University of Mumbai

T.Y.B. Pharm (sem 6)

Biopharmaceutics and Pharmacokinetics

Duration: 3hrs **Total Marks: 80**

Note: All Questions are Compulsory.
Figures to the right indicate full marks.
Draw diagrams wherever required.
Use of Scientific calculator is permitted

Question no		Marks
Q.I	**Choose the appropriate option for following multiple choice-based questions.**	**20*1**
1	The bioavailability of a drug from various dosage forms decreases in the following order:	1
a	Tablets > Coated Tablets > Sustained Release Products >Enteric Coated Tablets	
b	Tablets > Coated Tablets > Enteric Coated Tablets > Sustained Release Products.	
c	Tablets >Enteric Coated Tablets > Coated Tablets > Sustained Release Products.	
d	Enteric Coated Tablets >Tablets > Coated Tablets > Sustained Release Products.	
2	Amorphous form of Novobiocin is	1
a	10 times more soluble than crystalline form	
b	10 times less soluble than crystalline form	
c	Physical form does not affect solubility	
d	Novobiocin solubility is not affected by its physical form	
3	Clearance is	1
a	Hypothetical volume of body fluids containing drug from which the drug is completely removed in a specified period of time.	
b	Time period in which drug is completely removed from body.	
c	Amount of drug that is completely removed from body in specified period of time.	
d	Fraction of drug that is completely removed from body in specified period of time.	

4	Which statement about the Biopharmaceutical Classification System is true?	1
a	Class II- Low solubility, High permeability, Class III- High solubility, Low permeability	
b	Class II- High solubility, High permeability, Class III- High solubility, High permeability	
c	Class II- Low solubility, Low permeability, Class III- Low solubility, Low permeability	
d	Class II- High solubility, Low permeability, Class III- Low solubility, High permeability	
5	PEG 6000 is deleterious binder for phenobarbitone because	1
a	It forms poorly absorbable complex with drug	
b	It has no binding action	
c	It shows formulation defects	
d	It affects stability	
6	Flow Through Cell is official	1
a	USP Dissolution Test Apparatus II	
b	USP Dissolution Test Apparatus III	
c	USP Dissolution Test Apparatus IV	
d	USP Dissolution Test Apparatus V	
7	Area under curve represents	1
a	Rate of drug absorption	
b	Extent of drug absorption	
c	Duration of action	
d	Therapeutic index	
8	Paracellular transport means	1
a	Passage of drugs across GI membrane	
b	Transport of drugs through the junctions between the GI epithelial cells.	
c	It is not a mode of transport of drugs	
d	The permeation of drugs through temporary openings of two neighbouring epithelial cells into the lumen.	
9	The order of dissolution of different solid forms of drugs is	1
a	Amorphous > Metastable >Stable	
b	Amorphous > Stable > Metastable	
c	Stable > amorphous > Metastable	
d	Metastable > amorphous >Stable	
10	The inhibitory effect of various acids on gastric emptying decreases inn following order	1
a	HCl > acetic > lactic > tartaric > citric	
b	Citric > tartaric > HCl > acetic > lactic	
c	Lactic> HCl > acetic > tartaric > citric	

d	Acetic > HCl > lactic > tartaric > citric	
11	In presence of food, absorption of griseofulvin is	1
a	Delayed	
b	Decreased	
c	Increased	
d	Unaffected	
12	Which of the following statement is true?	1
a	Drugs with high protein binding have low apparent volume of distribution	
b	Drugs with low protein binding have low apparent volume of distribution	
c	Drugs with high protein binding have high apparent volume of distribution	
d	Drugs with low protein binding have low apparent volume of distribution	
13	Which of the following statements is true?	1
a	Rate of excretion = Rate of filtration - Rate of Secretion - Rate of reabsorption	
b	Rate of excretion = Rate of filtration -Rate of Secretion + Rate of reabsorption	
c	Rate of excretion = Rate of filtration +Rate of Secretion - Rate of reabsorption	
d	Rate of excretion = Rate of filtration +Rate of Secretion + Rate of reabsorption	
14	As per mammillary model, the number of rate constants that will appear in a particular compartment model (for intravenous administration) is given by	1
a	R= 2n – 1	
b	R= 2n	
c	R= 2n +1	
d	R= 2n -2	
15	Model independent approach is also termed as	1
a	Non-compartmental approach	
b	Compartment model	
c	Physiological model	
d	Distributed parameter model	
16	Select the equation that gives the rate of drug dissolution from a tablet	1
a	Fick’s law	
b	Handerson Hasselbatch equation	
c	Noyes Whitney equation	
d	Michelis Menten equation	
17	Favourable pH range for absorption through small intestine is	1
a	1 to 2.5	
b	4 to 4.5	

c	5 to 7.5	
d	10- 12.5	
18	Disposition of a drug following one compartment kinetics, IV bolus administration is,	1
a	$X = X_o e^{-K_E T}$	
b	$X = X_o e^{-Cl.T}$	
c	$X = X\ e^{-K_E T}$	
d	$X = X\ e^{-CL.T}$	
19	Extraction ratio is related to oral availability of drug by following expression:	1
a	F= 1 – ER	
b	ER= 1- F	
c	F= 100- ER	
d	ER= 100- F	
20	Most abundant abundant plasma protein with large drug binding capacity is	1
a	Human serum albumin (HSA)	
b	1-Acid Glycoprotein	
c	Orosomucoid	
d	Lipoproteins	
Q.IIa	Attempt any **one**	12
1a	Describe method of residuals for determination of absorption rate constant.	8
1b	Describe the assumptions of one compartment open model.	4
2a	After an intravenous bolus injection of 250 mg of a drug following one compartment kinetics. The plasma concentration time profile is represented by – $C = 160e^{-0.17t}$ Calculate a) Elimination half-life and AUC. b) Volume of distribution and clearance. c) Plasma concentration after 2 hours. d) Amount eliminated after 5 hours.	 2 2 2 2
2b	Define clearance. Derive mathematical expression for the total body clearance.	4
Q.IIb	Attempt any **four**	12x4
3a	Explain the physicochemical factors influencing the distribution of drugs.	8
3b	Describe absorption processes that may cause non-linearity in pharmacokinetics.	4
4a	Explain the pH Partition Hypothesis in drug absorption in GIT.	8
4b	Describe transcellular route of drug absorption.	4

5a	Discuss the effect of distribution and binding characteristics of the drug, drug interactions on renal excretion of drugs.	
5b	What are various levels in *in vitro-in vivo* correlations?	4
6a	What are various approaches aimed at enhancing bioavailability of drugs from its dosage form? Explain any four**.**	8
6b	Define apparent volume of distribution. Why cannot the volume of distribution of a drug have a true physiologic meaning?	4
7a	Draw a typical plasma drug concentration- time profile. Label and define all pharmacokinetic and pharmacodynamics parameters.	8
7b	Describe the characteristics of microsomal enzymes.	4

Subject: Pharmaceutical Biotechnology
Class: Third Year B.Pharm. (Sem-VI) R-2019

Maximum Marks: 80 **Duration: 3 Hrs**

N.B.: 1. All questions are compulsory
2. Figures to right indicate full marks

Q. I Choose the appropriate option for following multiple choice based questions. 20M

1. Which method is the easiest method of enzyme immobilization

a) Adsorption

b) Covalent bonding

c) Microencapsulation

d) Entrapment

2. Which is the correct flow chart of a biosensor

a) Bioreceptor-Biosample-Transducer-Display

b) Biosample-Bioreceptor-Transducer-Display

c) Transducer-Biosample-Bioreceptor-Display

d) Display-Biosample-Bioreceptor-Transducer

3. Which of the following is not obtained using Biotechnology

a) Insulin

b) Interferon

c) Golden rice

d) Diclofenac

4. Enzyme immobilization is done because

a) It protects the enzyme

b) It changes the action of the enzyme

c) It reduces the rate of the reaction

d) It helps the enzyme to mutate

5. Biosensors are developed for

a) Detection of an analyte

b) Increase the quantity of an analyte

c) Increase the rate of an enzymatic reaction

d) Mutating a gene

6. Restriction enzymes are called as

a) Molecular glue

b) Molecular scissors

c) Molecular degraders

d) Molecular blockers

7. Cloning Vectors are used in r DNA experiments to

a) Know the sequence of amino acids

b) Carry the gene into the host

c) Mutate the gene at a specific location

d) To know the sequence of the target gene

8. Plasmid vectors are obtained from

a) Plants

b) animals

c) bacteria

d) Algae

9. Restriction endonuclease enzyme

a) can recognize specific base sequence in a DNA

b) can join two genes

c) can join two RNA sequences

d) Can join two peptides

10. _____ works as an antigen detector in cell mediated immunity.

a) Phagocytes

b) B-Cells

c) Receptors

d) MHC molecules

11. Sera are_____ types of Immunity

a) Naturally acquired active

b) Naturally acquired passive

c) Artificially acquired active

d) Artificially stimulated passive

12. Which Antibody is present in high concentration in serum

a) IgG

b) IgA

c) IgM

d) IgD

13. _____ is the Antigen binding site of Antibody.

a) N terminus

b) C terminus

c) Disulphide bonds

d) H terminus

14. _____ is not an example of an anticoagulant used in blood collection.

a) Heparin

b) Citrates

c) Tartrate

d) Disodium EDTA

15. In the beads on a string model, the bead is made up of _____

a) 6 histone proteins

b) 8 histone proteins

c) 6 histone proteins and DNA

d) 8 histone proteins and DNA

16. When viral genome integrates into the bacterial genome it is known as _____

a) temperate phage

b) prophage

c) bacteriophage

d) episome

17. The _____ biotechnology involves the use of microbial biotransformation for generating products of interest.

a) White

b) Green

c) Blue

d) Purple

18. Aeration in fermenter is achieved by

a) Agitator

b) Impeller

c) Sparger

d) Baffles

19. Microorganism used for the production of Vitamin B12 by fermentation method is

a) Penicillium chrysogenum

b) Aspergillus niger

c) Pseudomonas denitrificans

d) Saccharomyces cerevisiae

20. Microorganism used for the production of Citric acid by fermentation method is

a) Penicillium chrysogenum

b) Aspergillus niger

c) Pseudomonas denitrificans

d) Saccharomyces cerevisiae

Q. II A) Answer any one question. 12M

a) Explain any two methods of enzyme immobilization with diagrams (06)

b) Describe in detail the parts of a biosensor (06)

OR

a) Write about restriction enzymes in detail (06)

b) Enlist any three cloning vectors and explain plasmid cloning vector in detail (06)

Q. II B) Answer any four questions. 48M

1. a) Draw and explain the diagram of MHC molecules and comment on its function. (06)

b) Define Hypersensitivity reaction, enlist the types and explain any one in detail (06)

2. a) Explain the principle of ELISA in detail and enlist its applications (06)

b) Define Mutation and write a short note on Induced mutation. (06)

3. a) Describe gene therapy in detail and explain its applications (06)

b) Write about DNA fingerprinting in detail (06)

4. a) Explain the methods of Fermentation and Comment on the Aeration process in Fermenter. (06)

b) What do you mean by Plasma Substitutes? Enlist their properties. (06)

5. a) Define Sera. Explain the process of production of Diphtheria antitoxin in detail. (06)

b) Elaborate Hybridoma technology and enlist the applications of Monoclonal antibodies. (06)

University of Mumbai
SEMESTER THEORY EXAMINATION
May-2022
Subject: Herbal Drug Technology
Subject code: BP603T
Third Year B. Pharm, Sem. VI, R-CBCS-2019

Q.1 Solve the following. **20M**

1. Herbal Crude drug means _____part of plant.
    a. Stem
    b. Leaves
    c. Fruit
    d. Any
2. The process includes removing dirt, discarding damaged part, trimming and remove seed from fruits is known as_____.
    a. Garbling
    b. Bleaching
    c. Drying
    d. Washing
3. _____ is a liquid obtained by boiling the herbal materials with water.
    a. Infusion
    b. Decoction
    c. Tinctures
    d. Powder extract
4. _____ is an undesired plant, it can produce losses more than any other pests or disease.
    a. Fungi
    b. Viruses
    c. Weeds
    d. Azatobacter
5. Leha is _____dosage Form
    a. Solid
    b. Liquid
    c. Powder
    d. Semisolid
6. Aflatoxin is one type of _____ .
    a. Fungus
    b. Virus
    c. bacteria
    d. Algae
7. Which should be not patented from following
    a. Traditional knowledge of plant
    b. Isolation of phytoconstituents

c. New uses of Phytoconstituents
d. New variety of plants

8. Name the institute which has filled reexamination of patent for curcumin.
    a. CSIR
    b. RRL
    c. AYUSH
    d. ICMR
9. Which regulatory body as per Drug & cosmetic act for ASU drugs under section 33 D?
    a. DCC ASU
    b. DTAB ASU
    c. CSIR
    d. ICMR
10. Which Schedule is proposed for clinical study of ASU drugs?
    a. Schedule Z
    b. Schedule T
    c. Schedule M
    d. Schedule Y
11. Name the machinary which is specifically required for Bhasma preparation.
    a. Muffle furnace
    b. Grinder
    c. Ball mill
    d. Disintigrator
12. Name the research institite which is funded by Government
    a. RRL Jammu
    b. Yucca
    c. Dabur
    d. Charak
13. Following drug can be used for Diabetes.
    a. Momordica
    b. Honey
    c. Ashwagandha
    d. Spirulina
14. Following is sulphur containing Nutraceutical drug
    a. Garlic
    b. Ashwagandha
    c. Chicory
    d. Spirulina
15. Garlic shows interaction with
    a. Chloroxazone
    b. PPIs
    c. Paracetamol
    d. Anti-cancer
16. Benzyl benzamide is found in
    a. Neem

b. Meswak
c. Clove
d. Reetha

17. Skin care constituent of Almond oil is
    a. Oleic acid
    b. Caprylic acid
    c. Acemannan
    d. Citric acid
18. Color of Henna is due to
    a. Plumbagin
    b. Crocin
    c. Aloin
    d. Lawsone
19. Linalool is used as
    a. Bleaching agent
    b. Perfuming agent
    c. Colorant
    d. Antiseptic
20. Which is NOT the method of phytosome preparation?
    a. Solvent evaporation
    b. Cosolvency
    c. Salting out
    d. Extrusion

Q.II .Answer any one of the following: **12M**

A. i. Define herb. Write about modified methods of authentication. **6M**
ii. Write a note on herbal cosmetics used in hair care. **6M**

B. i. Write a note on General aspects, Market, growth, scope of Nutraceuticals. **6M**
ii. Write down objective of WHO guide line and explain any two parameters in detail for safety of herbal drugs. **6M**

Q.III Answer any four **48M**

A. i. What will be the significance of organic farming over conventional farming in India . **6M**
ii. Explain the term of biopiracy and bioprospecting and discuss case study of Neem . **6M**

B. i. Write a note on Garlic & Ginger as health food. **6M**
ii. Discuss current & future prospects of herbal drug industry and give the name of herbal industry involve in isolation of phytoconstituents**.** **6M**

C. i. Write about classification mechanism and uses of any one biopesticide. **6M**
ii Write a note on Herbal colorants & sweeteners. **6M**

D. i. Write a note on herb drug interaction of Pepper & Ginseng. **6M**
ii. Give the full form of ASU DTAB and ASU DCC and explain any one in detail. **6M**

E. i. Define phytosome. Write a note on preparation and evaluation of phytosome . **6M**
ii. Outline the componant of shedule T and its objective. **6M**

Subject: Medicinal Chemistry III

Year and Sem: Third Year B.Pharm Semester VI

Duration: (3 hours)

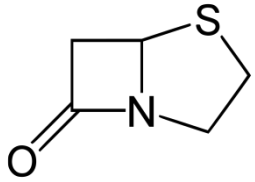
Total Marks: 80

N.B: 1. All questions are Compulsory.

2. Figures to right indicate full marks.

Q I Answer the following Multiple Choice Questions. Select the most appropriate option for each statement. (20 M)

1. Identify the following structure



a) β-lactam
b) Penam
c) Thiazolidine-5-one
d) Thiazepine-5-one

2. To obtain penicillinase resistant penicillins, strategy used is introduction of _____ on acyl amino side chain
a) bulky groups with electron withdrawing substitutents
b) bulky groups with electron donating substitutents
c) hydrophilic group like amino group
d) hydrophobic group like amino group

3. Example of a β-lactamase inhibitor is
a) Cloxacillin
b) Methicillin
c) Dicloxacillin
d) Clavulanic acid

4. In tetracycline, the pka value of conjugated trione system is in the range of
a) 7.2-7.8
b) 9.1-9.7
c) 2.8-3.3
d) 6.4-6.8

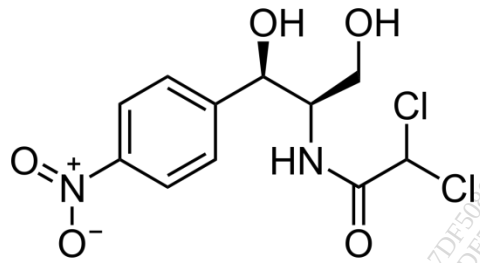
5. Starting materials for synthesis of Pamaquine are
a) 4-methoxy 2-nitrobenzenamine and glycerol
b) 3-chloroaniline and diethyl ethoxymethylenemalonate
c) 2,4-dichloro-5-fluoro-benzoyl chloride and diethyl malonate
d) 2-(4-chlorabenzoyl)-benzoic acid and ethylene diamine

6. Pivampicillin is example of
a) Bipartite prodrug

b) Tripartite prodrug
c) Bioprecursor
d) Mutual prodrug

7. Azithromycin consists of
a) 14 membered macrocyclic lactone ring
b) 14 membered macrocyclic lactam ring
c) 15 membered macrocyclic lactone ring
d) 15 membered macrocyclic lactam ring

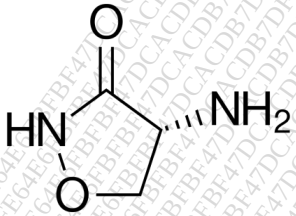
8. Identify the following drug



a) Chloramphenicol
b) Cefotaxime
c) Clindamycin
d) Clarithromycin

9. Ethambutol is marketed for antitubercular activity as
a) S, R (+) enantiomer
b) R, S (+) enantiomer
c) S, S (+) enantiomer
d) R, R (-) enantiomer

10. Identify the following drug



a) cycloserine
b) clindamycin
c) chloramphenicol
d) Capreomycin

11. Gatifloxacin exhibits its antibacterial activity by binding to the
a) DNA polymerase
b) DNA dependent RNA polymerase
c) 50S ribosomal subunit
d) DNA gyrase and Topoisomerase

12. Purine dideoxynucleoside analog of inosine is
a) Zalcitabine

b) Didanosine
c) Lamivudine
d) Idoxuridine

13. Ribavirin consists of following heterocyclic ring
a) 1,2,4-triazole
b) 1,2,3-triazole
c) Tetrazole
d) Imidazole

14. Itraconazole is a
a) 1,2,4-Triazole antifungal agent
b) Imidazole antifungal agent
c) Benzimidazole antifungal agent
d) 1,2,3-Triazole antifungal agent

15. Drug of choice for treatment of river blindness is
a) Ivermectin
b) Praziquantel
c) Eflornithine
d) Diethylcarbamazine

16. Prontosil on metabolic activation leads to formation of
a) Sulfacetamide
b) Sulfanilamide
c) Sulfadiazine
d) Sulfapyridine

17. Starting material and reagent used for the synthesis of Dapsone are
a) 1-chloro-4-nitro benzene and sodium sulfite
b) 2-nitro aniline and sodium sulfite
c) 1-chloro-4-nitro benzene and sodium sulfide
d) 2-nitro aniline and sodium sulfide

18. Electronic parameter used in QSAR is
a) Hammett constant
b) Taft constant
c) Dipole moment
d) Verloop parameter

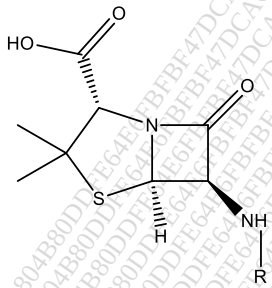
19. Structure Based Drug Design approach used in drug design is
a) 2D-QSAR
b) Molecular Docking
c) Pharmacophore modeling
d) 3D-QSAR

20. Wang resin used in combinatorial chemistry has the following linker
a) p-benzyloxybenzyl chloride

b) p-benzyloxybenzyl alcohol
c) p-benzyloxybenzoic acid
d) p-benzyloxybenzamide

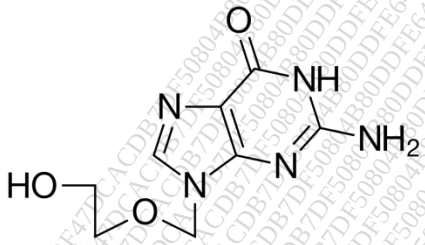
Q.II Attempt any ONE question from following questions. 12M

Q.1. A. Answer the following questions with reference to the structure of the compound given below **(4M)**

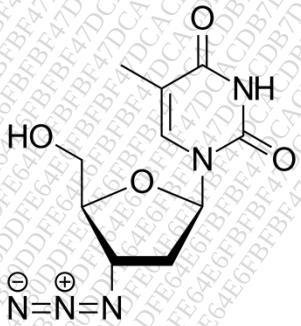


a) Identify the compound when R=H. How can it be synthesized using Penicillin G?
b) How many stereoisomers are possible for the compound?
c) Name the scaffold.
d) Give examples of two broad spectrum antibiotics containing the above scaffold.

B. With respect to the structures below, answer the following questions: **(4M)**



(i)

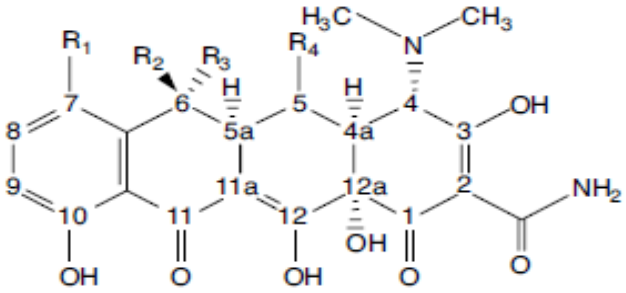


(ii)

a) Identify the drug (i) and its target.
b) Identify the drug (ii) and its target.
c) Name the drug which is hydroxymethyl derivative of structure (i)
d) Explain the metabolic activation of structure (ii).

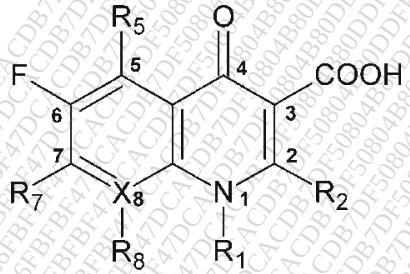
C. Answer the following questions **(4M)**
a) Give the reaction for metabolism of Proguanil? Comment on its activity.
b) Draw the structure of methyl ether of dihydroartemisinin. Comment on its solubility.

Q.2. A. Answer the following questions with reference to the structure given below (4M)



a) Give the generic name and structure of any drug containing above scaffold.
b) Replacement of amide group with nitrile or aldehyde group leads to _____ in activity of resulting compound.
c) Presence of hydroxyl group at position 6 leads to intramolecular nuclear reaction under alkaline condition to give _____ which is active/ inactive.
d) Give the reaction for hydrochloride salt formation of the compound.

B. With reference to the following scaffold, answer the following questions: (4 Marks)



a) Name the above scaffold, identify the target and mention the use.
b) Which is the predominant toxicity observed with presence of fluorine atoms at position 6 and 8? Name the drug.
c) Draw the structure of fluoroquinolone with N-cyclopropyl substitutent.
d) Presence of small alkyl group at position 1 dictates the spectrum of activity. State whether the statement is true or false. Justify.

C. Draw the structure and explain the stereochemistry of cinchona alkaloid useful as antimalarial agent. Explain its Mechanism of action. **(4M)**

Q. III Attempt any FOUR questions from following five questions. 48M

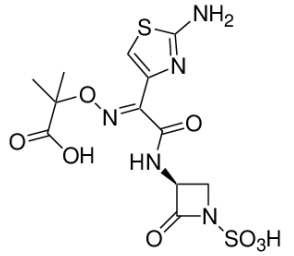
Q.1.A. Match the following: (4M)

Generic Name	Chemical Class	Mechanism of Action
Amphotericin	Allylamine	Lanosterol 14α-demethylase inhibitor
Fluconazole	Polyene antibiotic	Squalene epoxidase inhibitor
Naftifine	Naurally occurring spiro compound	Metabolic spindle poison
Griseofulvin	Azole antifungal	Binds to cell membrane ergosterol

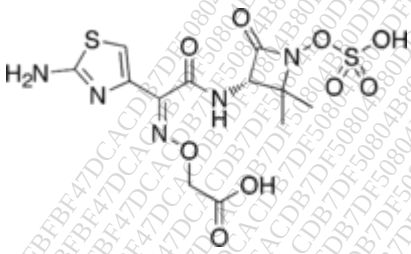
B. Explain briefly the structural features of macrolide antibiotics. What structural

modifications are made in macrolides to increase the acid stability? Give examples. **(4M)**

C. With respect to the following structures answer the following questions. **(4M)**



(i)

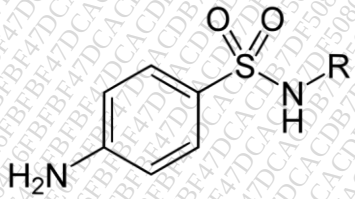


(ii)

a) Identify the chemical class of both the drugs.
b) Identify the generic names of the drugs. (i) and (ii)
c) Draw the structure of salt form of structure **(i)**
d) Comment on the spectrum of activity of the drugs (i) and (ii).

Q.2.A. Give the synthetic scheme for synthesis of Chloroquine. **(4M)**

B. Answer the following questions with reference to the following scaffold. **(4M)**



a) Name the class and use of drugs containing the above scaffold.
b) Comment on the pka and nature of the drugs.
c) Name the target of these drugs.
d) Give the structure of any prodrug belonging to the above class.

C. Justify the following statements. (Any 2) **(4M)**

a) Antitubercular drug, para amino salicylic acid increases the levels of Isoniazid on co-administration.
b) Pyrazinamide is a prodrug.
c) Antitubercular drugs are given in combination.

Q.3. A. Answer the following questions **(4M)**

(a) Explain the metabolism of Albendazole and identify the active metabolite.

(b) Explain the mechanism of action of Praziquantel.

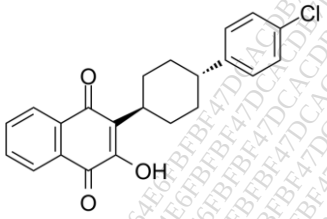
B. Give the synthetic scheme for the synthesis of Ciprofloxacin along with reagents and reaction conditions. **(4M)**

C. Classify prodrugs and explain two applications of prodrugs with suitable examples.

(4M)

Q.4. A. Write a short note on importance of (i) partition coefficient parameter and (ii) electronic parameter in QSAR studies. **(4M)**

B. Identify the following drug, its chemical class and explain the MOA of the drug **(4M)**



C. Explain the structural features of aminoglycosides. **(4M)**

Q.5. A. Write a short note on antiretroviral drug therapy. **(4M)**

B. Write a short note on solid phase synthesis in combinatorial chemistry. **(4M)**

C. With reference to the quinoline derivatives used as antimalarial drugs **(4M)**

a) Draw the structure of the first 8-amino quinoline introduced as antimalarial agent
b) Give example of drug of quinoline methanol class.
c) Mention the chemical class of Quinacrine.
d) For 4-amino quinolines, comment on the nature of substituent at 7^{th} position required for antimalarial activity.

QP 1

Ay 2021-22 T.Y. B. Pharm Sem VI Pharmacology III End Semester Exam

Date: 10-05-2022 Total Marks: (80)

QI. Choose the **ONE** best answer **20 Marks**

1**.** A 5-lipoxygenase (5-LOX) inhibitor used for the treatment of asthma is:

A) Zileuton

B) Montelukast

C) Sodium Cromoglycate

D) Ipratropium bromide

2. The drug oxymetazoline functions by:

A) Dialating the blood vessels on the human nasal mucosa

B) Increasing nasal mucosal blood flow, edema, and airflow resistance

C) Activation of α_1-adrenoceptors in the arterioles of the nasal mucosa

D) Vasoconstricting the respiratory microvasculature on the human nasal mucosa

3. The drug fenfluramine acts by:

A) Decreasing serotonin levels

B) Releasing serotonin by disrupting its vesicular storage

C) Increasing reuptake of serotonin

D) Stimulating the hypothalamus to release norepinephrine

4. Cisapride enhances the gastrointestinal motility by:

A) Activating muscarinic M3 receptor

B) Blocking dopamine D2 receptor

C) Activating serotonin 5-HT4 receptor

D) Inhibiting adrenergic beta-2 receptor

5. What is meant by antibiotic resistance?

A) It means the bacteria have developed resistance for the antibiotic

B) It means our body has become resistant to the antibiotic

C) It means that the antibiotic concentration has to be elevated

D) It means that our body has become resistant to the antibiotic's side effects

6. A typical side effect of penicillins is:

A) Cardiotoxicity

B) Neurotoxicity

C) Ototoxicity

D) Anaphylactic shock

7. Cotrimoxazole is a combination of:

A) Sulphadoxine + Trimethoprim

B) Sulphamethoxazole + Pyrimethamine

C) Sulphamethoxazole + Trimethoprim

D) Sulphamethoxazole + Ictaprim

8. Alteration in DNA gyrase of bacteria will lead to:

A) Increased activity of fluoroquinolones

B) Decreased absorption of fluoroquinolones

C) Resistance to fluoroquinolones

D)Toxicity to fluoroquinolones

9. The antimalarial drug chloroquine acts by:

A) Inhibiting heme polymerase

B) Inhibiting DNA-dependant RNA polymerase

C) Activating heme polymerase

D) Inhibiting schizonts of the parasite

10. The anthelmintic drug piperazine:

A) Inhibits tubulin polymerization

B) Acts as a GABA agonist to paralyze the worms

C) Inhibits glucose uptake

D) Uncouples oxidative phosphorylation

11. A phenazine dye which is antileprotic and anti-inflammatory is:

A) Dapsone

B) Ethionamide

C) Clofazimine

D) Rifamycin

12. A side effect of ethambutol is

A) Neurotoxicity

B) Nausea, vomiting and diarrhea

C) Hypersensitivity and urticarial

D) Loss of color vision due to optic neuritis

13. Daunorubicin is:

A) An inhibitor of cell reproduction by binding irreversibly with the nucleic acids (DNA)

B) A DNA intercalating agent that block the synthesis of DNA and RNA

C) An inhibitor of dihydrofolate reductase which is required for thymidine and purine synthesis

D) An inhibitor of thymidylate synthetase and prevents the synthesis of thymidine

14. An antibiotic used in resistant and mixed urinary tract infections for chronic suppressive therapy is:

A) Nitrofurantoin

B) Ampicillin

C) Tetracycline

D) Clindamycin

15. The immunosuppressant drug sirolimus inhibits the enzyme:

A) Calcineurin

B) m-TOR

C) TNF alpha

D) IL-2

16. An anthelmintic which restores depressed immune function of lymphocytes and macrophages is:

A) Tacrolimus

B) Levamisole

C) Thalidomide

D) Cyclophosphamide

17. Which of the following are characteristic of acute toxicity?

A) Slowly occurring

B) Sudden in onset

C) Slowly changing

D) Persistent over months

18. Mutagenicity refers to:

A) The ability or tendency of some substances to produce cancer

B) The ability of a substance to cause toxicity on DNA/genetic material of a cell

C) The ability of a substance to cause severe fetal damage by crossing the placenta

D) The induction of permanent transmissible changes in the genetic material of cells

19. Which of the following compounds inhibit AchE?

A) Organophosphates

B) Barbiturates

C) Pyrethroids

D) Ferric chloride

20. The risk of asthma is highest in the early morning due to:

A) Highest concentration of cortisol in the morning

B) Nocturnal vagus nerve hyperactivity

C) Small decrease in bronchi diameter in the day

D) Dominance of beta adrenergic activity

Q. II. Answer any **ONE** of the following: **12 Marks**

1) Classify antifungal agents with examples. Write briefly on azole antifungals with their mechanism of action, adverse effects and clinical uses

2) Classify antiasthmatic drugs with examples. Explain in details various bronchodilator drugs used for asthma pharmacotherapy

Q. III. Answer any **FOUR** of the following: **48 marks**

1) Classify drugs used in the treatment of constipation with examples. Discuss briefly the pharmacology of osmotic purgatives and diphenylmethanes in detail including their mechanisms of action

2) Write a note on the mechanism of action of beta lactam antibiotics. How do bacteria acquire resistance to beta lactam antibiotics? Classify penicillins with examples.

3) Classify antiretroviral drugs with examples from each category. Discuss mechanism of action and adverse effects of protease inhibitors.

4) Classify anticancer drugs with examples. Give a detailed account of antimetabolites as anticancer drugs

5) What is chronotherapy? Discuss about chronotherapy for peptic ulcers and diabetes mellitus

Subject: Pharmaceutical Quality Assurance (BP 606T)
Year and Sem: T. Y. B. Pharm. (Sem VI)
Duration: 3 Hrs **Total marks: 80**

N.B.: 1. All questions are compulsory
2. Figures to right indicate full marks

Q. I Choose appropriate option for following multiple choice-based questions. 20

1 Bracketing design for stability testing includes _____.
   a. Testing samples of all design factors at all time points
   b. Testing samples of extreme design factors at all time points
   c. Testing samples of all design factors at half time points
   d. Testing samples of extreme design factors at half time points

2 The dispensing of raw materials from Stores must follow the principle of _____.
   a. First Out Then In
   b. Fast Out Fast In
   c. Fast In Fast Out
   d. First In First Out

3 Investigation deviations in the manufacturing process is the responsibility of _____ department.
   a. Stores
   b. Quality Assurance
   c. Production
   d. Quality Control

4 Neutral glass is also called as _____.
   a. Type I glass
   b. Type II glass
   c. Type III glass
   d. NP glass

5 NABL is an autonomous body established under the aegis of _____.
   a. Department of Health & allied sciences
   b. Department of Science & Technology
   c. Department of Food & Drug testing
   d. Department of Pharmaceutical Sciences

6 Approval of release of finished product is the responsibility of ____.
   a. Head of Stores
   b. Head of Quality Control
   c. Head of Quality Assurance
   d. Head of Production

7 As per USFDA GLP guidelines, Subpart F is _____.

a. Facilities
b. Equipment
c. Records and Reports
d. Test and Control Articles

8 Tear strength measures the _____.

a. Energy required to make puncture in the paper
b. Force that a paper withstands before breaking
c. Degree of resistance offered by paper when it is folded
d. Force required to tear an initial cut in the paper

9 Microbial contamination of non-injectable product results in _____.

a. Class I recall
b. Class II recall
c. Class III recall
d. No recall

10 _____ is a subset of Quality Assurance.

a. Quality Control
b. Quality Management System
c. Quality Policy
d. Quality Framework

11 The following is verified during operational qualification of an equipment.

a. Equipment is installed and calibrated
b. Equipment operates consistently within operational limit
c. Equipment shows satisfactory performance over long period.
d. Equipment is installed and connected to utilities

12 Changes in an approved protocol for conduct of nonclinical laboratory study are signed by _____.

a. Sponsor
b. Scientist
c. Quality Assurance Personnel
d. Study Director

13 _____ is the closeness of agreement between a series of measurement obtained from multiple sampling of same homogenous sample.

a. Accuracy
b. Precision
c. LOD
d. Linearity

14 Service bay is maintained at _____.

a. Class 10
b. Class 20
c. Class 50
d. Class 1000

15 Self sealability test is intended for _____.

a. Rubber closures of single dose container
b. Rubber closures of multi dose containers
c. Plastic closures of single dose containers
d. Plastic closures of multidose containers

16 The SOP's are reviewed after _____.

a. One year
b. Two years
c. Three years
d. Five years

17 In the qualification of UV-visible spectrophotometer, photometric accuracy is determined using _____.

a. Potassium dichromate
b. Holmium perchlorate
c. Sodium iodide
d. Potassium chloride

18 The principles of GLP applies to _____.

a. Conduct of clinical studies
b. Conduct of nonclinical studies
c. Conduct of analytical studies
d. Conduct of microbiological studies

19 Airlock doors should be equipped with systems that_____.

a. Prevent simultaneous opening of both the doors
b. Allow simultaneous opening of both the doors
c. Prevent simultaneous opening of doors by unauthorized persons
d. Allow simultaneous opening of both the doors by authorized persons

20 Personal records are records of _____ in an organization.

a. Employer
b. Employees
c. Visitors
d. Auditors

Q. II Answer any one question. (Any 1) **12**

1	a.	Enlist the participants of ICH. Write in brief about photostability testing of drug products.	**6**
	b.	Enlist the quality control tests for glass containers. Discuss in brief the hydrolytic resistance test.	**6**
2	a.	What is Quality management System? Give the role of Quality Control and Quality Assurance departments in a Pharmaceutical Industry	**6**
	b.	Define SOP. Explain the general format of SOP and its implementation.	**6**

Q. III Answer any four questions (Any four) **48**

3	a.	Define validation. Explain in brief the types of process validation.	**6**
	b.	Explain in brief the objectives and elements of material management.	**6**
4	a.	Explain the design and construction of building for a pharmaceutical manufacturing unit.	**6**
	b.	Discuss the process of equipment selection and its maintenance.	**6**
5	a.	Define GLP. Discuss in brief the protocol for conduct of nonclinical study.	**6**
	b.	Discuss the quality control tests for plastic containers.	**6**
6	a.	What is recall? Explain in detail the process for handling of complaints.	**6**
	b.	State the purpose of distribution records. Write a note on Master Formula Record.	**6**
7	a.	Discuss the key elements of QbD. What is ISO? Discuss its benefits and the process of ISO registration.	**6**
	b.	What is NABL accreditation and its benefits? State the role of TQM in pharmaceutical industry and discuss its philosophy.	**6**