Paper / Subject Code: 87615 / Pharmaceutical Biotechnology

Duration: 3 Hrs **Maximum Marks: 75**

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

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

1. Which of the following best defines pharmaceutical biotechnology?

a) The study of plants used in traditional medicine

b) The application of biological systems and organisms to the development of drugs

c) The study of chemical synthesis of pharmaceuticals

d) The development of medical devices for drug delivery

2. Which of the following microorganisms is commonly used for the industrial production of catalase?

a) Bacillus subtilis

b) Candida albicans

c) Streptococcus pyogenes

d) Staphylococcus aureus

3. What advantage does enzyme immobilization offer in industrial biocatalysis?

a) Decreased production costs

b) Increased reaction rates

c) Greater substrate specificity

d) Reduced enzyme activity

4. Which of the following is an example of an ethical concern in pharmaceutical biotechnology related to access to healthcare?

a) Patent infringement

b) Animal testing

c) Informed consent

d) Drug pricing and affordability

5. Which of the following regions of an antibody molecule binds specifically to an antigen?

a) Variable region

b) Constant region

c) Fc region

d) Fa region

6. Which of the following features is essential for a plasmid vector used in rDNA technology?

a) Resistance to antibody

b) Ability to self-replicate in host cells

c) Large size

d) Ability to cut DNA at specific sequences

7. Which expression system is commonly used for the production of recombinant proteins in bacteria such as Escherichia coli?

a) Yeast expression system

b) Mammalian expression system

c) Bacterial expression system

d) Plant expression system

8. In RFLP analysis, what is the purpose of running the digested DNA fragments on an agarose gel?

a) To amplify DNA fragments

b) To visualize DNA fragments based on size differences

c) To synthesize DNA probes

d) To sequence DNA fragments

9. In Sanger sequencing, what is used to terminate DNA synthesis at specific bases?

a) Radioactive labels

b) Fluorescent dyes

c) DNA ligase

d) Dideoxynucleotides (ddNTPs)

10. What is the purpose of ligation in rDNA technology?

a) To isolate DNA from its source organism

b) To join DNA fragments together with a vector

c) To transform DNA into host cells

d) To express proteins from recombinant DNA

11. What is the purpose of the extension step in PCR?

a) To separate the DNA strands

b) To anneal primers to the template DNA

c) To amplify the DNA sequence

d) To extend the primers by adding nucleotides

12. Which class of antibodies is the most abundant in serum and is involved in secondary immune responses?

a) IgA

b) IgD

c) IgG

d) IgE

13. MHC class I molecules are composed of how many chains?

a) One α chain

b) One β chain

c) One α chain and one β chain

d) Two α chains and two β chains

14. Vaccines that combine a weak antigen with a strong antigen to enhance the immune response are called:

a) Live attenuated vaccines

b) Inactivated vaccines

c) Recombinant vector vaccines

d) Conjugate vaccines

15. What does vaccine stability refer to?

a) The ability of a vaccine to cause an immune response

b) The ability of a vaccine to maintain its potency over time and under various conditions

c) The ability of a vaccine to be easily administered

d) The ability of a vaccine to prevent all infectious diseases

16. What is the term for the process of selecting a hybridoma cells that produce a specific monoclonal antibody?

a) Cloning

b) Fusion

c) Screening

d) Transformation

17. Which of the following is a characteristic feature of eukaryotic gene expression regulation but not prokaryotic?

a) Transcription and translation occur simultaneously.

b) Operons regulate gene expression.

c) mRNA undergoes post-transcriptional modifications.

d) DNA is organized into circular chromosomes.

18. Transduction involves the transfer of bacterial DNA using:

a) Pili

b) Bacteriophages

c) Plasmids

d) Capsules

19. In which type of fermentor is the microbial culture immobilized on the surface of solid particles or within a porous matrix?

a) Stirred tank fermentor

b) Air-lift fermentor

c) Packed bed fermentor

d) Fluidized bed fermentor

20. Which device is used to measure the level of agitation in a fermentor?

a) Turbidity sensor

b) pH electrode

c) Dissolved oxygen probe

d) Tachometer

Q. II A) Answer any two of the following (Any TWO) **20M**

a) Define enzyme immobilization, enlist the methods of enzyme immobilization with diagrams. (10)
Describe the composition and working of Penicillin biosensor.

b) Define vectors, enlist them and write the ideal characteristics of vectors used in rDNA technology. (10)
Write a note on Transgenic animals and Transgenic Plants with examples.

c) Explain the method of preparation of diphtheria toxoid. (10)
Define Hypersensitivity reactions, enlist them and explain any one in details.

Q. III Answer any seven of the following (Any SEVEN) **35M**

a) Describe the methods of Protein Engineering (05)

b) What is gene therapy? Explain the same for SCID. (05)

c) Differentiate between Humoral and Cellular Immunity. (05)

d) Enlist the blotting techniques, explain the one used for protein. (05)

e) Explain Microbial Biotransformation, write its applications in pharmaceuticals. (05)

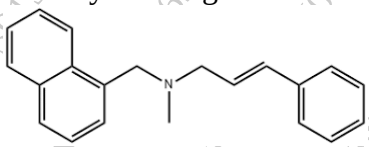
f) Define Mutation, classify it and Explain the various types of microbial mutants. (05)

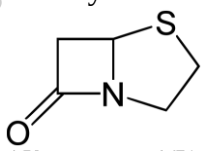
g) Explain fermentation media composition and Sterilization. (05)

h) Enlist the methods of fermentation. Explain the fermentation of vitamin B12 (05)

i) Write a short note on blood products and plasma substitutes. (05)

3 Hours **Total Marks: 75**

Q.I	Answer the following Multiple Choice Questions. Select the most appropriate option for each statement.			20M
	Questions		**Options**	
1	In tetracycline, the pka value of phenolic enone system is in the range of	a	6.4-6.8	
		b	9.1-9.7	
		c	7.2-7.8	
		d	2.8-3.3	
2	Hammett's electronic constant is represented by	a	ω	
		b	ρ	
		c	Es	
		d	σ	
3	Name active form of pyrazinamide	a	Pyrazinoic acid	
		b	Prrazinaldhyde	
		c	Isonicotinic acid	
		d	Isonicotinaldehyde	
4	Amodiaquine belongs to	a	2-amino quinoline class	
		b	4-amino quinoline class	
		c	3-amino quinoline class	
		d	5-amino quinoline class	
5	Which of the following is an aminoglycoside antibiotic	a	Kanamycin	
		b	Erythromycin	
		c	Chloramphenicol	
		d	Capreomycin	
6	β-lactam ring in cephalosporin is fused with	**a**	Dihydrothiazine ring	
		b	Dihydrothiazole ring	
		c	Dihydrothiadiazine ring	
		d	Dihydrothiadiazole ring	
7	Identify the drug 	a	Naftifine	
		b	Clotrimazole	
		c	Tolnaftate	
		d	Itraconazole	
8	Identify the reactant for synthesis of Pamaquine	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	

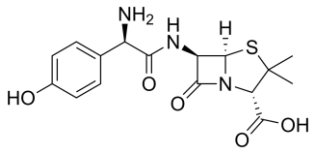
9	Purine dideoxynucleoside analog of inosine is	a	Didanosine	
		b	Indinavir	
		c	Zidovudine	
		d	Lamivudine	
10	Antiviral tri-cyclic primary amine drug.	a	Rimantadine	
		b	Acyclovir	
		c	Ganciclovir	
		d	Amantadine	
11	Identify the following ring 	a	Penam	
		b	Penem	
		c	Cepham	
		d	Cephem	
12	_____is treated with $KHCO_3$ and CO_2 to synthesize PAS	a	o- aminophenol	
		b	m-aminophenol	
		c	p-amino phenol	
		d	None of the above	
13	Rifamycin inhibit _____	a	DNA-dependent RNA polymerase	
		b	DNA ligase	
		c	DNA polymerase	
		d	RNA polymerase	
14	Identify Heterocyclic ring present in Nalidixic acid	a	Naphthyridine	
		b	Quinoline	
		c	Naphthalene	
		d	Pyrimidine	
15	Sultamicillin is prodrug of	a	ampicillin and clavulanic acid	
		b	ampicillin and tazobactam	
		c	ampicillin and sulbactam	
		d	amoxycillin and sulbactam	
16	Which of the following is anti-amoebic drug	a	Ketoconazole	
		b	Metronidazole	
		c	Albendazole	
		d	Sulfamethoxaole	

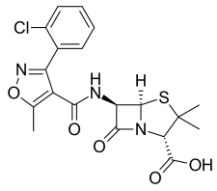
17	Molecular docking helps in understanding	a	physicochemical properties of drug	
		b	binding interactions of the drug	
		c	pharmacokinetic profile of the drug	
		d	bioavailability of the drug	
18	Identify which of the following is sulfone	a	Dapsone	
		b	Trimethoprim	
		c	Sulfisoxazole	
		d	Sulfacetamide	
19	Identify the most active isomer of Chloramphenicol.	a	L-threo isomer	
		b	L-erythro isomer	
		c	D-erythro isomer	
		d	D-Threo isomer	
20	π represents _____ in 2D QSAR	a	steric parameters	
		b	hydrophobicity	
		c	electronic parameters	
		d	electrostatic parameters	

Q.II **Attempt ANY TWO of the following. Draw structures wherever required.** **20M**

1A With reference to the following structures, answer the following questions **4M**

a) **b)**





i) Give the generic name of the above drug a.
ii) Give the generic name of the above drug b.
iii) Which of the above drugs is β-lactamase resistant.
iv) Narrow spectrum drug is _____ and Broad spectrum drug is _____.

1B Explain the structural features and mechanism of action of aminoglycosides. **4M**

1C Explain stability of macrolide antibiotics with suitable examples. **2M**

2A Explain the development of cephalosporins with suitable structures. Comment on the advantages of each generation. **4M**

2B a) Draw the structure and mention the generic name of any monobactam. **4M**
b) Clavulanic acid is given in combination with cloxacillin. State whether the statement is True or False. Justify.

2C Explain the activation and mechanism of action of proguanil. **2M**

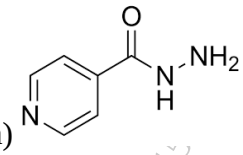
3A a) With the help of reaction explain the epimerization of tetracyclines and its effect on their activity. **4M**
b) Explain degradation of tetracycline in extreme acidic conditions.

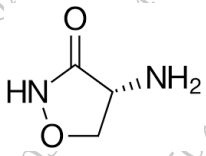
3B Draw the structures of drugs belonging to the monobactam class. Comment on their spectrum of activity. **4M**

3C Define Prodrug. Differentiate between bipartite and tripartite prodrugs. **2M**

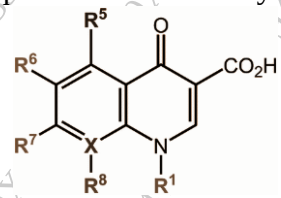
Q.III Attempt **any Seven out of given Nine questions.** **35M**

1. Identify the following two drugs and elaborate the mechanism of action. **5M**

a) 

b) 

2. Write the effect of substitutions on the following scaffold of fluoroquinolone at R1, R6, R7 and R8 positions with suitable examples for each. Mark essential pharmacophore required for the activity. **5M**



3. A. Outline the synthesis of acyclovir along with suitable reagents. **4M**

B. Name any one antiviral protease inhibitor. **1M**

4. A.Write chemical classification of azole antifungal drugs. Mention one example with structure for each class. **4M**

B. With structure write example of naturally occurring antifungal antibiotic. **1M**

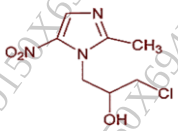
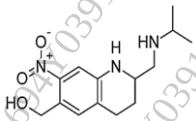
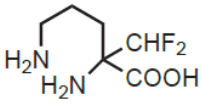
5. A.Outline synthesis of Sulfamethoxazole with suitable reagents and indicate its use. **3M**

B. Sulfasalazine is a prodrug. Answer true or false and justify. **2M**

6. A. Write the Name and structure of antiprotozoal agent which acts by inhibiting ubiquinone reductase. **2M**

B.With the help of suitable structures explain the role of alkoximino group in aminoacyl side chain at 7th position of cephalosporins. **3M**

7. Match the following **2M**

Name	Structure	Mechanism of Action
Ornidazole		Ornithine Decarboxylase inhibitor
Eflornithine		Bind to the protein tubulin and, thus, prevent tubulin polymerization to microtubules
		Generation of ROS

B. Outline synthesis of Mebendazole with suitable reagents. **3M**

8. Name two computer aided drug design techniques. Explain the steps involved in molecular docking. **5M**

9. Write a short note on solid phase synthesis. **5M**

Time: 3 hours **Total marks 75**

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

Q.I		**Choose the appropriate option for following multiple choice questions**	**20**
	1	Use of pharmacokinetic principles to the design, conduct and interpretation of drug safety evaluation studies	**1**
	a	Population pharmacokinetics	
	b	Clinical pharmacokinetics	
	c	Therapeutic drug monitoring	
	d	Toxicokinetics	
	2	Absorption of Vitamin B12 from small intestine is brought about by	**1**
	a	Active transport	
	b	Passive transport	
	c	Carrier mediated transport	
	d	Ion pair transport	
	3	BCS Class II drug molecule has	**1**
	a	Low solubility and high permeability	
	b	High solubility and high permeability	
	c	Low solubility and low permeability	
	d	High solubility and low permeability	
	4	Following route of drug administration will exhibit maximum bioavailability	**1**
	a	Oral	
	b	Rectal	
	c	Intravenous	
	d	Topical	
	5	_____ involves adsorptive uptake of solid particulate	**1**
	a	Pinocytosis	
	b	Phagocytosis	
	c	Ion pair transport	
	d	Diffusion	
	6	Apparent volume of distribution is described as	**1**
	a	correlation between dose administered and plasma concentration	
	b	correlation between dose eliminated and plasma concentration	
	c	correlation between rate of elimination and plasma concentration	
	d	correlation between rate of absorption and plasma concentration	
	7	Site II of Human Serum Albumin is referred to as _____ binding site	**1**
	a	Warfarin	
	b	Diazepam	
	c	Tamoxifen	
	d	Digitoxin	
	8	Following is active process of urinary excretion	**1**
	a	Glomerular filtration	

b	Tubular secretion	
c	Biliary secretion	
d	Tubular filtration	
9	Hepatic clearance is given by:	1
a	Elimination rate X plasma drug concentration	
b	Hepatic excretion rate/ plasma drug concentration	
c	Plasma drug concentration / Hepatic excretion rate	
d	Elimination rate / plasma drug concentration	
10	Phase II reaction involves following reaction	1
a	Oxidation	
b	Conjugation	
c	Reduction	
d	Hydrolysis	
11	USP Dissolution Apparatus IV is called as	1
a	Paddle over disc	
b	Paddle	
c	Basket	
d	Flow through Cell	
12	Following is the pharmacodynamic method for studying bioavailability	1
a	Plasma level time studies	
b	Urinary excretion studies	
c	Stool excretion studies	
d	Therapeutic response	
13	Comparison of AUC of drug given by oral route of administration with AUC of drug given by intravenous route of administration is called as	1
a	Biopharmaceutics	
b	Bioequivalence	
c	Absolute bioavailability	
d	Relative bioavailability	
14	The steady state concentration Css for IV infusion is given by	1
a	Css= Infusion Rate- Total Systemic Clearance	
b	Css = Infusion Rate / Total Systemic Clearance	
c	Css = Total Systemic Clearance/Infusion Rate	
d	Css = Infusion Rate x Total Systemic Clearance	
15	Unit of clearance is given by	1
a	mg / hr	
b	mL/hr	
c	mg/L*hr	
d	hr/mL	
16	Wagner Nelson method is used to determine	1
a	K_E	
b	K_A	
c	AUC	
d	CL_T	
17	In the two-compartment open model IV bolus, the initial rapid decline in the drug concentration is due to	1

a	Absorption	
b	Distribution	
c	Metabolism	
d	Elimination	
18	In case of Multi compartment model, elimination is indicated by	1
a	α	
b	β	
c	μ	
d	γ	
19	In Michaelis Menton equation when Km>>C	1
a	Rate of process is zero order	
b	Rate of process is first order	
c	Rate of process is half the maximum rate	
d	Rate of process is double the maximum rate	
20	Self induction of enzyme in case of carbamazepine causes _____ in half life of drug	1
a	decrease	
b	increase	
c	keeps constant	
d	decrease followed by increase	

Q.II a	**Attempt any Two.**	**2x10**
1 a	A single IV bolus injection containing 500 mg of an antibiotic is given to an adult patient (weight = 55 kg). The apparent volume of distribution is 0.1 L/kg and the elimination half-life is 0.75 hour. Assuming the drug is eliminated by first-order kinetics and described by one-compartment model, calculate the following a. Co	
	b. Elimination rate constant and AUC	1
	c. The amount of drug in the body 4 hours after the dose is given	2
	d. The time for the drug to decline to 0.5μg/ml the minimum inhibitory concentration for streptococci	2
		2
1 b	What is apparent volume of distribution? Derive the equation for apparent volume of distribution	3
2	Describe the concept of two compartment model and derive various pharmacokinetic parameters following two compartment open model IV bolus administration of drug.	10
3	Explain the concept of drug distribution and give a detailed note physicochemical properties of the drug affecting distribution with suitable examples	10

Q.II b	**Attempt any seven.**	**7x5**
1	Explain effect of any two dosage form related factors with suitable examples affecting drug absorption	5
2	Explain the mechanism of active transport of drug with suitable examples	5
3	Justify with reasons, human serum albumin considered a versatile protein for drug binding . Enlist various drug binding sites on human serum albumin	5
4	Explain the concept of IVIVC and discuss its significance.	5
5	Enlist the methods used for assessment of bioavailability of drug. Explain any one method in detail.	5
6	What are the causes on non linearity in absorption and metabolism of drug? Explain with suitable examples.	5
7	Explain the determination of absorption rate constant based on method of feathering following one compartment kinetics.	5

8	What is drug accumulation index? State the equations for determination of Maximum and minimum concentrations at steady state following multiple dosing.	**5**
9	Explain the concept of loading dose and maintenance dose of iv infusion.	**5**

Time : 3 Hours **Total Marks : 75**

N.B: 1. All questions are compulsory
2. Figures to right indicate full marks
3. Draw structure where ever necessary

Q1. Answer the Following **20**

1. What is the primary goal of authenticating herbal drugs?
a) To enhance their therapeutic effects
b) To ensure they are free from synthetic additives
c) To confirm their identity and purity
d) To increase their organoleptic properties

2. When selecting a plant for the development of a herbal drug, what is an important factor to consider regarding its source?
a) The plant's popularity in contemporary fashion
b) Ethnobotany & traditional uses
c) The geographical region and environmental conditions where the plant grows
d) The processing of the plant

3. What is a fundamental principle of biodynamic agriculture?
a) Using genetically modified organisms to improve crop yields
b) using form of alternative agriculture based on pseudo-scientific and esoteric concepts
c) Relying solely on synthetic fertilizers for plant nutrition
d) Focusing exclusively on animal husbandry & crop yield

4. Which of the following pest control methods is preferred in the cultivation of plants for herbal drugs to maintain their natural properties?
a) Use of isolated natural compounds
b) Introduction of natural predators of pests into the ecosystem
c) Spraying using Volatile plant constituents
d) Introducing Bt crops

5. Biopesticides are favored in sustainable agriculture due to their:
a) High toxicity to a wide range of non-target species
b) Ability to persist in the environment for long periods
c) Specific action against target pests, minimizing impact on non-target organisms
d) Dependence on chemical synthesis for production

6. Which of the following is not true for Bhasma
a) It is obtained completely by drug incineration
b) it is amorphous smooth powder
c) it can be standardised
d) Bhasmas are Homeopathic preparations.

6. Omega -3-fatty acids, known to lower LDL are recommended as nutraceuticals for
a) Cardio vascular diseases b) Irritable bowel syndrome
c) Diabetes d) Hepatoprotective

7. Kava should not be used with ……
a) Antipsychotics b) Anti inflammatory
c) Antiobesity d)Antimalerials

8. Which of these is not commonly used as Nutraceutical?
a) Aloe b)Vinca
c) Liquorice d) Alfalfa

9. Stievia is an example of
a) Natural Colour b) Natural Sweetner
c) Natural binder d) viscocity building agent

10 _____ is used as bleaching agents
a) Rose oil
b) Beeswax
c) Citrus peel
d) Morphine oil

11. ---------- is used commonly as a viscosity builder
a) Corn Starch b) Gelatin
c) Methyl Cellulose d) Lactose

12. A natural surfactant which is also used as a skin softener is
a) Coco Betaine b) Lawsone
c) Kava Kava d) Amla

13. Which of the following is a Novel drug dosage form
a) Herbal sprinkles b) Herbal Syrups
c) Phytosomes d) Herbal Lozenges

14. The microbial toxin evaluation as per WHO guidelines includes
a) Mycotoxins b) Endotoxins
c) Mycotoxins & Endotoxins d) Microbial bioburden

15. According to the WHO guidelines, what is essential for the quality control of herbal medicines?
a) The use of additives in formulation
b) Documentation of traditional use without scientific evidence
c) Detailed phytochemical analysis
d) Standardization and quality assurance of raw materials, intermediates, and finished products

16. Biopiracy means
a) Unethical exploitation of Natural resourses c) Ethical exploitation of Natural resourses
c) Experimentation d) Innovation & discovery

17. PBR means
a) Plant Breeder's Right
b) Plant Breeding Rights
c) Plant Breeding Race
d) Plants based Rights

18. Schedule z refers to
a) Only Herbal based products
b) Drugs & Cosmetics Act
c) Preformulation studies
d) Homeopathy & Unani Medicines

19. Which regulatory body as per Drug & cosmetic act for ASU drugs under section 33 C
a) DTAB ASU
b) DCC ASU
c) DCC
d) CDTL

20. Which should be not patented form following
a) Traditional knowledge of plant
b) Isolation of phytoconstituents
c) New uses of Phytoconstituents
d) New variety of plants

Q.II Answer **any Two** of the following: **20**

1. Discuss & describe different sources & raw materials of herbal origin with respect to colours & perfumes.
2. Justify & elaborate WHO & ICH guidelines for assessment of herbal drug stability testing.
3. Explain Pest Management & use of biopesticides in Medicinal Plants.

Q.III Answer **any seven** of the Following **35**

1. Explain the significance of Herbal drug identification & authentication. Mention differenet sources of drugs.
2. Explain formulation of Asava & Churna with suitable example.
3. Outline the health benefits & role of Nutraceuticals in Diabetes.
4. Briefly explain use of Ashwagandha & Alfaalfa as Nutraceuticals.
5. Give sources & use of fixed oils & antioxidants as raw materials in herbal cosmetics.
6. Provide an overview of any two conventional Herbal formulations.
7. Outline the different infrastructure requirements for Herbal drug manufacturing.
8. Discuss the Patent case study of Neem & write a note on geographical indications related to patents.
9. With suitable examples, explain possible herbal-drug interactions of Ginseng and Hypericum.

Time: 3 Hours **Total Marks: 75**

Q I. Choose the **ONE** best answer and write it down **20 Marks**

1. Which of the following drugs is a leukotriene receptor antagonist commonly used to treat asthma?
A) Albuterol
B) Montelukast
C) Prednisone
D) Theophylline

2. Sucralfate acts by:
A) Inhibiting proton pumps in the stomach
B) Antagonizing H2 receptors on parietal cells
C) Forming a protective barrier over the ulcer site
D) Antisecretory mechanism

3. Ondansetron prevents nausea and vomiting by:
A) Antagonizing serotonin's action on 5-HT3 receptors
B) Antagonizing central and peripheral D2 receptors in the medullary chemoreceptor trigger zone
C) Antagonizing cholinergic M3 receptors in the stomach
D) blocking dopamine receptors in the gut

4. Which of the following drugs is a non-opioid antitussive that suppresses cough reflex sensitivity?
A) Acetylcysteine
B) Bromhexine
C) Guaifenesin
D) Dextromethorphan

5. What is the primary advantage of combining sulfonamides with trimethoprim in cotrimoxazole therapy?
A) Enhanced bactericidal activity
B) Broader spectrum of activity
C) Reduced risk of resistance development
D) Reduced risk of adverse effects

6. Quinolone resistance in bacteria can occur due to mutations in genes encoding:
A) Beta-lactamases
B) Ribosomal RNA
C) DNA gyrase and topoisomerase IV
D) Efflux pumps

7. Which antibiotic class is typically avoided in children under the age of 8 due to its potential to cause tooth discolouration?
A) Penicillins
B) Tetracyclines
C) Macrolides
D) Aminoglycosides

8. Oxazolidinones, such as linezolid, exert their antibacterial effect by:
A) Inhibition of DNA gyrase
B) Inhibition of RNA polymerase
C) Inhibition of cell wall synthesis
D) Inhibition of bacterial protein synthesis at the initiation complex

9. What is the mechanism of action of metronidazole in the treatment of amoebiasis?
A) Inhibition of DNA synthesis
B) Inhibition of RNA synthesis
C) Inhibition of protein synthesis
D) Disruption of cell wall synthesis

10. Which of the following is a common side effect of rifampicin?
A) Peripheral neuropathy
B) Hepatotoxicity
C) Renal toxicity
D) QT prolongation

11. Which antimalarial drug acts by inhibiting heme polymerase in the malaria parasite?
A) Chloroquine
B) Quinine
C) Mefloquine
D) Artemisinin

12. Which point in the replication cycle appears most easily blocked by antivirals?
A) Virus penetration
B) Virus absorption
C) Nucleic acid replication
D) Exit of viruses from the cell

13. Which class of chemotherapy drugs primarily targets rapidly dividing cells by inhibiting DNA synthesis?
A) Alkylating agents
B) Antimetabolites
C) Anthracyclines
D) Vinca alkaloids

14. What is the primary symptom of syphilis in its early stage?
A) Painful urination
B) Vaginal discharge
C) Genital ulcers
D) Scrotal swelling

15. The immunosuppressant drug cyclosporine:
A. Binds to the immunophilin FKBP1A, followed by the binding of the complex to calcineurin
B) Binds to FKBP1A to inhibit the protein mTOR
C) Inhibits inosine monophosphate dehydrogenase involved in de novo synthesis of purines
D) Inhibits IL-1 and TNF gene expression and synthesis

16. Biosimilars are:
A) Generic versions of small molecule drugs
B) Synthetic drugs

C) Vaccines
D) Highly similar biological products with no clinically significant differences from approved reference products
17. Chronic toxicity typically manifests as:
A) Immediate and severe symptoms after a single exposure
B) Gradual and irreversible adverse effects after repeated exposure over months or years
C) Mild symptoms that resolve quickly after exposure
D) Symptoms that only occur after accidental exposure

18. What is the mechanism of action of organophosphorus compounds?
A) Inhibition of acetylcholinesterase
B) Blockade of opioid receptors
C) Activation of NMDA receptors
D) Inhibition of monoamine oxidase

19. The term "chronotherapy" refers to:
A) Treatment of chronic diseases with medications over extended periods
B) Use of drugs in emergencies to stabilize patients' conditions
C) Administration of drugs at specific times to optimize therapeutic outcomes and minimize side effects
D) Development of new drugs based on molecular rhythms

20. Chronotherapy of antiulcer drugs involves:
A) Taking proton pump inhibitors only in the morning to reduce gastric acid secretion during the day
B) Using antacids sporadically throughout the day to neutralize stomach acid
C) Avoiding antiulcer drugs altogether to allow the stomach to heal naturally
D) Administering H2 receptor antagonists primarily during the night to suppress nocturnal acid secretion

Q. II. Answer any TWO of the following: **20 Marks**

1. Classify antiulcer agents. Write the mechanism of action, adverse reactions, and therapeutic uses of proton pump inhibitors and antihistaminic drugs.

2. Write a note on the mechanism of action of beta-lactam antibiotics. How do bacteria acquire

resistance to beta-lactam antibiotics? Classify penicillin antibiotics with examples.

3. Classify antiretroviral drugs with examples. Describe Protease Inhibitors in detail.

Q. III. Answer any SEVEN of the following questions: **35 marks**

1. Classify laxatives and purgatives with examples. Give a brief account of bulk-forming agents.

2. Classify drugs used for the treatment of asthma with examples. Elaborate on mast cell stabilizers.

3. Discuss various mechanisms by which bacteria acquire resistance against antibiotics.

4. Classify azole antifungal drugs with examples. Give their mechanism of action, adverse effects and

clinical use.

5. Classify first and second-line anti-tubercular drugs and give the mechanism of action, adverse effects

and therapeutic uses of rifampin.

6. Classify immunosuppressant drugs with examples of each class. Add a note on Calcineurin

inhibitors

7. Classify anticancer agents. Describe the pharmacology of alkylating agents.

8. Compare and contrast Acute Toxicity and Chronic Toxicity.

9. Discuss about chronotherapy for peptic ulcers and antiasthmatic drugs.

Duration: 3 Hrs **Total marks: 75**

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

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

1 Which ICH guideline includes Risk management?
   a. Q3
   b. Q9
   c. Q10
   d. Q12

2 Following products cannot be manufactured in the same manufacturing facility
   a. Antiviral product & Anti-inflammatory product
   b. Antidiabetic & Antihypertensive product
   c. Antimalarial product & Anti-inflammatory product
   d. Penicillin products & Antidiabetic products

3 Which of the following does not belong to Juran's Quality Trilogy?
   a. Quality Planning
   b. Quality Assurance
   c. Quality Control
   d. Quality improvement

4 _____ test is specifically used for testing glass containers used for aqueous parenteral preparations.
   a. Light transmission test
   b. Arsenic test
   c. Thermal Shock test
   d. Internal bursting pressure test

5 Cleaning of the equipment is a part of
   a. Corrective maintenance
   b. Predictive maintenance
   c. Periodic maintenance
   d. Curative maintenance

6 The acceptance criteria for wavelength accuracy in the visible range for calibration of spectrophotometer is _____.
   a. ± 1 nm
   b. ± 2 nm
   c. ± 3 nm
   d. ± 5 nm

7 Installation qualification of an equipment verifies that ____.

a. User requirements are incorporated into equipment design
b. Equipment operates consistently within operational limit
c. Equipment shows satisfactory performance over long period.
d. Equipment is installed and connected to utilities

8 Recall due to Microbial contamination of injection is an example of _____ recall

a. Class I
b. Class II
c. Class III
d. Class IV

9 In "Quality by Design", what does CQA stand for?

a. Critical Quality Assessment
b. Critical Quality Attributes
c. Complex Quality Assessment
d. Complex Quality Attributes

10 Facility used for manufacturing of sterile products should be maintained at _____ differential pressure.

a. Constant
b. Variable
c. Positive
d. Negative

11 As per USP, the limit of fragments visible to the naked eye in fragmentation test for rubber closures is _____.

a. Not more than 50
b. Not more than 10
c. Not more than 5
d. Not more than 1

12 The OECD stands for _____.

a. Organization for Environmental Control and Discussion
b. Organization for Economic Cooperation and Development
c. Organization for Environmental Cooperation and Development
d. Organization for Economic Control and Discussion

13 _____ is a process that demonstrates a particular instrument produces results within specified limits, as compared to those produced by a traceable standard.

a. Validation
b. Qualification
c. Calibration
d. Verification

14 As per USFDA GLP guidelines, Subpart C is _____.
   a. Facilities
   b. Equipment
   c. Records and Reports
   d. Test and Control Articles

15 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

16 _____ is the test in which test piece is folded back and forth until rupture occurs.
   a. Folding endurance
   b. Tensile strength
   c. Burst Resistance
   d. Tear Strength

17 Records of a nonclinical study should be retained for _____ after termination / discontinuation of the study.
   a. One year
   b. Two years
   c. Three years
   d. Five years

18 Type III glass is also known as _____.
   a. Soda lime glass
   b. Borosilicate glass
   c. Treated Soda lime glass
   d. Treated borosilicate glass.

19 The efficiency of HEPA filters should be _____at 0.22-micron particle size.
   a. 95.55%
   b. 99.99%
   c. 93.22%
   d. 90.99%

20 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

Q. II Answer any two questions. (Any 2) **20**

1	Enlist the participants of ICH. Write in brief about photostability testing of drug products.	**10**
2	Define GLP. What is the role of Quality Assurance Unit in a testing facility? Discuss in brief the hydrolytic resistance test.	**10**
3	What is recall? Define Complaint and Discuss the steps involved in handling of complaints in a pharmaceutical company.	**10**

Q. III Answer any seven questions (Any Seven) **35**

1	What is Quality management System? Give the role of Quality Control and Quality Assurance departments in a Pharmaceutical Industry	**5**
2	Discuss the QC tests for rubber closures.	**5**
3	Define SOP. Discuss the general format of SOP.	**5**
4	What is ISO? Discuss its benefits and the process of ISO registration.	**5**
5	Explain the process of equipment selection and maintenance in the pharmaceutical manufacturing unit.	**5**
6	State the importance of inventory management. Discuss the Good warehousing practices in detail.	**5**
7	Enlist the types of documents maintained in pharmaceutical company. Write in brief about batch formula record.	**5**
8	Write a note on maintenance of sterile areas. Illustrate a layout for manufacturing of injectables.	**5**
9	Define validation. Explain in brief the types of process validation.	**5**