) Azetidinone

(d) None of the above

(iv) Phenoxy methyl penicillin is also known as :

(a) Penicillin-V

(b) Penicillin-G

(c) Amoxicillin

(d) Phenethicillin

(v) The reaction of 2, 6-dimethoxy benzoylchloride with 6-Aminopenicillanic acid will give which of the following drug?

(a) Ampicillin

(b) Amoxicillin

(c) Methicillin

(d) Carbenicillin

(vi) Which of the following heterocycle is fused with β -lactam ring in the structure of cephalosporins.

(a) Thiazine

(b) Thiazole

(c) Thiadiazole

(d) Thiadiazine

(vii) The nomenclature Cepham lead molecule is .....

(a) 5-thia-1-a2a bicyclo [4.2.0]-Oct-2-ene

(b) 5-thia-2-a2a bicyclo [4.2.1]-Oct-2-ene

(c) 4-thia-2-a2a bicyclo [4.2.0]-Oct-1-ene

(d) 5-thia-1-a2a bicyclo [4.2.0]-hept-1-ene

(viii) The example of semisynthetic tetracycline is .....

(a) Chlortetra cycline

(b) Doxycycline

(c) Methacycline

(d) (b) and (c) both

(ix) The fundamental required structure of tetracycline is :

(a) Linear arrangement of the 4 rings

(b) Phenolic diketone system of ring BCD

(c) Tricarbonyl methane of ring A

(d) All of the above

(x) Which of the following material can be used to synthesize chloramphenicol :

(a) P-amino phenol

(b) P-nitroacetophenone

(c) M-nitroacetophenone

(d) 2-6 dinitroacetophenone

(xi) Which of the following is mode of action of chloramphenicol :

(a) Freeze initiation of codon reading

(b) Bind with the 305 ribosomal subunit

(c) Inhibition of peptidy transferase enzyme

(d) Destruction of translation assembly

(xii) Azithromycin is N-methylated derivative at 9th position of following drug :

(a) Clarithromycin

(b) Erythromycin

(c) Roxithromycin

(d) None of the above

(xiii) Pamaquine belongs to which class of antimalarial drugs :

(a) 8-amino quinoline

(b) 4-amino quinoline

(c) Diamino pyrimidine

(d) Quinine methanol

(xiv) Chloroquine can be synthesize from :

(a) m-chloro aniline and acetyl acetone

(b) p-chloro aniline and ethyl oxalo acetate

(c) m-chloro aniline and ethyl acetoacetate

(d) m-chloroaniline and ethyloxalo acetate

(xv) Chloroquine belong to which of the following class :

(a) Cinchona alkaloid

(b) 9-amino acridine

(c) 4-amino quinoline

(d) 8-amino quinoline

(xvi) Nitrofuntion drug is containing which heterocycles :

(a) Imidazole

(b) Pyrimidine

(c) Pyridazine

(d) Pyridine

(xvii) 9- [(2-hydroxyethoxy) methyl] guanine is the nomenclature of following drug :

(a) Zidavudine

(b) Vidarabin

(c) Dedanosine

(d) Acyclovir

(xviii) Isoniazide drug can be synthesized from :

(a) Nicotinic acid

(b) Pyridine

(c) r-Picoline

(d) Benzoic acid

(xix) What does the symbol ' ρ ' represents in QSAR equation :

(a) pH

(b) Plasma concentration

(c) Partition coefficient

(d) None of the above

(xx) What does a negative value of ' σ ' signify for a substituent :

(a) Electron with drawing

(b) Electron donating

(c) Neutral

(d) Hydrophobic

Section-B 2×10=20

(Long Answer Type Questions)

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

2. Classify the penicillin antibiotics. Write the mode of action, SAR of penicillins with synthesis of any one drug.

3. Write malaria cycle. Give the classification of antimalarial drug. Discuss the mechanism of action and synthesis of chloroquine.

4. What is QSAR? Write the methodology and different parameters involved in QSAR.

Section-C 7×5=35

(Short Answer Type Questions)

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

5. Write the significance of β -lactase inhibitors along with the structure of clavulanic acid and salbactum.

6. Write a note on macrolide antibiotics.

7. Classify the tetracyclines with structure and its mechanism of action.

8. Write the synthesis and mechanism of action of sulfacet amide.

9. Classify the antifungal drugs. Write mode of action and synthesis of Tolnaftute.

10. Give the classification of antitubercular drugs. Discuss the synthesis and mode of action of isoniazide.

11. Explain the synthesis and mechanism of action of metronidazole.

12. Classify the antiviral drugs along with the sythesis of acyclovir.

13. Write a note on prodrug.

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

(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. Make a diagram wherever applicable.*

Part-'A' **20×1=20**

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

(i) Which of the following cell is responsible for the secretion of mucus :

(a) Parietal cell

(b) Goblet cell

(c) Lymphatic cell

(d) All of the above

(ii) Nasal decongestant act by which of the following mechanism of action :

(a) Alfa antagonist

(b) Alfa agonist

(c) Beta antagonist

(d) Beta agonist

(iii) Sucralfate is used in peptic ulcer, find the exact category of it :

(a) Gastic acid secretion inhibitors

(b) Antacid

(c) Ulcer protective

(d) Anti H. Pylori

(iv) Fast acting magnesium hydroxide and slow acting alumnium hydroxide are combined together for which of the following reason :

(a) To get a sustained effect

(b) As magnesium hydroxide are laxative in nature

(c) As aluminium hydroxide may produce constipation

(d) All of the above are correct

(v) What is the another name of Penicillin G :

(a) Benzyl penicillin

(b) Phenoxymethyl Penicillin

(c) Antipseudomonal penicillin

(d) All are the correct

(vi) Penicillin is an example of antibiotic. Find the exact matching class of it :

(a) Beta-lactum antibiotics

(b) Sulfonamide and related rugs

(c) Quinolones

(d) Tetracycline

(vii) Chloramphenicol mechanism of action is :

(a) Protein synthesis inhibitor

(b) Cell wall inhibitor

(c) DNA-Gyrase inhibitor

(d) Folic acid synthesis inhibitor

(viii) Which of the following may be adverse reaction related to the chloramphenicol :

(a) Bone marrow suppression

(b) Grey baby syndrome

(c) Super infection

(d) All of the above

(ix) Development of new infection after using antibiotic therapy is termed as :

(a) Counter infection

(b) Super infection

(c) Meta infection

(d) Microbial resistance

(x) Which of these are an example of STD (Sexually transmitted disease) :

(a) Gonorrhoea

(b) Syphilis

(c) AIDS

(d) All of the above

(xi) Which of the following is an example of protease inhibitors :

(a) Bortezomib

(b) Imatinib

(c) Etoposide

(d) None of the above

(xii) Which of the following is one of a major cause of UTI :

(a) E. Coli

(b) Entamoeba Histolytica

(c) H. Influenza

(d) None of the above

(xiii) Agent which can cause cancer is called :

(a) Carcinogenicity

(b) Carcinogen

(c) Mutagen

(d) Genotoxicity

(xiv) BAL is abbreviation of :

(a) British anti-Lewisite

(b) British again-Lewisite

(c) British anti-Lewinide

(d) British antihistaminic-Lewisite

(xv) EDTA is an example of :

(a) Chelating agents

(b) Neutralizing agents

(c) Universal antidotes

(d) All of the above

(xvi) Mechanism of action of activated charcoal is :

(a) Adsorption

(b) Absorption

(c) Neutralization

(d) All of the above

(xvii) Methanol poisoning is a very serious poisoning, how it can be treated :

(a) Ethanol

(b) Methanol itself

(c) Butanol

(d) Any of the alcohol

(xviii) Opioid toxicity can be treated by using which of the antidote :

(a) Naloxone

(b) Activated charcoal

(c) Emetics

(d) None of the above

(xix) Study of effect of time on ADME is called :

(a) Chronopharmacodynamic

(b) Chronopharmacokinetic

(c) Chronobiology

(d) All of the above

(xx) Circadian cycle is related with :

(a) Cardiac rhythm

(b) Blood pressure

(c) Sleep-wake pattern

(d) None of the above

Part-'B' 2×10=20

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

(i) What do you understand by peptic ulcer? Classify anti-ulcer drugs. Give mechanism of action of proton pump inhibitors.

(ii) Define Antibiotics. Explain the principle of chemo-therapy alongwith various factors which govern the selection of antibiotics in details.

(iii) Explain the poisoning and give detail account on different method of treatment of poisoning with advantages and limitations.

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) Write short note any **two** of the following :

(a) Appetite stimulant with example

(b) Digestant with example

(c) Carminative with example

(ii) Classify antibiotics on the basis of thier mechanism of action.

(iii) Explain the DNA-Gyrase inhibitors as a mechanism of action for antibiotics.

(iv) Explain mechanism of action of alkylating agents in case of cancer therapy.

(v) What is biological drugs?

(vi) Explain mechanism of action of activated charcoal.

(vii) Explain mutation with its types.

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

(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. Each question carries 1 mark (~~200~~ 20×1). 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) The members of D.T.A.B. holds the office for a period of :

(a) 3 years

(b) 2 years

(c) 5 years

(d) 15 years

(ii) Among the following which is used for treating kidney disorders :

(a) Honey

(b) Amla

(c) Alfalfa

(d) Shankh Pushpi

(iii) Which drug have beneficial effects in dietary conditions.

(a) Ginger

(b) Ginseng

(c) Safed Musali

(d) None

(iv) The topics included under 7CH studies are :

(a) Quality

(b) Efficacy

(c) Safety

(d) All

(v) A change in the action of a drug caused by concomitant administration with a food or another drug is called as :

(a) Adulteration

(b) Drug interaction

(c) Supplement drug

(d) Herbal medicines

(vi) Which of the following is used in hair care products :

(a) Pepper

(b) Ephedra

(c) Amla

(d) None

(vii) The term 'IPR' with reference to regulatory requirements of natural products denotes to :

(a) Indian population rate

(b) Indonesia people rhymes

(c) Intellectual property rights

(d) None

(viii) Following is used in skin care product :

(a) Aloevera

(b) Turmeric

(c) Sandalwood

(d) All

(ix) The WHO guidelines for standardization of herbal drugs includes the following examination :

(a) Macroscopic & Microscopic

(b) Extractive values

(c) Ash values

(d) All

(x) A solution of herbs in concentrated sugar is known as :

(a) Phytosome

(b) Herbal Gel

(c) Herbal Syrup

(d) None

(xi) D.T.A.B. deals with organizing meetings of :

(a) Director of Teachers Association Board

(b) Director of Technical Administration Board

(c) Drug Technical Advisory Board

(d) None

(xii) Asavas and Aristas are fermented :

(a) For removal of alcohol

(b) For liberation of alcohol

(c) For removal of water

(d) For liberation of water

(xiii) Lehas are :

(a) Solid preparation

(b) Semisolid preparation

(c) Liquid preparation

(d) Emulsified preparation

(xiv) Churna is defined as :

(a) Fine powder of crude drug/drugs

(b) Fine paste of crude drug/drugs

(c) Coarse powder of crude drug/drugs

(d) None

(xv) Siddha system of medicine is based on :

(a) Scientific principles and pharmacology

(b) Combination of ancient medicinal practices and spiritual disciplines

(c) Good medicinal practices

(d) Treatment of body with parasites

(xvi) Henna contents major category of compounds :

(a) Nephthoquinones

(b) Flavonoids

(c) Alkaloids

(d) Anthraquinones

(xvii) Glycerine is used as ..... in herbal product.

(a) Toner

(b) Moisturizing agent

(c) Sweetening agent

(d) Cleansing agent

(xviii) Siddha systems generated from :

(a) Parsi culture

(b) Islamic culture

(c) Tamil culture

(d) All

(xix) Natural gum used as :

(a) Gelling agent

(b) Thickening agent

(c) Emulsifying agent

(d) All

(xx) Starch and hemicellulose identified by :

(a) Yellow colour with ninhydrine

(b) Blue colour with iodine solution

(c) Violet colour with nicotine solution

(d) None

Part-B

2. Long answer type questions :

(Answer **two** out of three) 2×10=20

(i) Write a note on Indian systems of medicines. Add a note on Ayurvedic formulations.

(ii) Give a detail note on herbal cosmetics and their excipients.

(iii) Write a note on WHO & ICH guidelines for the assessment of herbal drugs.

Part-C

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

(i) Write a note on herbal medicine and herbal drug preparation.

(ii) Give the identification and authentication process of herbal materials.

(iii) What do you understand by organic farming and biopesticides.

(iv) Write a note on health food.

(v) Write notes on any one :

(a) Herbal-drug interaction and classification

(b) Herbal products for cancer disease

(c) Phytosomes

(vi) Define the term Patent, IPR and biopiracy.

(vii) Write notes on any **two** :

(a) ASU

(b) DCC

(c) Schedule-Z of drugs and cosmetic act

(d) Documentation and records in GMP of herbal medicines.

(viii) Write a note on herbal drug industry.

(ix) Write a note on GMP of Indian system of medicine.

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

(PCI Scheme)

(Pharmacy Branch)

BIOPHARMACEUTICS and PHARMACOKINETICS

THEORY (BP604T)

Time Allowed : Three hours

Maximum Marks : 75

Note : *Attemp all the section A, B, C. Carefully read the internal choice of questions.*

Section- 'A'

(Multiple Choice Questions) **20×1=20**

Note : *Attempt all question. Each question carries 1 mark.*

1. Choose the correct answer :

(i) Acetazolamide binds to :

(a) Carbonic hydrase

(b) Haemoglobin

(c) RBC membrane

(d) None

(ii) Which is not patient related factor of drug absorption :

(a) Gastric emptying time

(b) Age

(c) Pharmaceutic ingredients

(d) Intestinal transit time

(iii) Two most important sites for drug elimination are :

(a) Pulmonary and liver

(b) Skin and liver

(c) Kidney and liver

(d) Liver and gastrointestinal tract

(iv) When compartments are joined in series it is called as :

(a) Catenary model

(b) Mammillary model

(c) Both

(d) None

(v) Non linear kinetics is also termed as :

(a) Mixed order

(b) Capacity limited

(c) Dose dependent

(d) All of the above

(vi) Urinary excretion data studies plot is between :

(a) Rate of excretion

(b) Mid point time of urine collection period

(c) Both

(d) None

(vii) As peak plasma concentration :

(a) Absorption rate is higher

(b) Elimination rate is higher

(c) Absorption and elimination rates are equal

(d) Variation

(viii) Reason for low Bioavailability is :

(a) High first pass metabolism

(b) High solubility

(c) High absorption

(d) Intravenous administration

(ix) Which statistical tool is used for Bioequivalence studies?

(a) Null hypothesis

(b) *t* test

(c) ANOVA

(d) None of the above

(x) Which of the following parameter is for pharmacodynamic method of Bioavailability?

(a) Duration of action

(b) Onset of action

(c) Both

(d) Area under the curve

(xi) Following route is the example of passive diffusion :

(a) Intraocular

(b) Vaginal

(c) Subcutaneous

(d) All of the above

(xii) Primary route of excretion of drugs and their metabolites is :

(a) Saliva

(b) Urine

(c) Sweat

(d) Bile

(xiii) Flip Flop kinetics of drugs is associated with :

(a) Method of residuals

(b) Wagner - Nelson method

(c) Loo - Riegelman method

(d) None

(xiv) The area under the plasma level time profile curve represents :

(a) The amount of drug excreted

(b) The amount of drug absorbed

(c) Biological half life

(d) None

(xv) In compartment modelling highly perfused tissues form :

(a) Central compartment

(b) Peripheral compartment

(c) Tissue compartment

(d) None

(xvi) Four major binding sites on human serum are :

(a) Reversible

(b) Irreversible

(c) Stable

(d) Carcinogenic

(xvii) When drug molecules are bound to plasma or tissue proteins they are :

(a) Inactive

(b) Excreted

(c) More potent

(d) Metabolised

(xviii) One compartment model is also known as :

(a) Instantaneous distribution model

(b) Delayed distribution model

(c) Both

(d) None

(xix) Model independent method of analysis is :

(a) One compartment analysis

(b) Two compartment analysis

(c) None compartment analysis

(d) None

(xx) Renal function can be assessed by :

(a) Creatinine clearance

(b) Inuline clearance

(c) Both

(d) None

Section-'B'

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

Note : *Attempt any* ***two*** *questions out of three questions. Each question carries 10 marks.*

2. Define Bioavailability, classify various methods used for the measurement of bioavailability and explain any one method in detail.

3. What are Compartment Models? Explain one compartment open model for intravenous injection.

4. Define Non-linear pharmacokinetics and explain factors causing non linearity giving examples.

Section-'C'

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

Note : *Attempt any* ***seven*** *questions out of nine questions. Each question carries 5 marks.*

5. Explain factors affecting protein drug binding.

6. Discuss non-renal routes of drug excretion of drugs.

7. Explain biotransformation of drugs giving examples.

8. Discuss invitro, invivo correlations.

9. Write note on multiple dosage regimen.

10. Explain bioequivalence studies.

11. Explain any one mechanism of drug absorption through GIT.

12. Define and explain absolute bioavailability.

13. Explain volume of drug distribution.

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

(PCI Scheme)

PHARMACEUTICAL BIOTECHNOLOGY

THEORY (BP605T)

Time Allowed : Three hours

Maximum Marks : 75

Note : *Attempt all sections as directed.*

Section-'A'

(Multiple Choice Questions) 1×20=20

Note : *Attempt all questions. All questions carry equal (1 × 20) marks.*

1. Choose the corcect answer :

(i) The full form of ELISA is ..... .

(a) Enzyme linked immunoassay

(b) Enzyme lived immunoassay

(ii) The full form of MHC is ..... .

(a) Minor Hybridoma complex

(b) Major Histocompatibility complex

(iii) The full form of PCR is ..... .

(a) Polymer change reactor

(b) Polymerase chain reaction

(iv) Change in DNA sequence of an organism/virus is known as :

(a) rRNA

(b) Mutation

(c) None

(v) Types of DNA mutation is :

(a) Base substitution

(b) Deletions

(c) Insertion

(d) All (a), (b) and (c)

(vi) Immunoglobulins are known as antibodies :

(a) False

(b) True

(c) None

(vii) Types of Immunoglobulins are :

(a) IgE, IgG

(b) IgM, IgD

(c) Both (a) and (b)

(d) None

(viii) An overreaction of the Immune system to an antigen is called :

(a) Hypersensitivity

(b) Immunosuppression

(c) None

(ix) Anaphylactic Hypersensitivity is ..... type.

(a) Type-V

(b) Type-III

(c) Type-I

(x) Stimulatory Hypersensitivity is ..... type.

(a) Type-III

(b) Type-I

(c) Type-V

(xi) The term vaccine was orginally derived from the latin world 'Vacca' :

(a) True

(b) False

(c) None

(xii) Pharmaceutical suspension or solutions of a Immunogenic substance intended to Induce active activity is known as :

(a) Prodrug

(b) Vaccine

(c) NDDS

(xiii) Cholera vaccine is a type of ..... vaccine.

(a) Live attenuated

(b) Inactivated

(c) None

(xiv) The short term of monoclonal antibodies is :

(a) MAAB

(b) MABs

(c) None

(xv) Direct gene transfer is the introduction of DNA into plant cell without involvement of any biological agent :

(a) True

(b) False

(c) None

(xvi) Biosensors are enzyme electrode :

(a) True

(b) False

(c) None

(xvii) Enzyme Immobilization methods are :

(a) Adsorption and Covalent bonding

(b) Entrapment and Encapsulation

(c) Both (a) and (b)

(d) (b) only

(xviii) Gene transfer can be done by :

(a) Lipofection

(b) Macro injection

(c) Both (a) and (b)

(xix) The design of fermentation process can be categorized in ..... technology.

(a) Submerged type

(b) Down streaming

(c) Both (a) and (b)

(xx) Antibiotics are produced industrially by fermentation :

(a) True

(b) False

(c) None

Section-'B'

(Long Answer Questions) **2×10=20**

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

2. Write a detail noe on Immunity.

3. Write a detail note on Recombinant DNA Technology.

4. Discuss fermentation methods in detail with reference to Antibiotic production.

Section-'c'

(Short Answer Questions) **7×5=35**

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

5. Write a short note on Hybridoma technology.

6. Discuss Microbial transformation and its application.

7. Define Hypersensitivity and discuss its types.

8. What are Immno globulins? Write down by types of it.

9. Write a short note on Immuno blotting techniques.

10. Define mutation and write down the types of mutation.

11. Write a short note on Enzyme immobilization.

12. Write a short note on Genetic Engineering.

13. Write a short note on '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.